BIOFIRE® Blood Culture Identification 2 (BCID2) Panel

IVD CE 2797

Rx Only

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Instructions for Use	https://www.biofiredx.com/e-labeling/ITI0048
Quick Guide	https://www.biofiredx.com/e-labeling/ITI0068
Safety Data Sheet (SDS)	https://www.biofiredx.com/e-labeling/ITI0088
Panel Pouch Module Software	https://www.biofiredx.com/e-labeling/ITIFA20BCID210
Summary of Safety and Performance (Applicable for EU Customers)	https://www.biofiredx.com/e-labeling/ITIBCID29954

Customer and Technical Support Information *For more information on how to contact Customer and Technical Support, refer to Appendix B.*	**U.S. Customers**	Phone: 1-800-735-6544 (toll free) E-mail: BioFireSupport@biomerieux.com Website: www.biofiredx.com
	Outside of the U.S.	Contact the local bioMérieux sales representative or an authorized distributor

INTENDED PURPOSE

Intended Use

The BIOFIRE® Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® Torch Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BIOFIRE BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. The following organism types and subtypes are identified using the BIOFIRE BCID2 Panel:

Gram Positive Bacteria		
Enterococcus faecalis	*Staphylococcus* spp.	*Streptococcus* spp.
Enterococcus faecium	*Staphylococcus aureus*	*Streptococcus agalactiae* (Group B)
Listeria monocytogenes	*Staphylococcus epidermidis*	*Streptococcus pneumoniae*
	Staphylococcus lugdunensis	*Streptococcus pyogenes* (Group A)
Gram Negative Bacteria		
Acinetobacter calcoaceticus-baumannii complex		*Enterobacterales*
Bacteroides fragilis		*Enterobacter cloacae* complex
Haemophilus influenzae		*Escherichia coli*
Neisseria meningitidis (encapsulated)		*Klebsiella aerogenes*
Pseudomonas aeruginosa		*Klebsiella oxytoca*
Stenotrophomonas maltophilia		*Klebsiella pneumoniae* group
		Proteus spp.
		Salmonella spp.
		Serratia marcescens
Yeast		
Candida albicans	*Candida krusei*	*Cryptococcus neoformans/gattii*
Candida auris	*Candida parapsilosis*	

Candida glabrata	*Candida tropicalis*

The BIOFIRE BCID2 Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA/C* and *mecA/C* in conjunction with MREJ), vancomycin (*vanA* and *vanB*), ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems (*bla*$_{CTX-M}$, *bla*$_{IMP}$, *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA48-like,}$ *bla*$_{VIM}$) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant *mcr-1*, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, ß-lactams, and colistin exist.

Antimicrobial Resistance Genes				
CTX-M	KPC	*mecA/C*	NDM	*vanA/B*
IMP	*mcr-1*	*mecA/C* and MREJ (MRSA)	OXA-48-like	VIM

The BIOFIRE BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BIOFIRE BCID2 Panel. The BIOFIRE BCID2 Panel is not intended to monitor treatment for bloodstream infection.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the BIOFIRE BCID2 Panel, and for determination of species detected but not identified within complexes, groups, or genera by the BIOFIRE BCID2 Panel assays.

Intended User and Use Environment

The BIOFIRE BCID2 Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

SUMMARY AND EXPLANATION OF THE TEST

Bloodstream infections (BSIs) occur when pathogenic organisms (e.g., bacteria or yeast) enter the bloodstream and cause disease. These infections are commonly identified by the growth of the pathogenic organism in blood culture. BSIs can lead to the development of sepsis, defined as life-threatening organ dysfunction caused by a dysregulated host response[1] to infection. Globally, over 30 million BSIs are estimated to occur each year, leading to approximately 19 million cases of sepsis and 5 million sepsis-related deaths[2]. Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to BSI and sepsis. The BIOFIRE BCID2 Panel tests a single positive blood culture sample to simultaneously provide results for multiple organisms and organism groups that cause BSIs and genetic markers associated with antimicrobial resistance. Rapid identification of the organism(s) in the blood culture, along with information about antimicrobial resistance gene status for select microorganisms, may aid the physician in making appropriate treatment decisions.

Summary of Detected Organisms

Gram-Positive Bacteria

Enterococcus faecalis* and *faecium are gram-positive facultative anaerobes that normally inhabit the gastrointestinal tract of humans, but are among the most common nosocomial pathogens[3]. Enterococcal infections include urinary tract infections, hepatobiliary sepsis, endocarditis, surgical wound infection, bloodstream infection, and neonatal sepsis. There are 28 species of *Enterococcus*[3] and although at least 12 species have been shown to cause human disease, *E. faecalis* (80-90%) and *E. faecium* (5-15%) cause the majority of clinical infections[4]. Enterococci can carry vancomycin-resistance genes such as *vanA* and *vanB*. Infection with a vancomycin-resistant enterococcus (VRE) increases the risk of death to 75%, compared with 45% for infection with a susceptible strain[3]. Although *E. faecalis* is more pathogenic than *E. faecium,* the latter exhibits more resistance and is associated with the majority of VRE infections[5].

***Listeria monocytogenes**,* the causative agent of listeriosis, is a gram-positive bacillus that is ubiquitous in soil and water and can be found in the gastrointestinal tract of up to 5% of healthy adults[6–8]. Only three of the 12 known serotypes of *L. monocytogenes* (1/2a, 1/2b, and 4b) account for more than 90% of human cases of listeriosis[9]. Listeriosis is considered the most severe bacterial foodborne infection due to its high mortality rate, despite early antibiotic treatment (11 – 60%). Populations at risk for developing invasive listeriosis include the immunosuppressed, pregnant women, neonates, fetuses, and the elderly[6,7]. Invasive listeriosis can result in abortion, sepsis, and meningoencephalitis[6,9]. BSIs can account for greater than 50% of invasive listeriosis cases with a mortality rate of up to 70% when associated with severe underlying conditions[8,9].

***Staphylococcus* spp. –** Staphylococci are gram-positive cocci that are usually catalase positive and tend to appear as irregular, grape-like clusters on a Gram stain. Nearly all species in the genus are facultative anaerobes. *Staphylococcus* species are common colonizers of the skin and mucous membranes. They are opportunistic pathogens that can cause infection following breaks in the cutaneous epithelial barrier through trauma or medical interventions[10]. Diagnostically, the genus is divided between coagulase-positive staphylococci and coagulase-negative staphylococci (CoNS). Due to being commensal organisms, CoNS species are regularly isolated from clinical specimens and care must be taken to assess clinical significance to differentiate between contamination, colonization, and true infection.

> ***Staphylococcus aureus*** is the most clinically relevant coagulase-positive *Staphylococcus* spp. and is capable of causing a wide range of diseases. *S. aureus* possesses extensive virulence factors, has various strategies to evade the host immune response, and has become resistant to many therapeutic agents. Second only to CoNS, *S. aureus* is a major cause of primary bloodstream infection in hospitals. It is estimated that approximately 40% of *S. aureus* isolates may be methicillin resistant (MRSA)[11]. The primary mediator of methicillin resistance in staphylococci is the acquisition of the *mecA* or *mecC* genes encoded on the staphylococcal chromosome cassette *mec* (SCC*mec*), a mobile genetic element that can transfer between *Staphylococcus* spp.[11]

Staphylococcus epidermidis is the most frequently isolated staphylococcal species colonizing the body surface. It is particularly prevalent in moist areas such as the axillae, inguinal, and perineal areas; anterior nares; and toe webs. It has been increasingly recognized as a nosocomial pathogen. *S. epidermidis* is the major cause of infections associated with prosthetic vascular grafts, prosthetic orthopedic devices, and cerebrospinal fluid shunts[10]. The pathogenesis of medical-device-related *S. epidermidis* infections is associated with its ability to establish highly resistant biofilms, which aid the bacteria's colonization on the surface of the artificial devices[12]. *S. epidermidis* is the second-most-common pathogen that causes nosocomial bloodstream infection and is typically associated with the use of intravascular catheters[13]. In neonatal intensive care units, *S. epidermidis*, along with other CoNS, account for 46-75% of all late-onset BSIs in preterm infants[14].

Staphylococcus lugdunensis is an integral part of the normal skin flora with the lower abdomen and extremities being the predominant niches. It is an uncommon contaminant of blood cultures and more similar to *S. aureus* than to other CoNS in terms of pathogenicity and virulence[15]. Fulminant cases of native-valve endocarditis, characterized by an aggressive clinical course with high mortality and septic shock, have been attributed to *S. lugdunensis* and speak to its virulence[16]. In addition, skin and soft tissue infections also represent a prominent portion of the total infections caused by *S. lugdunensis*[17]. Unlike most other CoNS, *S. lugdunensis* remains susceptible to a wide array of antimicrobial agents, although the acquisition of the SCC*mec* cassette confers resistance to β-lactam and strains resistant to aminoglycosides (via other mechanisms) have been reported sporadically[16].

***Streptococcus* spp. –** Streptococci are gram-positive, catalase-negative cocci that appear in chains or pairs on a Gram stain. *Streptococcus* species are frequently found as commensal bacteria on mucous membranes and are occasionally present as transient skin microbiota[10]. Streptococci have historically been grouped as β-hemolytic or non-β-hemolytic, pyogenic (pus-forming) or non-pyogenic, and also divided according to the presence of specific surface antigens (i.e., Lancefield grouping). Lancefield groups A, B, C, and G are pyogenic and most are also β-hemolytic[10]. Of these, the Group A streptococci (represented primarily by *S. pyogenes*) and the Group B streptococci (*S. agalactiae*) are the most common in BSIs. The non-pyogenic streptococci are subdivided into five groups (mitis, anginosus, salivarius, mutans, and bovis groups). The mitis, anginosus, and salivarius groups are also referred to as viridians streptococci; these bacteria produce no Lancefield antigens and are alpha-hemolytic or non-hemolytic. Viridans streptococci are also fairly common agents of BSI causing 0.5% of sepsis cases in non-neutropenic patients and up to 2% in neutropenic patients[11]. *S. pneumoniae* has been classified into the mitis group but is often considered as its own separate group.

Streptococcus agalactiae (Group B *Streptococcus* or GBS) belongs to Lancefield group B and can cause both early-onset neonatal disease, characterized by sepsis and pneumonia within the first seven days of life, and late-onset disease with meningitis and sepsis between day seven and three months of age[10]. In adult patients, the spectrum of *S. agalactiae* infections includes BSI, pneumonia, meningitis, and endocarditis[10].

Streptococcus pneumoniae colonizes the upper respiratory tract and is the most frequently isolated respiratory pathogen in community-acquired pneumonia. *S. pneumoniae* was responsible for approximately 31,000 invasive infections in the U.S. in 2017, leading to an estimated 3,590 deaths[18]. There are two licensed, multivalent pneumococcal vaccines in the US (PPV23 and PCV13) that are recommended for neonates, the immunocompromised, and those over the age of 65, and that help reduce the risk of both invasive disease and pneumococcal pneumonia by 50-80%[19].

Streptococcus pyogenes (Group A *Streptococcus* or GAS) colonizes the human skin and upper respiratory tract, with these sites serving as primary focal sites of infections and principal reservoirs of transmission of these gram-positive bacteria[10]. *S. pyogenes* possesses complex virulence mechanisms to avoid host defenses[20,21] and is responsible for deep or invasive infections, especially bloodstream infection, sepsis, and deep soft tissue infections [10].

Gram-Negative Bacteria

***Acinetobacter calcoaceticus-baumannii* complex** organisms (*A. baumannii, A. calcoaceticus, A. dijkshoorniae*, *A. nosocomialis* (genomospecies 13TU), *A. pittii* (genomospecies 3), and *A. seifertii*) are related *Acinetobacter* species not

reliably differentiated from one another by some manual or automated phenotypic microbial identification systems. These organisms are ubiquitous, non-fermentative, and gram-negative coccobacilli that primarily act as opportunistic pathogens infecting critically ill patients. They are uncommon members of the normal skin flora. Nosocomial infections caused by *A. baumannii* are increasing in frequency[22]. Multi-drug resistant strains demonstrate resistance to most antibiotic classes, including carbapenems. Various carbapenem-hydrolyzing metallo-β-lactamases may also be carried by these bacteria[23].

Bacteroides fragilis is an obligately anaerobic, gram-negative, non-spore-forming rod that belongs to the family *Bacteroidaceae*[24]. *Bacteroides* species, of which *B. fragilis* is the most commonly encountered, are part of the normal microbiota of the human colon and are host symbionts critical to metabolism and systemic immunity. However, they can cause significant infection if displaced into the bloodstream or surrounding tissue. *B. fragilis* is the most common anaerobic organism found in BSIs, in part due to its potent virulence factors[25,26]. *Bacteroides* species have the highest resistance rates of all anaerobic pathogens due to intrinsic resistance to several classes of structurally unrelated antibiotics.

Enterobacterales – The order *Enterobacterales* is composed of seven families (*Budviciaceae*, *Enterobacteriaceae*, *Erwiniaceae*, *Hafniaceae*, *Morganellaceae*, *Pectobacteriaceae*, and *Yersiniaceae*)[27], many genera, and over 250 species of gram-negative, facultatively anaerobic rods and coccobacilli. While some genera and species within the order are harmless to humans, many are medically important and associated with BSI and other illnesses. Members of the *Enterobacteriaceae* family are among the most commonly recognized organisms seen in healthcare-associated infections, along with genera and species of *Morganellaceae* and *Yersiniaceae*. *Erwiniaceae*, *Hafniaceae*, and *Budviciaceae* are less common while species of *Pectobacteriaceae* are not generally isolated from humans. The emergence and spread of antimicrobial resistance in *Enterobacteriaceae* (and other *Enterobacterales*) has increased the complexity of treating BSI associated with the gram-negative bacteria. Resistance to third- and fourth-generation cephalosporins is mediated primarily by the production of extended-spectrum β-lactamases (ESBLs) and overproduction of AmpC β-lactamases. While the majority of *Enterobacteriaceae* remain susceptible to carbapenems, KPC-type carbapenemases are emerging and spreading (carbapenem-resistant *Enterobacteriaceae*; CRE) in certain locations within the United States and worldwide[28]. As genomic technologies evolve, bacterial taxonomy is changing, and several genera that were formerly classified as *Enterobacteriaceae* were reclassified into new families in 2016[27]. However, the BIOFIRE BCID2 Panel has been designed to identify nearly all clinically relevant (and some non-relevant) former and current species of *Enterobacteriaceae* as well as the other families and genera of *Enterobacterales*.

***Enterobacter cloacae* complex** organisms (*Enterobacter cloacae, Enterobacter asburiae, Enterobacter hormaechei, Enterobacter kobei, Enterobacter ludwigii,* and *Enterobacter mori*) are gram-negative, rod-shaped bacteria. *E. cloacae* complex organisms have been implicated in numerous nosocomial infections, which are notable for their severity in ICU patients[29]. *Enterobacter* spp. is the fourth most common gram-negative pathogen isolated from blood cultures in the USA (after *Klebsiella* spp., *E. coli*, and *Pseudomonas aeruginosa*), with *E. cloacae* being the most common species. A similar trend has also been observed in Latin America and Europe[30].

Escherichia coli are gram-negative bacteria that are part of the normal flora of the intestines of humans and animals. While most pathogenic *E. coli* infections are associated with gastrointestinal illness, certain strains may cause extraintestinal infections in healthy as well as immunocompromised individuals. These include urinary tract infections, BSIs, and meningitis. Overall, *E. coli* infections are responsible for approximately 5.6% of BSIs[11]. As with other *Enterobacteriaceae*, extended-spectrum β-lactamases (ESBLs), including CTX-M and AmpC β-lactamases, and *Klebsiella pneumoniae* carbapenemase (KPC) pose a significant antibiotic resistance problem[10]. Moreover, the recently identified, plasmid-mediated genetic determinant, *mcr-1*, has been found primarily in *E. coli* and other *Enterobacteriaceae*. This gene marks the emergence of some pan-drug-resistant strains.

***Klebsiella aerogenes*,** previously known as *Enterobacter aerogenes*, is a gram-negative, facultatively anaerobic, rod-shaped bacterium[31]. It is a nosocomial and opportunistic pathogen generally found in the gastrointestinal tract, urine, and skin of colonized patients. It can be spread by the hands of healthcare staff and contaminate bedpans and urinals. Specific antibiotic treatments, venous catheter insertions, and/or surgical procedures are all risk factors associated with *K. aerogenes* infection[32].

Klebsiella oxytoca is an aerobic gram-negative, rod-shaped bacterium that is carried on mucosal surfaces (nasopharynx and bowel) and found in agricultural environments. Opportunistic infections due to *K. oxytoca* include soft tissue infections, urinary tract infections, pneumonia, and BSIs. An increasing proportion of *K. oxytoca* bloodstream infection isolates demonstrate resistance to extended-spectrum β-lactams, especially when there is a history of prior antibiotic use[33]. Additionally, carbapenem resistance has been observed in nosocomial outbreaks of *K. oxytoca*[34].

The ***Klebsiella pneumoniae* group** includes three phylogroups classified as distinct species; *K. pneumoniae* (KPI), *K. quasipneumoniae* (KPII), and *K. variicola* (KPIII)[35,36]. All three species have many of the same virulence factors and share biochemical and genetic similarities, which makes it difficult to distinguish *K. quasipneumoniae* and *K. variicola* from *K. pneumoniae* clinically or by standard culture methods[37]. These organisms are gram-negative, rod-shaped bacteria that are found as part of the normal flora of the human mouth and skin[35]. *K. pneumoniae* is associated most often with nosocomial infections in the elderly or immunocompromised[38]. *Klebsiella* spp. are opportunistic pathogens accounting for ~8% of all nosocomial bacterial infections in the United States and in Europe[39]. *K. pneumoniae* group species may carry the *Klebsiella pneumoniae* carbapenemase gene, *bla*KPC, which confers resistance to carbapenem antibiotics[33], as well as several other genetic determinants of resistance to various classes of antibiotics.

Proteus spp. are commonly isolated in the clinical laboratory, with *Proteus mirabilis* observed most frequently. Most infections (approximately 85%) are thought to be community acquired[40]; however, nosocomial outbreaks have also occurred[41]. Antimicrobial resistance has become an increasing problem in *Proteus* infections, with approximately 32% of isolates producing extended-spectrum β-lactamases[42].

Salmonella spp. are motile, gram-negative, facultatively anaerobic rods that are associated with infection following the consumption of contaminated meat, fresh produce, and manufactured products[43]. Strains of *Salmonella* are categorized as typhoidal and non-typhoidal, corresponding to the particular disease syndromes they are related to. Strains of non-typhoidal *Salmonella* can be transferred from animals to humans and from humans to humans and usually cause gastrointestinal infections. Approximately 5% of individuals with gastrointestinal infections caused by non-typhoidal *Salmonella* will develop BSI, especially in immunocompromised patients[44]. Strains of typhoidal *Salmonella*, on the other hand, can only be transferred from human to human and cause typhoid fever, a serious BSI commonly seen in the developing world.

Serratia marcescens is a gram-negative bacterium that is a common nosocomial pathogen and colonizer. *S. marcescens* is the primary pathogenic species of the *Serratia* genus. It is of particular concern due to its emerging antibiotic resistance to commonly used agents like β-lactams, aminoglycosides, carbapenems, and fluoroquinolones. Non-pigmented *S. marcescens* are more resistant to antibiotics and are associated with most outbreaks[45]. Transmission may occur from person-to-person contact, via medical apparatus, intravenous fluids, or other solutions[46].

Haemophilus influenzae is a gram-negative coccobacillus, isolated exclusively from humans[47], that can be present as normal flora of the oropharynx and can cause infections when introduced into the lower respiratory tract[48–50]. Strains of *H. influenzae* are divided into two groups based on the presence or absence of a capsular polysaccharide[51,52]. Encapsulated strains are further divided into six serotypes (a through f). Prior to the widespread use of the *H. influenzae* type b (Hib) conjugate vaccines, Hib caused >80% of invasive *H. influenzae* infections, predominantly in children under the age of five[51,52]. In areas of routine vaccination, the majority of invasive *H. influenzae* infections are caused by non-typeable strains and predominantly affect children under the age of one and the elderly [51], with a mortality rate of 13-20%[52]. Approximately 20-35% of isolated strains are resistant to amoxicillin[51].

***Neisseria meningitidis* (Encapsulated)** is a fastidious, aerobic, gram-negative diplococcus that is spread by mucus or respiratory droplets, often from asymptomatic carriers. Twelve different serotypes of encapsulated *N. meningitidis* (A, B, C, H, I, K, L, X, Y, Z, W135, and 29E) can be distinguished. Serotypes B, C, and Y are the most prevalent in developed countries and serogroup A is predominant in the rest of the world[53]. The serotypes are determined by a polysaccharide capsule that aids bacterial survival inside the human host. *N. meningitidis* is the only species of *Neisseria* to produce a

capsule. However, it is estimated that ~16% of *N. meningitidis* bacteria are not encapsulated[54]; such strains are commonly found as commensal bacteria in the nasopharyngeal tract. However, clinical studies have recovered disease-causing unencapsulated strains of *N. meningitidis* from both immunocompetent and immunocompromised patients.[55] BSI with *N. meningitidis* is associated with fever and a characteristic hemorrhagic rash that may be transient[56]. The disease can progress extremely quickly (<24 hours) with hypotension, multi-organ dysfunction, shock, peripheral ischemia, and limb loss and has a mortality rate of approximately 5-10%[57].

Pseudomonas aeruginosa is an opportunistic, gram-negative pathogen that rarely causes disease in healthy individuals but can cause sepsis in patients with burn wounds, malignancies, immunodeficiency, or in preterm infants[58,59]. *P. aeruginosa* is a leading cause of nosocomial infections and is responsible for 10% of all hospital-acquired infections[60]. Mortality rates due to *P. aeruginosa* BSI are greater than 20%, and may be as high as 50% for intensive care unit patients and burn victims[58,59]. *P. aeruginosa* is susceptible to a limited number of antibiotics (antipseudomonal penicillins and cephalosporins, carbapenems, fluoroquinolones, and ciprofloxacin)[58], and multi-drug resistant (MDR) *P. aeruginosa* infection is becoming an increasing problem in hospitals[60].

Stenotrophomonas maltophilia is a gram-negative, obligate aerobe. This rod-shaped, environmental bacterium is commonly isolated from plant rhizospheres, animals, food, and water sources[61]. Typically not pathogenic for healthy persons, it is a well-known opportunistic human pathogen. *S. maltophilia* can infect both children and adults. Hospital-acquired infections associated with substantial morbidity and mortality are increasing, particularly in the immunocompromised patient population. In addition, community-acquired *S. maltophilia* infections have been reported from patients that often presented some form of comorbidity (trauma, central venous catheter, prior antibiotic use, malignancy, HIV infection, etc.)[62]. Polymicrobial infections of *S. maltophilia* and *P. aeruginosa* have been observed in the respiratory tract of cystic fibrosis patients. *S. maltophilia* has also been found to be present with CoNS, *Corynebacterium* species, *Pseudomonas* species, *Acinetobacter* species, and *Candida* species in blood and soft tissue of hematopoietic stem cell transplantation recipients[63]. *S. maltophilia* is intrinsically resistant to multiple classes of antibiotics.

Yeast

Candida species are yeasts that are ubiquitous in the environment and as members of the normal human microbiota, especially in the digestive tract and on mucous membranes. These fungi are important agents of opportunistic nosocomial infections ranging from superficial (e.g. oral thrush) to systemic (e.g. BSI). *Candida* spp. are the 4th most common cause of BSIs, having been detected in approximately 10% of cases in a large U.S. surveillance study[11]. The mortality rate for *Candida* bloodstream infection is approximately 40% and they often occur in combination with other bacteria or a second *Candida* spp.[64]. The five most common species causing BSIs are *C. albicans*, *C. glabrata*, *C. parapsilosis*, *C. tropicalis*, and *C. krusei.* In addition, *C. auris*, an emerging fungus, has recently been identified as a causative pathogen of BSI[65].

C. albicans accounted for over 65% of all *Candida* BSI cases reported in North America, Latin America, Europe, Asia, and the Middle East from 1997 to 2003[66]. Among the non-*C. albicans* species, ***C. glabrata*** is the most common cause of BSI in the United States, while ***C. parapsilosis*** and ***C. tropicalis*** are the major players in other countries[67]. ***Candida krusei*** is well known as a fungal pathogen among patients with hematologic malignancies and among blood and marrow transplant recipients. It contributes to 2% to 4% of all *Candida* BSIs[68] with similar overall mortality as *C. albicans* (20–40%)[69]. Less common *Candida* species may be misidentified as one of the five common species using standard laboratory culture methods as well as some molecular methods. The emergence of mass spectrometry using MALDI-TOF technology has shown promising results for yeast identification. However, the lack of sufficient mass spectrometry spectra of closely related species and of unusual species from suitable reference strains limits the ability of MALDI-TOF MS database for accurate identification of these species[70].

Candida auris was first reported in 2009 as an isolate from the external ear canal of a patient from Japan[71]. This report was followed by the first three cases of nosocomial BSI caused by *C. auris* in 2011 from South Korea[65]. A collaborative project led by the US Centers for Disease Control and Prevention (CDC) described the multidrug-resistant (MDR) nature of *C. auris* and its global emergence as a nosocomial pathogen: 93% of the 54 isolates from this study were reported to be resistant to fluconazole, the standard antifungal drug of choice in many countries, 41% were resistant to two antifungal

classes, and 4% were resistant to three classes[72]. The complexity of its MDR nature is compounded by how difficult it is to accurately identify *C. auris* by routine (non-molecular) identification systems in the laboratory[73,74].

Cryptococcus neoformans/gattii are fungi found in soil and bird droppings that can become pathogenic following their inhalation and hematogenous spread to the brain and meninges. *C. neoformans* is considered an opportunistic pathogen of immunocompromised individuals. It is the AIDS-defining illness in up to 50% of AIDS patients[75,76]. *C. gattii* infections are relatively rare but appear to be increasing. While typically associated with tropical and subtropical climates, since the 1990s *C. gattii* infections have been reported in British Columbia, Canada, the U.S. Pacific Northwest region, the Northeastern US, and in Europe[77–80]. In addition to those with reduced immune function, *C. gattii* can also cause disease in the immunocompetent, particularly in persons with underlying health conditions[75].

Antimicrobial Resistance Genes

CTX-M is a class A extended-spectrum β-lactamase (ESBL) that originated due to a mobilization of chromosomal genes (*bla*) from *Kluyvera* spp. and confers resistance to a broad spectrum of cephalosporins. This group of β-lactamases can be plasmid-borne and the *bla*$_{\text{CTX-M}}$ gene may be found in multiple copies per cell within a variety of gram-negative bacteria. Phylogenetic analyses of CTX-M describes five main lineages or phylogroups (CTX-M groups 1, 2, 8, 9, and 25) and over 200 types or variants[81]. CTX-M ESBLs are predominantly found in the *Enterobacteriaceae* family. However, they have also been reported in other non-enteric, gram-negative bacteria such as *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Acinetobacter baumannii, Vibrio* spp. and *Aeromonas* spp. Over the last decade, CTX-M enzymes have overtaken other ESBLs, including TEM and SHV ESBL variants, in prevalence[82].

IMP β-lactamases are plasmid-borne metallo-β-lactamases (MBLs) belonging to Ambler class B1 MBLs. More than 80 distinct IMP types have been identified which have the potential to confer different levels of antibiotic resistance to broad-spectrum β-lactams like carbapenems, cephamycins, and oxymino cephalosporins[83,84]. MBLs hydrolyze almost all β-lactams, rendering ineffective products, resulting in bacterial resistance to this class of antibiotics[85]. Carriage of a *bla*$_{\text{IMP}}$ gene has been detected in strains of *Serratia marcescens, Klebsiella pneumoniae, P. aeruginosa, Escherichia coli, and Enterobacter cloacae*[86].

KPC – The *Klebsiella pneumoniae* carbapenemase gene (*bla*$_{\text{KPC}}$ or referred to here as KPC), confers resistance to the carbapenem class of β-lactams and currently is thought to be the most common and rapidly emerging carbapenemase in the United States. KPCs are frequently carried on mobile genetic elements with the potential to spread between organisms. Though originally isolated from *Klebsiella pneumonia*e, the gene has since disseminated to other genera/species including *Acinetobacter*, *Pseudomonas*, *Enterobacter, Serratia, Salmonella, Escherichia coli, Klebsiella oxytoca*, and other *Enterobacteriaceae*. There are more than 40 known KPC variants that have been identified (named up to KPC-46), with the most commonly isolated types being KPC-2 and KPC-3 (www.bldb.eu)[87]. Carbapenem-resistant *Enterobacteriaceae* (CRE) are increasingly important pathogens in the hospital setting. Limited treatment options exist for CRE and they are associated with high mortality rates. Those most at risk include patients receiving long courses of antibiotics and those with indwelling devices (e.g. ventilators, urinary catheters, or intravenous catheters)[88]. Detection of KPCs using phenotypic susceptibility testing (e.g., MIC breakpoints or Modified Hodge Test) is very difficult, not only because other mechanisms of carbapenem-resistance exist, but also because KPC activity is regulated by multiple mechanisms that may not be accurately assessed *in vitro* resulting in incorrect susceptibility reporting[89,90]. Alternatively, molecular methods (e.g., PCR) are increasingly being used to specifically identify KPC genes in clinical isolates[91].

mcr-1 – Theplasmid-borne mobilized genetic determinant *mcr-1* is an emerging marker of public health importance. It is associated with elevated MICs to colistin, a last-resort drug for some multidrug-resistant infections[92]. To date, nine homologous *mcr* genes termed *mcr-1* through *mcr-9* have been identified in various *Enterobacteriaceae*[93]. The *mcr-1* gene was first described in *E. coli* (strain SHP45) from a pig located in China in 2015. pHNSHP45, the plasmid containing *mcr-1*, is capable of not only transferring between *E. coli* strains at a very high rate but also of transferring into other *Enterobacteriaceae*[94]. Mechanistically, *mcr* genes encode phosphoethanolamine transferases, which transfer a phosphoethanolamine residue to the bacterial lipid A and greatly reduces its affinity for colistin and related polymyxins[95].

mecA/C – Methicillin-resistant (MR) staphylococci are a serious concern in both hospital-acquired and community-acquired infections. Few options exist for the treatment of these infections because the bacteria are resistant to both natural and semi-synthetic β-lactam antibiotics (e.g. oxacillin/methicillin)[10]. The primary mechanism of methicillin resistance is through the acquisition of the ***mecA*** gene that encodes a penicillin-binding protein (PBP2a) that has a low affinity for β-lactams. The *mecA* gene is carried on a chromosomally integrated mobile genetic element called the staphylococcal cassette chromosome *mec* (*SCCmec*). In 2011, an *SCCmec* type XI cassette carrying a divergent *mecA* homologue (***mecC***), which also confers methicillin resistance, was identified in Europe[96].

***mecA/C* and MREJ (MRSA) –** The *SCCmec* cassette integrates into a specific region in the *Staphylococcus* genome[97,98]. In *S. aureus,* this insertion creates **MREJ** (*SCCmec* right-extremity junction), and molecular identification of this junction region provides specific identification of an *S. aureus* that carries the *SCCmec* cassette. A combined molecular detection of *mecA/C,* MREJ, and *S. aureus* indicates MRSA. However, it is possible for *S. aureus* to carry *SCCmec* that has lost the *mecA/C* gene (an 'empty cassette', estimated to be 3.9-5% of methicillin-susceptible *S. aureus*[99,100]); such a strain would be a methicillin-susceptible *S. aureus* but could be misidentified by molecular methods if there is a co-detection of an additional *Staphylococcus* spp. that carries the *mecA/C* gene. The junction, or point of insertion of the *SCCmec* cassette, can lead to a variety of MREJ types (i-xxi).

NDM – The New Delhi metallo-β-lactamase (NDM) is a plasmid-mediated enzyme that confers resistance to all current β-lactam antibiotics, with the exception of aztreonam[101,102]. There are currently close to 40 different NDM types that may be found in a variety of gram-negative species, with NDM-1 recognized throughout the world. NDM is widely and rapidly disseminated throughout the *Enterobacteriaceae*, as well as other gram-negative bacteria[102–106]. The plasmids encoding NDM are easily transferable and capable of wide rearrangement, suggestive of extensive transmission, as well as plasticity, amongst bacterial populations[103]. Multi-drug resistant NDM-producing bacteria are now the most prevalent carbapenemase producers in Europe, and this trend is expected to continue worldwide.

OXA-48-like is an oxacillinase (OXA) β-lactamase that is part of a group of primarily plasmid-mediated enzymes that confer resistance to penicillins, cephalosporins, and carbapenems. The *bla*$_{\text{OXA-48}}$ gene and its variants have been identified in various gram-negative bacteria in the *Enterobacteriaceae* family[107,108]. OXA-48 hydrolyzes penicillins at a high level and carbapenems at a low level, with greater activity against imipenem than meropenem[107], and demonstrates extremely weak activity against expanded-spectrum cephalosporins[108]. Several OXA-48-like variants maintain the hydrolytic properties and substrate profile of OXA-48 (-162, -181, -199, -204, -232, -244, -245, -252, -370, -484, -505, -514, -515, -519, -546, -547, and -566). Other variants retain activity against extended-spectrum cephalosporins but do not have the carbapenemase activity of OXA-48 (-163, -247, -405, -436, -438, -439, -517, -535, -538, -548, -549, -550, -551, -552, -553, -567, and -731).

vanA/B – Vancomycin resistance in *Enterococcus* spp. is conferred by the *vanA* and *vanB* genes. The prevalence of vancomycin-resistant enterococcus (VRE) has increased rapidly, with VRE accounting for 60% of *E. faecium* and 2% of *E. faecalis* isolated from the bloodstream[3,11]. Infection with a VRE increases the risk of death to 75%, compared with 45% for infection with a susceptible strain[3]. Nine gene clusters associated with vancomycin resistance have been identified to date (*vanA*, *vanB*, *vanC*, *vanD*, *vanE*, *vanG*, *vanL*, *vanM,* and *vanN*), with *vanA* and *vanB* being the most common in clinical isolates[109]. Both the *vanA* and *vanB* gene clusters are borne on mobile genetic elements (transposons) and can be located either on the chromosome or carried on a plasmid. Enterococci carrying *vanA* or *vanB* are resistant to high levels of vancomycin. Isolates carrying *vanA* are also resistant to high levels of teicoplanin[110].

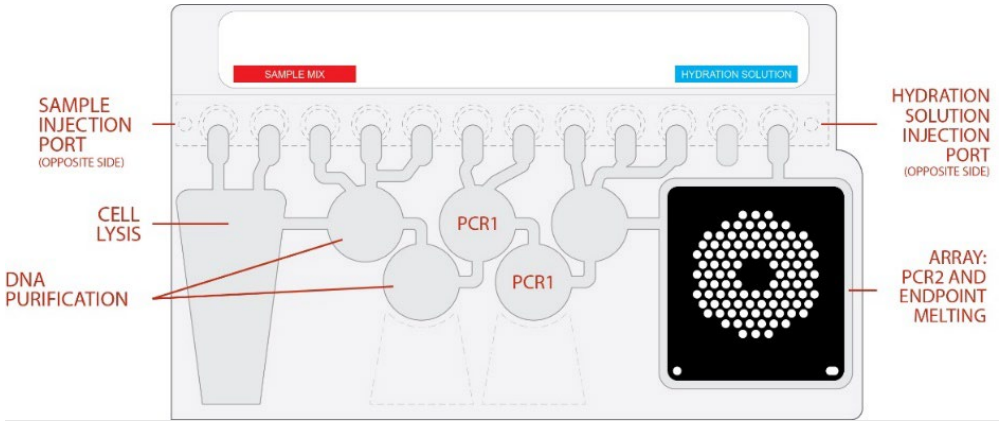
VIM – Verona Integron-Encoded Metallo-β-Lactamase (VIM) is an integron-encoded carbapenemase. There are reports of both plasmid and chromosomal localization of the *bla*$_{\text{VIM}}$ integron[111], however, the majority of *bla*$_{\text{VIM}}$ alleles are found on plasmids. There are over 60 distinct VIM types. VIMs are found mainly in gram-negative bacteria, including *Enterobacterales*, with a vast majority associated with various species of *Pseudomonas*.

PRINCIPLE OF THE PROCEDURE

The BIOFIRE BCID2 Panel pouch is a closed-system disposable that stores all the necessary reagents for sample preparation, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple pathogens and antimicrobial resistance genes contained in blood culture samples identified as positive by a continuous monitoring blood culture system. After sample collection, the user injects Hydration Solution and sample combined with Sample Buffer into the pouch, places the pouch into a BIOFIRE® FILMARRAY® Instrument module, and starts a run. The entire run process takes about an hour. Additional detail can be found in the appropriate BIOFIRE® FILMARRAY® System Operator's Manual.

During a run, the BIOFIRE System:

- Lyses the sample by agitation (bead beating) in addition to chemical lysis mediated by the Sample Buffer.
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
    - First performing a single, large volume, massively multiplexed reaction (PCR1)
    - Then performing multiple singleplex second-stage PCR reactions (PCR2) to amplify sequences within the PCR1 products
- Uses endpoint melting curve data to detect and generate a result for each target on the BIOFIRE BCID2 Panel array.



MATERIALS PROVIDED

The BIOFIRE BCID2 Panel contains materials consisting of primers, buffers, dNTPs, polymerase, molecular grade water, guanidinium chloride (50 - < 60%), Triton-X 100 (10 - < 20%), and LCGreen® Plus.

Each kit contains sufficient reagents to test 30 samples (30-test kit; RFIT-ASY-0147):

- Individually packaged BIOFIRE BCID2 Panel pouches
- Single-use Sample Buffer ampoules
- Single-use pre-filled Hydration Injection Vials (blue)
- Single-use Sample Injection Vials (red)
- Individually packaged Transfer Pipettes
- BIOFIRE BCID2 Panel Pouch Module Software
  This software is required to run the BIOFIRE BCID2 Panel and can be downloaded at https://www.biofiredx.com/e-labeling/ITIFA20BCID210 if not already installed on the BIOFIRE 2.0 or BIOFIRE Torch Systems.

MATERIALS REQUIRED BUT NOT PROVIDED

- BIOFIRE System including:
  - BIOFIRE 2.0 or BIOFIRE Torch Systems including accompanying system-specific core software
  - BIOFIRE® Pouch Loading Station
- Syringe capable of measuring 0.2 mL (200 µL) sample volume OR alternate subculture device (e.g., needle-less safe subculture device) and sterile secondary container
- 10% bleach solution or a similar disinfectant

WARNINGS AND PRECAUTIONS

General Precautions

1. For *in vitro* diagnostic use only.
2. A trained healthcare professional should carefully interpret the results from the BIOFIRE BCID2 Panel in conjunction with a patient's signs and symptoms, results from Gram stain and other diagnostic tests, and any relevant epidemiological information.
3. BIOFIRE BCID2 Panel pouches are only for use with BIOFIRE 2.0 and BIOFIRE Torch systems.
4. Always check the expiration date on the pouch. Do not use a pouch after its expiration date.
5. Pouches are stored under vacuum in individually wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that an instrument/module will be available and operational before unwrapping any pouches for loading.

Safety Precautions

1. Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable, clean, powder-free gloves and lab coats. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.
2. Handle all samples and waste materials as if they were capable of transmitting infectious agents. Observe safety guidelines such as those outlined in:
   - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*[112]
   - CLSI Document M29 *Protection of Laboratory Workers from Occupationally Acquired Infections*[113]
3. Follow your institution's safety procedures for handling biological samples.
4. Dispose of materials used in this test (including reagents, samples, and used buffer vials) according to federal, state, and local regulations.
5. Sample Buffer contains Guanidinium chloride and Triton X100.

The following statements apply.

- Health Hazards
  - Acute Toxicity, oral (Category 4)
    - H302 – Harmful if swallowed.
  - Skin corrosion/irritation (Category 2)
    - H315 - Causes skin irritation.
  - Serious eye damage/eye irritation (Category 1)
    - H318 - Causes serious eye damage.
- Environment Hazards
  - Hazardous to the aquatic environment, acute aquatic hazard (Category 1)
    - H400 - Very toxic to aquatic life.
  - Hazardous to the aquatic environment, long-term aquatic hazard (Category 1)
    - H410 - Very toxic to aquatic life with long lasting effects.
- Precautionary Statements
  - Prevention
    - P273 – Avoid release to the environment.
    - P280 – Wear protective gloves/protective clothing/eye protections/face protection.
- Response
    - P332 + P313 - If skin irritation occurs: Get medical advice/attention.
    - P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
    - P301 + P312 - IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
    - P337 + P313 - If eye irritation persists: Get medical advice/attention.

Please refer to the BIOFIRE BCID2 Safety Data Sheet (SDS) for more information: https://www.BIOFIREdx.com/e-labeling/ITI0088.

6. Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.

WARNING: Never add Bleach to Sample Buffer or sample waste.

7. Bleach, a recommended disinfectant, is corrosive and may cause severe irritation or damage to eyes and skin. Vapor or mist may irritate the respiratory tract. Bleach is harmful if swallowed or inhaled.
    - Eye contact: Hold eye open and rinse with water for 15–20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention.
    - Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
    - Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, seek medical attention.
    - Please refer to the appropriate Safety Data Sheet (SDS) for more information.

Laboratory Precautions

1. Preventing organism contamination

Due to the sensitive nature of the BIOFIRE BCID2 Panel, it is important to guard against contamination of the sample and work area by carefully following the testing process outlined in this instruction document, including these guidelines:

- Positive blood culture samples contain high concentrations of organisms; careful adherence to the sample processing steps described in this document is recommended to avoid possible contamination. Samples should be processed in a clean biosafety cabinet if available, or according to local laboratory guidelines. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield can be used when preparing samples instead.
- It is recommended to avoid handling specimens or pouches in an area used to routinely process primary samples (excluding positive blood culture bottles), for bacterial or fungal Gram stains, rapid antigen testing, and/or cultures, unless the area is thoroughly cleaned first.
- Prior to processing specimens, thoroughly clean both the work area and the Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue build-up and potential damage to the specimen or interference from disinfectants, wipe disinfected surfaces with water.
- Specimens and pouches should be handled and/or tested one at a time. Always change gloves and clean the work area between each pouch and specimen.
- Use clean gloves when removing Sample Buffer ampoules and Sample/Hydration Injection Vials from bulk packaging bags and reseal bulk packaging bags when not in use.

2. Preventing amplicon contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the BIOFIRE BCID2 Panel pouch is a closed system, the risk of amplicon contamination is low, provided that the pouches remain intact after the test is completed. Adhere to the following guidelines, in addition to those above, to prevent amplicon contamination:

- Discard used pouches in a biohazard container immediately after the run has completed.
- Avoid excessive handling of pouches after test runs.
- Change gloves after handling a used pouch.

- Avoid exposing pouches to sharp edges or anything that might cause a puncture.

WARNING: If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and workspace must be decontaminated as described in the appropriate BIOFIRE System Operator's Manual.

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

3. **Blood culture media may contain non-viable organisms and/or nucleic acids at levels that can be detected by the BIOFIRE BCID2 Panel.**

   The presence of non-viable organisms and/or nucleic acids in blood culture media may lead to false positive test results. Increases in false positive results due to non-viable *Enterococcus, P. aeruginosa*, *Proteus* and *E. coli* have been previously identified in various media types; the organism involved and frequency of such occurrences may change in the future. Typically, these false positives present with more than one positive result because the BIOFIRE BCID2 Panel may also detect the organism that is growing in the culture bottle.

   - Do not use blood culture media that contains charcoal.
   - In some cases, the Gram stain result and results from the BIOFIRE BCID2 Panel may be discrepant (for example, detection of gram-positive cocci by the BIOFIRE BCID2 Panel when gram-positive cocci are not observed in the Gram stain). In these cases, the BIOFIRE BCID2 Panel results should be confirmed (e.g. by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.

Precaution Related to Public Health

Local, state, and federal/national regulations for notification of reportable disease are continually updated and include a number of organisms for surveillance and outbreak investigations.[114,115] Several initiatives are also in place worldwide for notification and surveillance of antibiotic resistance, including carbapenemase-producing *Enterobacteriaceae* (CPE)/carbapenem-resistant *Enterobacteriaceae* (CRE) as well as colistin-resistant *Enterobacteriaceae* (CCRE).

The U.S. Centers for Disease Control and Prevention (CDC) recommends that when pathogens from reportable diseases are detected by a culture-independent diagnostic test (CIDT), the laboratory should facilitate obtaining the isolate or clinical materials for submission to the appropriate public health laboratory to aid in outbreak detection and epidemiological investigations.

Laboratories are responsible for following applicable regulations and should consult their local, state and/or national public health or reference laboratories for reporting as well as isolate and/or clinical sample submission guidelines.

Precaution Related to REACH Regulation (EC 1907/2006)

This statement only applies to countries within the European Union (EU) with regards to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006):

It is recommended that all material associated with the test, including the material used to clean up spills, contaminated packaging, and/or unused and expired IVD tests, is incinerated. Please ensure that you follow local regulations regarding disposal.

REAGENT STORAGE, HANDLING, AND STABILITY

1. Store the test kit, including reagent pouches and buffers, at room temperature (15–25 ºC).
2. Avoid storage of any materials near heating or cooling vents or in direct sunlight.
3. All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
4. Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
5. Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

SAMPLE REQUIREMENTS

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results.

Table 1. Sample Requirements for the BIOFIRE BCID2 Panel

Specimen Type	**Blood Culture Samples** identified as positive by a continuous monitoring blood culture system.
Minimum Sample Volume	0.2 mL (200 µL)
Sample Age	Specimens should be processed and tested with the BIOFIRE BCID2 Panel as soon as possible after positive bottle indication by a blood culture system. If not processed immediately, specimens can be kept: • At room temperature for up to 24 hours (15–25 °C) after positivity • In the blood culture system for up to 24 hours after positivity

NOTE: Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.

PROCEDURE

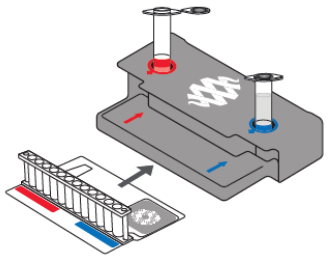
Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and samples. Only prepare one BIOFIRE BCID2 Panel pouch at a time and change gloves between samples and pouches. Once sample is added to the pouch, promptly transfer to the instrument to start the run. After the run is complete, discard the pouch in a biohazard container.

Step 1: Prepare Pouch

1. Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective canister.

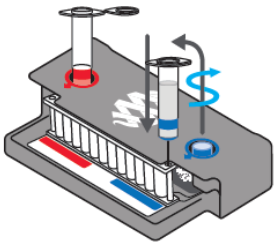
NOTE: The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

3. Check the expiration date on the pouch. Do not use expired pouches.
4. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
5. Place a red-capped Sample Injection Vial into the red well of the Pouch Loading Station.
6. Place a blue-capped Hydration Injection Vial into the blue well of the Pouch Loading Station.



Step 2: Hydrate Pouch

1. Unscrew the Hydration Injection Vial from the blue cap.
2. Remove the Hydration Injection Vial, leaving the blue cap in the Pouch Loading Station.
3. Insert the Hydration Injection Vial's cannula tip into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.
4. Forcefully push down in a firm and quick motion to puncture seal until a faint "pop" is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.



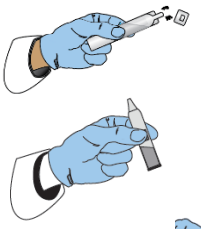
   - If the Hydration Solution is not automatically drawn into the pouch, repeat Step 2 to verify that the seal of the pouch hydration port was broken. If Hydration Solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
5. Verify that the pouch has been hydrated.
   - Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
   - If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the pouch hydration port was broken. If Hydration Solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

Step 3: Prepare Sample Mix

1. Add Sample Buffer to the Sample Injection Vial.
    - Hold the Sample Buffer ampoule with the tip facing up.

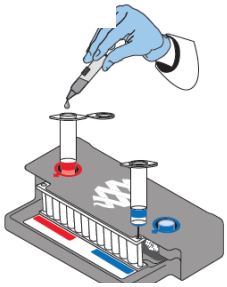
NOTE: Avoid touching the ampoule tip during handling, as this may introduce contamination.

- To open the Sample Buffer Ampoule:
    - If the ampoule has a plastic tab on the tip: Gently twist and remove tab at the tip of the Sample Buffer Ampoule.
    - If the ampoule does not have a plastic tab at the tip: Firmly pinch at the textured plastic tab on the side of the ampoule until the seal snaps.



NOTE: There are 2 possible configurations of the Sample Buffer ampoule.

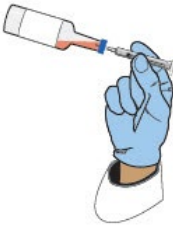
- Invert the ampoule over the red-capped Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.



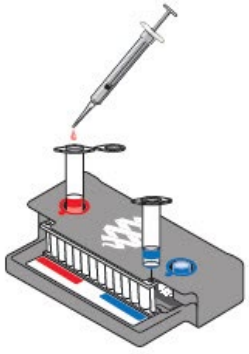
NOTE: Avoid squeezing the ampoule additional times to avoid foaming.

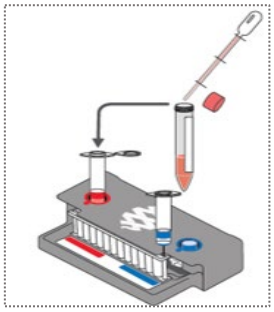
WARNING: The Sample Buffer is harmful if swallowed and can cause serious eye damage and skin irritation.

2. Thoroughly mix the positive blood culture bottle by inverting it several times.
3. Wipe the bottle septum with alcohol and air dry.
4. Using a syringe, withdraw 0.2 mL of blood culture sample through the bottle septum, taking care to avoid the formation of bubbles.



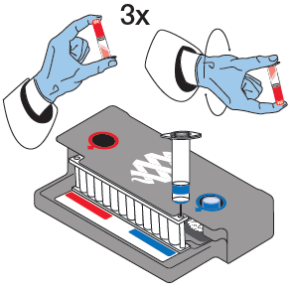
5. Add sample directly to Sample Buffer in the Sample Injection Vial. Discard syringe in an appropriate biohazard sharps container and tightly close the lid of the Sample Injection Vial.





Alternatively: Draw the desired amount of blood culture sample (> 0.2 mL) from the bottle into the syringe and transfer to a sterile secondary container OR remove blood culture sample (> 0.2 mL) using an alternate subculture device (*e.g.* needle-less safe subculture device) into a sterile secondary container. Draw the blood culture sample from the secondary container to the second line of the Transfer Pipette (0.2 mL) and add the sample to Sample Buffer in the Sample Injection Vial. Tightly close the lid of the Sample Injection Vial and discard the Transfer Pipette in a biohazard waste container.

NOTE: DO NOT use the Transfer Pipette to mix the sample once it is loaded into the Sample Injection Vial.



6. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 3 times to mix.
7. Return the Sample Injection Vial to the red well of the Pouch Loading Station.

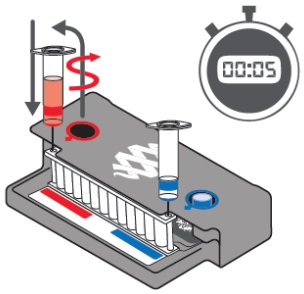
Step 4: Load Sample Mix

1. Slowly twist to unscrew the Sample Injection Vial from the red cap and wait for 5 seconds with the vial resting in the cap.

   NOTE: Waiting 5 seconds decreases the risk of dripping and contamination from the sample.

2. Lift the Sample Injection Vial, leaving red cap in the well of the Pouch Loading Station, and insert the Sample Injection Vial cannula tip into the pouch sample port located directly below the red arrow of the Pouch Loading Station.

3. Forcefully push down in a firm and quick motion to puncture seal (a faint “pop” is heard) and sample is pulled into the pouch by vacuum.



4. Verify that the sample has been loaded.

   - Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
   - If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.

5. Discard the Sample Injection Vial and the Hydration Injection Vial in the appropriate biohazard sharps container.

6. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

Step 5: Run Pouch

The BIOFIRE® FILMARRAY® Software includes step-by-step, on-screen instructions that guide the operator through performing a run. Brief instructions for BIOFIRE 2.0 and BIOFIRE Torch Systems are given below. Refer to the appropriate BIOFIRE System Operator’s Manual for more detailed instructions.

BIOFIRE 2.0

1. Ensure that the BIOFIRE 2.0 system (module[s] and computer) is powered on and the software is launched.

2. Follow on-screen instructions and procedures described in the Operator’s Manual to place the pouch in a module, enter pouch, sample, and operator information.

3. Pouch identification (Lot Number and Serial Number), Pouch Type, and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BIOFIRE BCID2 Panel pouch.

4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.

5. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop-down list. The BIOFIRE BCID2 Panel has a single protocol available in the drop-down list.

6. Enter a username and password in the Name and Password fields.

NOTE: The font color of the username is red until the username is recognized by the software.

7. Review the entered run information on the screen. If correct, select Start Run.

   Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.

8. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard waste container.
9. The run file is automatically saved in the BIOFIRE Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

BIOFIRE Torch

1. Ensure that the BIOFIRE Torch system is powered on.
2. Select an available module on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number), Pouch Type, and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BIOFIRE BCID2 Panel pouch.

4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. Insert the pouch into the available module.
   - Ensure that the pouch fitment label is lying flat on top of the pouch and not folded over. As the pouch is inserted, the module will grab onto the pouch and pull it into the chamber.
6. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop-down list. The BIOFIRE BCID2 Panel has a single protocol available in the drop-down list.
7. Enter a username and password, then select Next.

NOTE: The font color of the username is red until the username is recognized by the software.

8. Review the entered run information on the screen. If correct, select Start Run.

   Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.

9. At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.
10. The run file is automatically saved in the BIOFIRE Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

QUALITY CONTROL

Process Controls

Two process controls are included in each pouch:

1. **DNA Process Control**

   The DNA Process Control assay targets a DNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the BIOFIRE BCID2 Panel pouch were successful.

2. **PCR2 Control**

   The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that PCR2 was successful.

Both control assays must be positive for the test run to pass. If the controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The BIOFIRE Software will automatically fail the run if the melting temperature (Tm) for either the DNA Process Control or the PCR2 Control is outside of an acceptable range (77.3-81.3°C for the DNA Process Control and 73.7-77.7°C for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintain records according to standard laboratory quality control practices.[116,117] Refer to the appropriate BIOFIRE System Operator's Manual for instructions on obtaining control assay Tm values. The PCR2 Control is used in several BIOFIRE® FILMARRAY® Pouch types and can, therefore, be used to monitor the system when multiple pouch types are used on the same BIOFIRE System or instrument.

External Controls

External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Un-inoculated blood culture media can be used as an external negative control; however, external negative controls may not identify sporadic nucleic acid contamination in blood culture bottles. Previously characterized positive blood culture samples or samples spiked with well-characterized organisms can be used as external positive controls. Commercially produced control materials may also be available from other manufacturers; use according to the control manufacturer's instructions.

INTERPRETATION OF RESULTS

Assay Interpretation

When PCR2 is complete, the BIOFIRE Instrument performs a high-resolution DNA melting analysis on the PCR products and records the change in fluorescence signal generated in each well (for more information see appropriate BIOFIRE System Operator's Manual). The BIOFIRE Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The BIOFIRE Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve and compares it against the expected Tm range for the assay. If the software determines that the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, two associated melt curves must be called positive, and both Tms must be similar. Assays that do not meet these criteria are called negative.

Organism and Antimicrobial Resistance Gene Interpretation

Each positive and negative assay result is interpreted by the BIOFIRE Software to provide results for the identification of specific bacteria, yeast, and antimicrobial resistance (AMR) genes as shown in Table 2.

For most species detected by the BIOFIRE BCID2 Panel, the organism is reported as Detected if a single corresponding assay is positive. Results may also be reported for groups or complexes of closely related species (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae* complex, and *Klebsiella pneumoniae* group), genera containing multiple clinically relevant species (*Proteus* spp., *Salmonella* spp., *Staphylococcus* spp. and *Streptococcus* spp.), and for a variety of species within multiple genera of the order *Enterobacterales*. Results for these groups are reported qualitatively as Detected or Not Detected based on one assay, or in some cases, multiple relevant assays. Reporting of AMR genes with one or more applicable bacteria also requires interpretation based on more than one assay result, as discussed below.

NOTE: Polymicrobial blood cultures with four or more distinct organisms are possible but rare. If Detected results are reported for four or more organisms in a sample, a retest of the sample is recommended to confirm the polymicrobial result.

NOTE: In some cases, the Gram stain result and BIOFIRE BCID2 Panel results may be discrepant (for example, detection of gram-positive cocci by BIOFIRE BCID2 Panel when gram-positive cocci were not observed in the Gram stain). In these cases, the BIOFIRE BCID2 Panel results should be confirmed (e.g. by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.

Table 2. Analytes Detected by the BIOFIRE BCID2 Panel

Gram Positive Bacteria		
Enterococcus faecalis	*Staphylococcus* spp.	*Streptococcus* spp.
Enterococcus faecium	*Staphylococcus aureus*	*Streptococcus agalactiae* (Group B)
Listeria monocytogenes	*Staphylococcus epidermidis*	*Streptococcus pneumoniae*
	Staphylococcus lugdunensis	*Streptococcus pyogenes* (Group A)
Gram Negative Bacteria		
Acinetobacter calcoaceticus-baumannii complex		*Enterobacterales*
Bacteroides fragilis		*Enterobacter cloacae* complex

Haemophilus influenzae				*Escherichia coli*
Neisseria meningitidis (encapsulated)				*Klebsiella aerogenes*
Pseudomonas aeruginosa				*Klebsiella oxytoca*
Stenotrophomonas maltophilia				*Klebsiella pneumoniae* group
				Proteus spp.
				Salmonella spp.
				Serratia marcescens
Yeast				
Candida albicans		*Candida krusei*	*Cryptococcus neoformans/gattii*	
Candida auris		*Candida parapsilosis*		
Candida glabrata		*Candida tropicalis*		
Antimicrobial Resistance Genes				
CTX-M	KPC	*mecA/C*	NDM	*vanA/B*
IMP	*mcr-1*[a]	*mecA/C* and MREJ (MRSA)	OXA-48-like	VIM

[a] As of February 2020, the United States Food and Drug Administration has not established or recognized minimum inhibitory concentration (MIC) breakpoints for colistin antimicrobial susceptibility testing (AST) related to *mcr-1.*

Results Interpretation for Gram-Positive Bacteria

The BIOFIRE BCID2 Panel contains assays for the specific detection of the major species associated with *Enterococcus* bloodstream infections (*Enterococcus faecium* and *Enterococcus faecalis*), *Listeria monocytogenes*, as well as clinically important Staphylococci (*S. aureus*, *S. epidermidis,* and *S. lugdunensis*) and Streptococci (*S. agalactiae*, *S. pneumoniae,* and *S. pyogenes*). Results for these gram-positive bacteria are reported as Detected or Not Detected based on an individual corresponding assay result. If the assay is positive the result will be Detected, and if the assay is negative, the result will be Not Detected.

Information about detection of specific subspecies, strains, isolates, or serotypes of gram-positive bacteria is provided in the Analytical Reactivity (Inclusivity) section (Table 87 - Table 97). Based on *in silico* analysis and empirical testing, each of the gram-positive species-specific assays is specific for detection of the indicated species with the exception of the Saureus assay, which will also amplify the closely related species of the *S. aureus*-complex (*S. argenteus* and *S. schweitzeri*), as noted in the Analytical Specificity (Cross-Reactivity and Exclusivity) section (Table 130).

In addition, the panel detects other species identified as *Staphylococcus* spp. and *Streptococcus* spp. based on the results of multiple assays, as described below.

Staphylococcus spp.

The BIOFIRE BCID2 Panel contains four assays for the detection of *Staphylococcus* species. Species-specific genus-level are included for the detection of *Staphylococcus aureus, Staphylococcus epidermidis*, and *Staphylococcus lugdunensis*. The fourth assay is a genus-level assay (Staphylococcus) designed to react with *Staphylococcus* species not specifically identified by one of the other assays on the panel (see Table 90). The BIOFIRE Software integrates the results of all four assays into a *Staphylococcus* spp. result as shown in Table 3. If all four assays are negative, the test result will be *Staphylococcus* spp. Not Detected. Alternatively, if any of the four assays are positive, the test result will be *Staphylococcus* spp. Detected and results for each species-specific assay will also be reported independently.

Based on testing and sequence analysis, it is predicted that five species within the *Staphylococcus* genus (*S. equorum*, *S. fluerettii*, *S. lentus*, *S. muscae,* and *S. rostri*) may not be detected by the panel, even at positive blood culture levels, due to sequence variation under the assay primers. Of these, only *S. equorum* has been reported to be isolated in a clinical setting. Sequence analysis predicts a low risk of cross-reactivity between the Staphylococcus assay and homologous sequences from *Aerococcus viridans*, *Enterococcus cecorum*, and *Granulicatella adiacens*, although only at very high concentrations.

Table 3. Assay and Results Interpretation for the *Staphylococcus* spp., *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Staphylococcus lugdunensis* Test Results

BIOFIRE BCID2 Panel Results	Staphylococcus assay	Saureus assay	Sepidermidis assay	Slugdunensis assay	Description
Staphylococcus spp. Not Detected *Staphylococcus aureus* Not Detected *Staphylococcus epidermidis* Not Detected *Staphylococcus lugdunensis* Not Detected	Negative	Negative	Negative	Negative	No *Staphylococcus* species detected in the sample
***Staphylococcus* spp. Detected** *Staphylococcus aureus* Not Detected *Staphylococcus epidermidis* Not Detected *Staphylococcus lugdunensis* Not Detected	**Positive**	Negative	Negative	Negative	One or more *Staphylococcus* species detected in the sample (not *S. aureus*, *S. epidermidis*, or *S. lugdunensis*)
***Staphylococcus* spp. Detected** ***Staphylococcus aureus* Detected** *Staphylococcus epidermidis* Not Detected *Staphylococcus lugdunensis* Not Detected	Any result	**Positive**	Negative	Negative	*Staphylococcus aureus* detected in the sample Note: additional *Staphylococcus* species (not *S. epidermidis* or *S. lugdunensis*) may also be in the sample
***Staphylococcus* spp. Detected** *Staphylococcus aureus* Not Detected ***Staphylococcus epidermidis* Detected** *Staphylococcus lugdunensis* Not Detected	Any result	Negative	**Positive**	Negative	*Staphylococcus epidermidis* detected in the sample Note: additional *Staphylococcus* species (not *S. aureus* or *S. lugdunensis*) may also be in the sample
***Staphylococcus* spp. Detected** *Staphylococcus aureus* Not Detected *Staphylococcus epidermidis* Not Detected ***Staphylococcus lugdunensis* Detected**	Any result	Negative	Negative	**Positive**	*Staphylococcus lugdunensis* detected in the sample Note: additional *Staphylococcus* species (not *S. aureus* or *S. epidermidis*) may also be in the sample

NOTE: Multiple Staphylococcus species assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

Streptococcus spp.

The BIOFIRE BCID2 Panel contains four assays for the detection of *Streptococcus* species. Species-specific assays are included for the detection of Group A Strep (Spyogenes), Group B Strep (Sagalactiae), and *S. pneumoniae* (Spneumoniae). The fourth assay is a genus-level assay (Streptococcus) designed to react with most Viridans group and other *Streptococcus* species that are not specifically identified by one of the other assays on the panel. The BIOFIRE Software integrates the results of all four *Streptococcus* assays into a *Streptococcus* spp. result as shown in Table 4. If all four assays are negative, the test result will be *Streptococcus* spp. Not Detected. Alternatively, if any of the four assays are positive, the test result will be *Streptococcus* spp. Detected and results for each species-specific assay will also be reported independently.

Based on testing and analysis of available sequence data, all species within the *Streptococcus* genus will be amplified by one or more of the assays on the panel at positive blood culture levels. However, there are some species (*Streptococcus equi*, *S. entericus*, *S. halitosis*, *S.hyovaginalis*, *S. minor,* and *S. pantholopis*) and variant sequences identified as *S. minor*, *S. oralis*, *S. sobrinus*, *S. suis,* and *S. uberis* that may be amplified less efficiently than others and may not be detected if present in a blood culture at a concentration lower than approximately 7.6E+06 CFU/mL.

Table 4. Assay and Results Interpretation for the *Streptococcus* spp., *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, and *Streptococcus pyogenes* (Group A) Test Results

BIOFIRE BCID2 Panel Results	Streptococcus Assay	Sagalactiae Assay	Spneumoniae Assay	Spyogenes Assay	Description
Streptococcus spp. Not Detected *Streptococcus agalactiae* (Group B) Not Detected *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* (Group A) Not Detected	Negative	Negative	Negative	Negative	No *Streptococcus* species detected in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* (Group B) Not Detected *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* (Group A) Not Detected	**Positive**	Negative	Negative	Negative	One or more *Streptococcus* species detected in the sample (not *S. agalactiae*, *S. pneumoniae*, or *S. pyogenes*)
***Streptococcus* spp. Detected** ***Streptococcus agalactiae* (Group B) Detected** *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* (Group A) Not Detected	Any result	**Positive**	Negative	Negative	*Streptococcus agalactiae* detected in the sample. Note: additional *Streptococcus* species (not *S. pneumoniae* or *S. pyogenes*) may also be in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* (Group B) Not Detected ***Streptococcus pneumoniae* Detected** *Streptococcus pyogenes* (Group A) Not Detected	Any result	Negative	**Positive**	Negative	*Streptococcus pneumoniae* detected in the sample Note: additional *Streptococcus* species (not *S. agalactiae* or *S. pyogenes*) may also be in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* (Group B) Not Detected *Streptococcus pneumoniae* Not Detected ***Streptococcus pyogenes* (Group A) Detected**	Any result	Negative	Negative	**Positive**	*Streptococcus pyogenes* detected in the sample Note: additional *Streptococcus* species (not *S. agalactiae* or *S. pneumoniae*) may also be in the sample

NOTE: Multiple Streptococcus species assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

Results Interpretation for Gram-Negative Bacteria

The BIOFIRE BCID2 Panel contains assays for the specific detection of many gram-negative species associated with bloodstream infections. Species are identified individually (*Bacteroides fragilis*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Neisseria meningitidis*, *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Stenotrophomonas maltophilia*) or as complex, group, or genus results (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae* complex, *Klebsiella pneumoniae* group, *Proteus* spp., and *Salmonella* spp.). Each of these is reported as Detected or Not Detected based on an individual corresponding assay result. If the assay is positive, the result will be Detected; if the assay is negative, the result will be Not Detected.

In addition, the panel detects a large number of additional gram-negative species identified as *Enterobacterales* based on the results of multiple assays, as described below.

Information about the detection of specific subspecies, strains, isolates, or serotypes of gram-negative bacteria is provided in the Analytical Reactivity (Inclusivity) section (Table 98 – Table 112). Based on testing and *in silico* analysis, each of the gram-negative assays is specific for detection of the indicated genus, complex, group or species with the exception of the cross-reactivities noted below and in the Analytical Specificity (Cross-Reactivity and Exclusivity) section (Table 130 and Table 131).

- *Bacteroides xylanisolvens*, a commensal species that naturally resides in the human intestine, can be misidentified as *Bacteroides fragilis* due to non-specific interaction with the Bfragilis assay. At particularly high concentrations, a cross-reactive interaction may also be seen with *Bacteroides ovatus*, a species of the *B. fragilis* group.
- The *Enterobacter cloacae* complex is comprised of multiple species (*E. asburiae*, *E. cloacae*, *E. hormaechei*, *E. kobei*, *E. ludwigii and E. mori*) that may all be identified as *E. cloacae* by phenotypic laboratory methods. The Ecloacae assay will detect each of these species and subspecies (e.g. *Enterobacter hormaechei* ssp. *xiangfangensis*) and will also cross-react with another closely related and more recently identified species, *Enterobacter bugandensis*. In addition, at high concentrations, the Ecloacae assay will cross-react with *Trabulsiella guamensis* due to non-specific interaction of the assay with a distantly related gene sequence in this species.
- The Ecoli assay cross-reacts with *Shigella* species (*S. boydii*, *S. dysenteriae*, *S. flexneri*, and *S. sonnei*); which are practically indistinguishable from *E. coli* by both phenotypic and genetic analyses but are only very rarely isolated from blood culture. Cross-reactivity has also been observed with *Escherichia fergusonii*, a rare but emerging veterinary and human pathogen, and *Escherichia albertii* (only at high concentration), a species more typically associated with gastrointestinal infections.
- *Haemophilus aegyptius*, generally considered a subgroup or biotype of *Haemophilus influenzae*, is difficult to differentiate by most laboratory methods and will be detected as *Haemophilus influenzae* by the BIOFIRE BCID2 Panel due to cross-reactivity.
- The Koxytoca assay will cross-react with two recently identified *Klebsiella* species, *K. grimontii* (identified in 2018; previously *Klebsiella oxytoca* phylogroup Ko6) and *K. michiganensis* (identified in 2013). The assay does not cross-react with other *Klebsiella* species; however, *K. pneumoniae* or *Raoultella ornithinolytica* can be misidentified as *K. oxytoca* by standard laboratory methods leading to instances of apparent false negative *K. oxytoca* results.
- The Salmonella assay will react with both species of *Salmonella* (*S. bongori* and *S. enterica*), including all known subspecies and serotypes. Although not detected when tested at a high concentration of ~7.0E+09 CFU/mL, sequence analysis predicts a low risk of cross-reactivity between this assay and a homologous gene sequence found in *Plesiomonas shigelloides*.
- The Proteus assay can cross-react with an insect-associated species (*Cosenzaea myxofaciens*) that was formerly classified as *Proteus myxofaciens*.

Enterobacterales

The BIOFIRE BCID2 Panel contains ten assays for the detection of most species within multiple families of the order *Enterobacterales*. Two assays (Enteric1 and Enteric2) are designed to react with relevant (and some non-relevant) species within the following families: *Enterobacteriaceae*, *Erwiniaceae*, *Hafniaceae*, *Morganellaceae*, *Yersiniaceae, Pectobacteriaceae,* and *Budviciaceae;* though species within the latter two families are generally not associated with human disease[27].

The BIOFIRE BCID2 Panel also contains eight other assays for the detection of specific species, genera, or groups of species within the *Enterobacterales* order including *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Serratia marcescens*.

The BIOFIRE Software integrates the results of all ten assays into an *Enterobacterales* result as shown with examples in Table 5. If all ten assays are negative, the test result will be *Enterobacterales* Not Detected. Alternatively, if any of the ten assays are positive, the test result will be *Enterobacterales* Detected and results for the genus, complex, group, or species-specific assays will also be reported independently.

Based on testing and analysis of available sequence data, the Enteric1 and Enteric2 assays will amplify all *Enterobacteriaceae* evaluated, as well as most species of the other families within the *Enterobacterales* order. However, a few species of *Morganellaceae* (*Providencia heimbachae*, *Photorhabdus asymbiotica*, and *Arsenophonus nasoniae*) which are rarely or never isolated from human clinical samples, will not be detected. In addition, *Yersinia pseudotuberculosis* and *Mixta* (formerly *Pantoea*) *calida* and species with similar sequences may be amplified less efficiently than others and may not be detected if present in a blood culture at a concentration lower than approximately 1.1E+07 CFU/mL.

Table 5. Assay and Results Interpretation for the *Enterobacterales* Test Result

BIOFIRE BCID2 Panel Results	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Description
Enterobacterales Not Detected *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	No *Enterobacterales* detected in the sample.
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	One or more *Enterobacterales* detected in the sample (not *E. cloacae* complex, *E. coli*, *K. aerogenes*, *K. oxytoca*, *K. pneumoniae* group, *Proteus* spp., *Salmonella* spp., or *S. marcescens*)
***Enterobacterales* Detected** ***Enterobacter cloacae* complex Detected** *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Any result	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	One or more species of the *Enterobacter cloacae* complex detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected ***Escherichia coli* Detected** *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Any result	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	*Escherichia coli* detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected ***Klebsiella aerogenes* Detected** *Klebsiella oxytoca* Not Detected	Any result	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	*Klebsiella aerogenes* detected in the sample

BIOFIRE BCID2 Panel Results	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Description
Klebsiella pneumoniae group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected										Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected ***Klebsiella oxytoca* Detected** *Klebsiella pneumoniae* group Not Detected *Proteus spp.* Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Any result	Neg	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg	*Klebsiella oxytoca* detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected ***Klebsiella pneumoniae* group Detected** *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Any result	Neg	Neg	Neg	Neg	**Pos**	Neg	Neg	Neg	One or more species in the *Klebsiella pneumoniae* group detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected ***Proteus* spp. Detected** *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected	Any result	Neg	Neg	Neg	Neg	Neg	**Pos**	Neg	Neg	One or more *Proteus* species detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected ***Salmonella* spp. Detected** *Serratia marcescens* Not Detected	Any result	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	Neg	One or more *Salmonella* species detected in the sample Note: additional *Enterobacterales* may also be in the sample
***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected ***Serratia marcescens* Detected**	Any result	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	*Serratia marcescens* detected in the sample Note: additional *Enterobacterales* may also be in the sample

NOTE: Multiple Enterobacterales assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

Results Interpretation for Antimicrobial Resistance (AMR) Genes

The BIOFIRE BCID2 Panel contains assays for the specific detection of several genetic determinants of resistance to multiple classes of antibiotics found in select gram-positive (*mecA*/*C*, *mecA*/*C,* and MREJ, and *vanA*/*B*) or gram-negative bacteria (CTX-M, IMP, KPC, *mcr-1*, NDM, OXA-48, and VIM). Results for the AMR genes are not reported unless an applicable bacterium is also detected, therefore the results are based on multiple assays, as described below.

The results for each of the antimicrobial resistance genes will be listed as:

- Detected – when an applicable bacterium is detected AND the antimicrobial resistance gene assay(s) are positive.
- Not Detected – when an applicable bacterium is detected AND the antimicrobial resistance gene assay(s) are negative.
- N/A – when all applicable bacteria are Not Detected, regardless of the result for the antimicrobial resistance gene assay(s).

Each AMR gene result is associated with a single corresponding AMR gene assay [with the exception of the *mecA/C* and MREJ (MRSA) result] and one or more assay(s) for the detection of applicable bacteria, as indicated in Table 6, Table 7, Table 8, that provide an example of how to interpret results when a corresponding AMR gene is detected with an associated organism. Table 7 describes how to interpret a *vanA/B* AMR gene result with corresponding gram-positive bacteria while Table 8 describes how to interpret the KPC AMR gene result with corresponding gram-negative bacteria. All other AMR genes [with the exception of the *mecA/C* and MREJ (MRSA) result] follow these interpretation rules.

Information about the detection of specific AMR gene types is provided in the Analytical Reactivity (Inclusivity) section (Table 113 - Table 122). Overall, each AMR gene assay was found to detect the majority of AMR gene types based on testing and analysis of available sequence data. However, there are some types and variant sequences identified that may be amplified less efficiently or may not be detected (MREJ types xv, xviii, and xix; CTX-M-151; IMP-31, IMP-35, IMP-46, and IMP-63; OXA-54, OXA-416 and OXA-48-like types that lack carbapenemase activity; VIM-39, VIM-45, VIM-46, VIM-65, and VIM-67).

Information on cross-reactivity of AMR gene assays with related AMR genes or due to non-specific interactions is described in the Analytical Specificity (Cross-Reactivity and Exclusivity) section. Most AMR gene assays are specific for detection of the indicated AMR genes; however, cross-reactivity may be observed between AMR gene assays and related AMR genes (CTX-M with related *bla* genes and vanA/B with *vanM*) or due to non-specific interactions that are unlikely to be reported at blood culture titers (KPC with *Acinetobacter nosocomialis* and *Moraxella osloensis*) and/or in the absence of an applicable bacterium (CTX-M with *Acinetobacter schindleri*).

Table 6. Antimicrobial Resistance (AMR) Genes and Applicable Bacteria

BIOFIRE BCID2 Panel AMR Gene Result	*Enterococcus faecalis*	*Enterococcus faecium*	*Staphylococcus aureus*	*Staphylococcus epidermidis*	*Staphylococcus lugdunensis*	*Acinetobacter calcoaceticus-baumannii* complex	*Enterobacterales*	*Enterobacter cloacae* complex	*Escherichia coli*	*Klebsiella aerogenes*	*Klebsiella oxytoca*	*Klebsiella pneumoniae* group	*Proteus* spp.	*Salmonella* spp.	*Serratia marcescens*	*Pseudomonas aeruginosa*
vanA/B	×	×														
mecA/C				×	×											
***mecA/C* and MREJ (MRSA)**			×													
mcr-1								×	×	×	×	×		×		

BIOFIRE BCID2 Panel AMR Gene Result	*Enterococcus faecalis*	*Enterococcus faecium*	*Staphylococcus aureus*	*Staphylococcus epidermidis*	*Staphylococcus lugdunensis*	*Acinetobacter calcoaceticus-baumannii* complex	*Enterobacterales*	*Enterobacter cloacae* complex	*Escherichia coli*	*Klebsiella aerogenes*	*Klebsiella oxytoca*	*Klebsiella pneumoniae* group	*Proteus* spp.	*Salmonella* spp.	*Serratia marcescens*	*Pseudomonas aeruginosa*
CTX-M						×	×	×	×	×	×	×	×	×	×	×
IMP						×	×	×	×	×	×	×	×	×	×	×
KPC						×	×	×	×	×	×	×	×	×	×	×
NDM						×	×	×	×	×	×	×	×	×	×	×
OXA-48-like							×	×	×	×	×	×	×	×	×	
VIM						×	×	×	×	×	×	×	×	×	×	×

NOTE: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A Detected result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BIOFIRE BCID2 Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.

Table 7. Possible Assay and Corresponding vanA/B Test Result

BIOFIRE BCID2 Panel Test Result		Efaecium assay	Efaecalis assay	vanA/B assay
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected Not Detected N/A	Negative	Negative	Any result
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** Not Detected Not Detected	**Positive**	Negative	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected **Detected** Not Detected	Negative	**Positive**	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** **Detected** Not Detected	**Positive**	**Positive**	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** Not Detected **Detected**[a]	**Positive**	Negative	**Positive**
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected **Detected** **Detected**[a]	Negative	**Positive**	**Positive**
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** **Detected** **Detected**[a,b]	**Positive**	**Positive**	**Positive**

[a] Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the blood culture sample.

[b] It is not possible to determine the species with which the *vanA/B* gene is associated.

Table 8. Possible Assay Results and the Corresponding KPC Test Results (Example for Gram-Negative Antimicrobial Result Interpretation)

BIOFIRE BCID2 Panel Test Results	Acinetobacter assay	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Paeroginosa assay	KPC Assay	Description
Acinetobacter calcoaceticus-baumannii complex Not Detected *Enterobacterales* Not Detected *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* group Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected KPC N/A	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Any result	No applicable gram-negative bacteria detected in the sample. KPC results are not applicable (N/A)
***Acinetobacter calcoaceticus-baumannii* complex Detected** ***Enterobacterales* Detected** ***Enterobacter cloacae* complex Detected** ***Escherichia coli* Detected** ***Klebsiella aerogenes* Detected** ***Klebsiella oxytoca* Detected** ***Klebsiella pneumoniae* Detected** ***Proteus* spp. Detected** ***Salmonella* spp. Detected** ***Serratia marcescens* Detected** ***Pseudomonas aeruginosa* Detected** KPC Not Detected	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	**Pos**	Neg	More than one applicable gram-negative bacteria detected in the sample **AND** KPC not detected
***Acinetobacter calcoaceticus-baumannii* complex Detected** *Enterobacterales* Not Detected *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	*Acinetobacter calcoaceticus-baumannii* complex species detected in the sample **AND** KPC detected

BIOFIRE BCID2 Panel Test Results	Acinetobacter assay	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Paeroginosa assay	KPC Assay	Description
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* detected in the sample (not *E. cloacae* complex, *E. coli*, *K. aerogenes*, *K. oxytoca*, *K. pneumoniae* group, *Proteus* spp., *Salmonella* spp., or *S. marcescens*) **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** ***Enterobacter cloacae* complex Detected** *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Neg**	**Pos**	One or more *Enterobacterales* (including species of the *Enterobacter cloacae* complex) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected ***Escherichia coli* Detected** *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* (including *Escherichia coli*) detected in the sample **AND** KPC detected

BIOFIRE BCID2 Panel Test Results	Acinetobacter assay	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Paeroginosa assay	KPC Assay	Description
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected ***Klebsiella aerogenes* Detected** *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* (including *Klebsiella aerogenes*) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected ***Klebsiella oxytoca* Detected** *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* (including *Klebsiella oxytoca*) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected ***Klebsiella pneumoniae* Detected** *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	Neg	Neg	Neg	**Pos**	Neg	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* (including species in the *Klebsiella pneumoniae* group) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected ***Proteus* spp. Detected**	Neg	Any result	Neg	Neg	Neg	Neg	Neg	**Pos**	Neg	Neg	Neg	**Pos**	One or more *Enterobacterales* (including *Proteus* species) detected in the sample **AND**

BIOFIRE BCID2 Panel Test Results	Acinetobacter assay	Enteric1 and/or Enteric2 assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Koxytoca assay	Kpneumoniae assay	Proteus assay	Salmonella assay	Smarcescens assay	Paeroginosa assay	KPC Assay	Description
Salmonella spp. Not Detected *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**													KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected ***Salmonella* spp. Detected** *Serratia marcescens* Not Detected *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	Neg	Neg	**Pos**	One or more *Enterobacterales* (including *Salmonella* species) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected ***Enterobacterales* Detected** *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected ***Serratia marcescens* Detected** *Pseudomonas aeruginosa* Not Detected **KPC Detected**	Neg	Any result	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	Neg	**Pos**	One or more *Enterobacterales* (including *Serratia marcescens*) detected in the sample **AND** KPC detected
Acinetobacter calcoaceticus-baumannii complex Not Detected *Enterobacterales* Not Detected *Enterobacter cloacae* complex Not Detected *Escherichia coli* Not Detected *Klebsiella aerogenes* Not Detected *Klebsiella oxytoca* Not Detected *Klebsiella pneumoniae* Not Detected *Proteus* spp. Not Detected *Salmonella* spp. Not Detected *Serratia marcescens* Not Detected ***Pseudomonas aeruginosa* Detected** **KPC Detected**	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	**Pos**	**Pos**	*Pseudomonas aeruginosa* detected in the sample **AND** KPC detected

The *mecA/C* result is intended to aid in the identification of methicillin-resistant *Staphylococcus epidermidis* and *Staphylococcus lugdunensis*. When the Sepidermidis and/or Slugdunensis assay(s) are positive, the *mecA/C* result will be reported as Detected or Not Detected based on whether the mecA/C assay is positive or negative, respectively. The Saureus and Staphylococcus assays are not considered in the reporting of the *mecA/C* result, except for the *mecA/C* and MREJ (MRSA) result, which is dependent on both the *mecA/C* assay and the MREJ assay (see Table 10). Detection of *Staphylococcus aureus* and positive *mecA/C* and MREJ results is indicative of methicillin-resistant *Staphylococcus aureus* (MRSA).

Table 9. Assay and Results Interpretation for the *mecA/C* Test Result

BIOFIRE BCID2 Panel Test Result		Sepidermidis assay	Slugdunensis assay	mecA/C assay
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	Not Detected Not Detected N/A	Negative	Negative	Any result
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	**Detected** Not Detected Not Detected	**Positive**	Negative	Negative
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	Not Detected **Detected** Not Detected	Negative	**Positive**	Negative
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	**Detected** **Detected** Not Detected	**Positive**	**Positive**	Negative
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	**Detected** Not Detected **Detected**[a]	**Positive**	Negative	**Positive**
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	Not Detected **Detected** **Detected**[a]	**Negative**	**Positive**	**Positive**
Staphylococcus epidermidis *Staphylococcus lugdunensis* *mecA/C*	**Detected** **Detected** **Detected**[a,b]	**Positive**	**Positive**	**Positive**

[a] Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the blood culture sample.

[b] It is not possible to determine the species with which the *mecA/C* gene is associated.

Table 10. Possible *Staphylococcus aureus* Results and *mecA/C* and MREJ Assay Combinations for the *mecA/C* and MREJ (MRSA) Result

BIOFIRE BCID2 Panel Test Result		Saureus assay	mecA/C assay	MREJ assay
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	Not Detected N/A	Negative	Any Result	Any Result
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	**Detected** **Detected** [a]	**Positive**	**Positive**	**Positive**
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	**Detected** Not Detected	**Positive**	Negative	Negative
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	**Detected** Not Detected	**Positive**	**Positive**	Negative
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	**Detected** Not Detected	**Positive**	Negative	**Positive**

[a] Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the blood culture sample.

NOTE: It is possible for the BIOFIRE BCID2 Panel to report both the mecA/C result and the mecA/C and MREJ (MRSA) result if Staphylococcus epidermidis and/or Staphylococcus lugdunensis are detected in the same sample as Staphylococcus aureus.

NOTE: It is possible to obtain a Detected result for *Staphylococcus aureus mecA/C* and MREJ (MRSA) using the BIOFIRE BCID2 Panel but to recover an isolate from culture that is characterized as methicillin sensitive *S. aureus* (MSSA) using phenotypic AST methods. This can occur when a sample contains a strain of *S. aureus* that carries the orfX gene (MREJ) with an empty *mecA/C* (phenotypically MSSA) in a co-culture with a second *Staphylococcus* species carrying the *mecA/C* gene. This may also be observed in instances of heterogeneous cultures of MRSA and MSSA.

Results Interpretation for Yeast

Species-specific assays are included in the BIOFIRE BCID2 Panel for each of the five most common *Candida* species associated with BSI (*Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*), the emerging pathogen *Candida auris*, and two species of *Cryptococcus* (*Cryptococcus neoformans/gattii*). Results for all yeast are reported as Detected or Not Detected based on an individual corresponding assay result. If the assay is positive the result will be Detected, and if the assay is negative, the result will be Not Detected.

Additional information about the detection of specific strains, isolates, or serotypes/genotypes of yeast is provided in the Analytical Reactivity (Inclusivity) section (Table 123 – Table 129). Based on *in silico* analysis and empirical testing, each assay is specific for the detection of the indicated species with the exceptions described below and in the Analytical Specificity (Cross-Reactivity and Exclusivity) section (Table 130 and Table 131).

- *Candida glabrata* is closely related to *Candida bracarensis and Candida nivariensis*, and they have been described together as the *Candida glabrata* complex. Misidentification of these species by laboratory methods does occur, and cross-reactivity between the Cglabrata assay and *C. bracarensis* or *C. nivariensis* may be observed.
- At positive blood culture levels, the Ckrusei assay may cross-react with related species of *Candida, Pichia, or Issatchenkia,* including *Candida inconspicua* and *Pichia* (*Candida*) *norvegensis*.

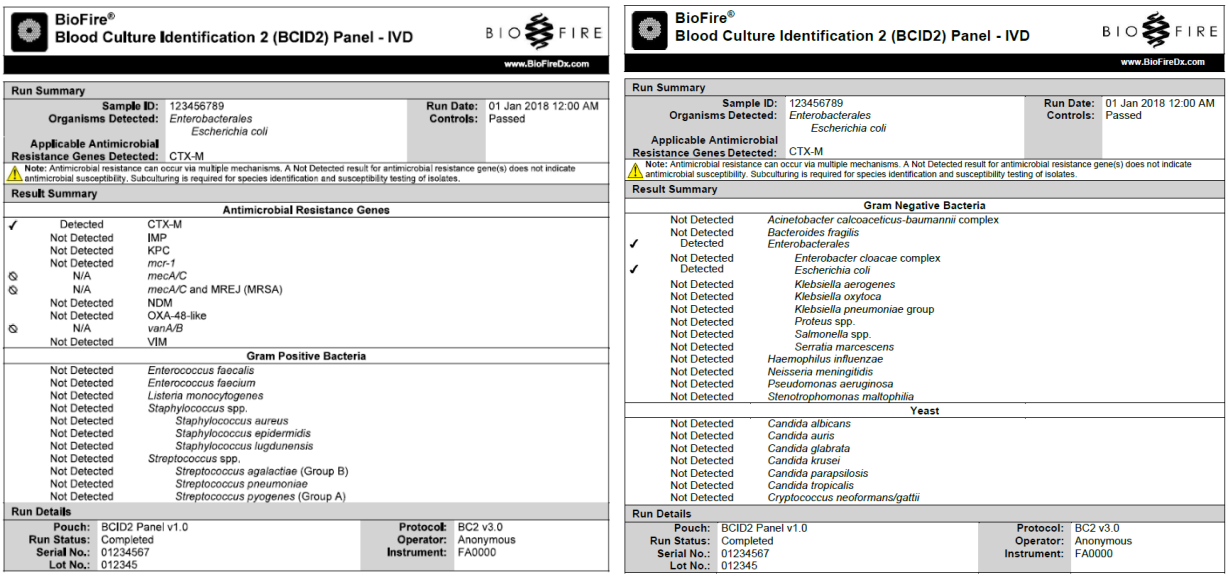
NOTE: Candida krusei is also known as Issatchenkia orientalis and Pichia kudriavzevkii.

- The assay for detection of *C. parapsilosis* cross-reacts with *Candida tropicalis* at high concentration, and the assay for detection of *C. tropicalis* can cross-react with *C. parapsilosis* at high concentration. Either cross-reactive interaction would produce a dual result of *Candida parapsilosis* Detected and *Candida tropicalis* Detected.
- The Cryptococcus assay (*Cryptococcus neoformans/gattii*) can cross-react with environmental or insect-associated species of *Cryptococcus* that are not implicated in human infection.

NOTE: Assays for the detection of Candida albicans, Candida glabrata, Candida parapsilosis, and Candida tropicalis amplify gene targets within the mitochondrial genome, and the panel will not be able to detect 'petite' strains that have lost their mitochondrial DNA.

BIOFIRE BCID2 Panel Test Report

The BIOFIRE BCID2 Panel two-page test report (Figure 1) is automatically displayed upon completion of a run and can be printed or saved as a PDF file. Each report contains a Run Summary, a Result Summary, and a Run Details section.



BioFire®
Blood Culture Identification 2 (BCID2) Panel - IVD
www.BioFireDx.com

Run Summary

Sample ID:	123456789	Run Date:	01 Jan 2018 12:00 AM
Organisms Detected:	*Enterobacterales* *Escherichia coli*	Controls:	Passed
Applicable Antimicrobial Resistance Genes Detected:	CTX-M		

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for antimicrobial resistance gene(s) does not indicate antimicrobial susceptibility. Subculturing is required for species identification and susceptibility testing of isolates.

Result Summary

Antimicrobial Resistance Genes		
✓	Detected	CTX-M
	Not Detected	IMP
	Not Detected	KPC
	Not Detected	*mcr-1*
⦸	N/A	*mecA/C*
⦸	N/A	*mecA/C* and MREJ (MRSA)
	Not Detected	NDM
	Not Detected	OXA-48-like
⦸	N/A	*vanA/B*
	Not Detected	VIM
Gram Positive Bacteria		
	Not Detected	*Enterococcus faecalis*
	Not Detected	*Enterococcus faecium*
	Not Detected	*Listeria monocytogenes*
	Not Detected	*Staphylococcus* spp.
	Not Detected	*Staphylococcus aureus*
	Not Detected	*Staphylococcus epidermidis*
	Not Detected	*Staphylococcus lugdunensis*
	Not Detected	*Streptococcus* spp.
	Not Detected	*Streptococcus agalactiae* (Group B)
	Not Detected	*Streptococcus pneumoniae*
	Not Detected	*Streptococcus pyogenes* (Group A)

Run Details

Pouch:	BCID2 Panel v1.0	Protocol:	BC2 v3.0
Run Status:	Completed	Operator:	Anonymous
Serial No.:	01234567	Instrument:	FA0000
Lot No.:	012345		

BioFire®
Blood Culture Identification 2 (BCID2) Panel - IVD
www.BioFireDx.com

Run Summary

Sample ID:	123456789	Run Date:	01 Jan 2018 12:00 AM
Organisms Detected:	*Enterobacterales* *Escherichia coli*	Controls:	Passed
Applicable Antimicrobial Resistance Genes Detected:	CTX-M		

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for antimicrobial resistance gene(s) does not indicate antimicrobial susceptibility. Subculturing is required for species identification and susceptibility testing of isolates.

Result Summary

Gram Negative Bacteria		
	Not Detected	*Acinetobacter calcoaceticus-baumannii* complex
	Not Detected	*Bacteroides fragilis*
✓	Detected	*Enterobacterales*
	Not Detected	*Enterobacter cloacae* complex
✓	Detected	*Escherichia coli*
	Not Detected	*Klebsiella aerogenes*
	Not Detected	*Klebsiella oxytoca*
	Not Detected	*Klebsiella pneumoniae* group
	Not Detected	*Proteus* spp.
	Not Detected	*Salmonella* spp.
	Not Detected	*Serratia marcescens*
	Not Detected	*Haemophilus influenzae*
	Not Detected	*Neisseria meningitidis*
	Not Detected	*Pseudomonas aeruginosa*
	Not Detected	*Stenotrophomonas maltophilia*
Yeast		
	Not Detected	*Candida albicans*
	Not Detected	*Candida auris*
	Not Detected	*Candida glabrata*
	Not Detected	*Candida krusei*
	Not Detected	*Candida parapsilosis*
	Not Detected	*Candida tropicalis*
	Not Detected	*Cryptococcus neoformans/gattii*

Run Details

Pouch:	BCID2 Panel v1.0	Protocol:	BC2 v3.0
Run Status:	Completed	Operator:	Anonymous
Serial No.:	01234567	Instrument:	FA0000
Lot No.:	012345		

Figure 1. BIOFIRE BCID2 Panel Example Test Report (Page 1 – on left; Page 2 – on right)

Run Summary

The Run Summary section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the organism assays were negative, then ‘None’ will be displayed in the Organisms Detected field. If an organism was detected and an applicable antimicrobial resistance gene assay was positive, the applicable antimicrobial resistance gene will be listed as Detected in the corresponding field of the summary. If all of the applicable antimicrobial resistance gene assays were negative, then ‘None’ will be displayed in the Applicable Antimicrobial Resistance Genes Detected field. Controls are listed as Passed, Failed, or Invalid. Table 11 provides additional information for each of the possible control field results.

Table 11. Interpretation of Controls Field on the BIOFIRE BCID2 Panel Test Report

Control Result	Explanation	Action
Passed	The run was successfully completed AND Both pouch controls were successful.	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls (DNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error).	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate BIOFIRE System Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test on the same module or on a different module.

Result Summary

The Result Summary section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid. Possible results for each antimicrobial resistance gene are Detected, Not detected, N/A, or Invalid. Table 12 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 12. Reporting of Results and Required Actions

Result	Explanation	Action
Detected[a]	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were POSITIVE[a]	Report results.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were NEGATIVE	Report results.
Invalid	The pouch controls were not successful (Failed) OR The run did not complete successfully (Run Status displayed as: Aborted, Incomplete, Instrument Error, or Software Error)	See Table 11 for instruction
N/A (Antimicrobial Resistance Genes only)	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism(s) associated with the antimicrobial resistance gene were NEGATIVE so the results of the antimicrobial resistance gene are not applicable to the test results.	Report results.

[a] If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

Run Details

The **Run Details** section provides additional information about the run including pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Change Summary

It is possible to edit the Sample ID once a run has completed. If this information has been changed, an additional section called **Change Summary** will be added to the test report. This Change Summary section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Change Summary				
Field	Changed To	Changed From	Operator	Date
[1]Sample ID	Positive_example_XYZ	Positive _example	Jane Doe (JD)	16 Sept 2017

Figure 2. BIOFIRE BCID2 Panel Change Summary Section in Report

LIMITATIONS

1. For prescription use only.
2. The performance of the BIOFIRE BCID2 Panel has not been established for the screening of blood or blood products.
3. Results from this test must be correlated with clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
4. BIOFIRE BCID2 Panel performance has only been established on the BIOFIRE 2.0 and BIOFIRE Torch systems.
5. The BIOFIRE BCID2 Panel is a qualitative test and does not provide a quantitative value for the organism(s) in the specimen.
6. This test has not been validated for testing samples other than human blood culture samples identified as positive by a continuous monitoring blood culture system.
7. Blood culture samples must be tested within 24 hours of being flagged as positive by a continuous monitoring blood culture system.
8. All identification results provided by the BIOFIRE BCID2 Panel are intended to be interpreted in conjunction with results obtained from Gram stain of the positive blood culture. Gram reaction (gram-positive or gram-negative) and cellular morphology (gram-positive cocci in clusters, pairs, or chains, gram-negative rods) should be considered in correlation with the BIOFIRE BCID2 Panel results.
9. In some cases, the Gram stain result and results of the BIOFIRE BCID2 Panel may be discrepant (for example, detection of gram-positive cocci by the BIOFIRE BCID2 Panel when gram-positive cocci were not observed in the Gram stain). In these cases, the BIOFIRE BCID2 Panel results should be confirmed (e.g., by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.
10. The performance of this test was found to be equivalent for the specific blood culture bottle types evaluated in the clinical study (Table 18) and analytically (Table 84-Table 85). Performance for other blood culture bottle types was not evaluated.
11. This product should not be used to test blood culture media that contain charcoal. Charcoal containing media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BIOFIRE BCID2 Panel.
12. Any blood culture media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BIOFIRE BCID2 Panel leading to false positive test results. Typically, these false positives may present with more than one positive result because the BIOFIRE BCID2 Panel may also detect the organism that is growing in the culture bottle.
13. Only encapsulated strains of *N. meningitidis* will be detected by the BIOFIRE BCID2 Panel. Unencapsulated *N. meningitidis* will not be detected.
14. The BIOFIRE BCID2 Panel may not distinguish mixed cultures when two or more species of the same genus or organism group are present in a specimen (e.g., *Staphylococcus aureus* and *Staphylococcus hominis*).
15. In mixed cultures, the BIOFIRE BCID2 Panel may not identify all targeted organisms in the specimen, depending upon the concentration of each target present. In particular, false negative results for *Pseudomonas aeruginosa* or *Stenotrophomonas* spp. may occur if another organism is present in the blood culture. Conversely, standard subculture methods may also not identify all organisms in a mixed culture, depending upon the concentration and growth characteristics of each organism present.
16. Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates are required to determine antimicrobial susceptibility.
17. The results for the antimicrobial resistance gene assays do not specifically link the resistance gene to the applicable bacteria detected. In mixed cultures, the resistance gene may be associated with any of the applicable bacteria detected or an organism that was not detected by the panel.
18. Discrepancies between the BIOFIRE BCID2 Panel test result and other microbial identification methods may be caused by the inability to reliably differentiate closely related species based on standard phenotypic microbial identification methods or the design of other molecular assays.

19. The detection of bacterial, yeast, and antimicrobial resistance gene nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive or false negative values resulting from improperly collected, transported, or handled samples.
20. A negative BIOFIRE BCID2 Panel result does not exclude the possibility of bloodstream infection. Negative test results may occur from sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up, or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antibacterial/antifungal therapy or levels of organism in the sample that are below the limit of detection for the test (especially in the case of mixed cultures). Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions.
21. There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section.
22. False positives and false negatives can be the result of a variety of sources and causes. It is important that results be used in conjunction with other clinical, epidemiological, or laboratory information.
23. If four or more distinct organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.
24. Cross-reactivity with organisms other than those listed in the Analytical Specificity section below may lead to erroneous results.
25. The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the Interference section below could lead to erroneous results.
26. BIOFIRE BCID2 Panel assays can cross-react with several organisms, typically closely related or near-neighbor species to those detected by the panel. All confirmed or predicted cross-reactive species have been identified in Table 130 and Table 131 in the Analytical Specificity (Cross-Reactivity and Exclusivity) section below.
27. The BIOFIRE BCID2 Panel Ctropicalis assay may cross-react with high titers of *C. parapsilosis* present in a sample and the Cparapsilosis assay may cross-react with high titers of *C. tropicalis.* Detected results for both *C. tropicalis* and *C. parapsilosis* in the same sample may be due to cross-reactivity or may be due to both organisms being present in the blood culture.
28. Borderline oxacillin-resistant *Staphylococcus aureus* (BORSA) and moderately resistant *S. aureus* (MODSA) strains demonstrate reduced susceptibility to oxacillin due to hyperproduction of β-lactamases or modification of penicillin-binding proteins respectively. BORSA and MODSA strains do not contain the *mecA* or *mecC* gene. A *mecA/C* and MREJ (MRSA) Not Detected result will be reported by the BIOFIRE BCID2 Panel for these strains.
29. The *vanA/B* result is not reported in the absence of *Enterococcus faecalis* or *Enterococcus faecium* detection and will therefore not be reported for blood cultures containing other vancomycin-resistant Enterococci or vancomycin-resistant *Staphylococcus aureus* (VRSA).
30. Continuous monitoring blood culture systems may falsely signal positive in a low percentage of bottles (estimated to be near 1%) when no organisms are growing in the sample. This may be due to hyperleukocytosis (very high white blood cell counts).
31. The performance of the BIOFIRE BCID2 Panel has not been established for monitoring the treatment of infection with any of the panel organisms.

EXPECTED VALUES

In the prospective clinical evaluation of the BIOFIRE BCID2 Panel, 1074 positive blood culture (PBC) specimens were collected and tested at nine study sites across the United States and Europe over approximately eight months (October 2018 to May 2019). Expected value summaries (as determined by the BIOFIRE BCID2 Panel) are stratified by subject age in Table 13 and by specimen enrollment site in Table 14.

Table 13. Expected Value (as determined by the BIOFIRE BCID2 Panel) Summary by Age Group for PBC Specimens Collected during the BIOFIRE BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BIOFIRE BCID2 Panel Result	Overall (N=1074)		<1 year (N=118)		1-17 years (N=143)		18-44 years (N=125)		45-64 years (N=257)		65-84 years (N=333)		85+ years (N=98)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria														
Enterococcus faecalis	***32***	***3.0%***	4	3.4%	1	0.7%	4	3.2%	8	3.1%	14	4.2%	1	1.0%
Enterococcus faecium	***30***	***2.8%***	0	0%	0	0%	3	2.4%	10	3.9%	15	4.5%	2	2.0%
Listeria monocytogenes	***3***	***0.3%***	0	0%	0	0%	1	0.8%	1	0.4%	0	0%	1	1.0%
Staphylococcus spp.	***484***	***45.1%***	70	59.3%	68	47.6%	67	53.6%	111	43.2%	137	41.1%	31	31.6%
Staphylococcus aureus	***151***	***14.1%***	13	11.0%	28	19.6%	20	16.0%	35	13.6%	41	12.3%	14	14.3%
Staphylococcus epidermidis	***250***	***23.3%***	46	39.0%	25	17.5%	35	28.0%	58	22.6%	74	22.2%	12	12.2%
Staphylococcus lugdunensis	***7***	***0.7%***	0	0%	0	0%	1	0.8%	3	1.2%	3	0.9%	0	0%
Streptococcus spp.	***123***	***11.5%***	25	21.2%	28	19.6%	10	8.0%	23	8.9%	30	9.0%	7	7.1%
Streptococcus agalactiae (Group B)	***9***	***0.8%***	1	0.8%	0	0%	0	0%	1	0.4%	7	2.1%	0	0%
Streptococcus pneumoniae	***26***	***2.4%***	7	5.9%	7	4.9%	2	1.6%	3	1.2%	5	1.5%	2	2.0%
Streptococcus pyogenes (Group A)	***13***	***1.2%***	0	0%	10	7.0%	2	1.6%	0	0%	1	0.3%	0	0%
Gram-Negative Bacteria														
Acinetobacter calcoaceticus-baumannii complex	***13***	***1.2%***	0	0%	0	0%	2	1.6%	4	1.6%	7	2.1%	0	0%
Bacteroides fragilis	***9***	***0.8%***	0	0%	0	0%	0	0%	2	0.8%	5	1.5%	2	2.0%
Enterobacterales	***323***	***30.1%***	32	27.1%	30	21.0%	32	25.6%	78	30.4%	109	32.7%	42	42.9%
Enterobacter cloacae complex	***16***	***1.5%***	1	0.8%	0	0%	0	0%	5	1.9%	7	2.1%	3	3.1%
Escherichia coli	***160***	***14.9%***	16	13.6%	10	7.0%	13	10.4%	36	14.0%	61	18.3%	24	24.5%
Klebsiella aerogenes	***2***	***0.2%***	0	0%	0	0%	0	0%	2	0.8%	0	0%	0	0%
Klebsiella oxytoca	***8***	***0.7%***	1	0.8%	2	1.4%	0	0%	3	1.2%	1	0.3%	1	1.0%
Klebsiella pneumoniae group	***55***	***5.1%***	2	1.7%	1	0.7%	5	4.0%	20	7.8%	22	6.6%	5	5.1%
Proteus spp.	***15***	***1.4%***	0	0%	0	0%	0	0%	3	1.2%	8	2.4%	4	4.1%
Salmonella spp.	***5***	***0.5%***	2	1.7%	2	1.4%	0	0%	0	0%	1	0.3%	0	0%
Serratia marcescens	***11***	***1.0%***	0	0%	3	2.1%	2	1.6%	2	0.8%	2	0.6%	2	2.0%
Haemophilus influenzae	***8***	***0.7%***	2	1.7%	4	2.8%	0	0%	1	0.4%	1	0.3%	0	0%
Neisseria meningitidis	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Pseudomonas aeruginosa	***31***	***2.9%***	0	0%	3	2.1%	4	3.2%	8	3.1%	11	3.3%	5	5.1%

BIOFIRE BCID2 Panel Result	Overall (N=1074)		<1 year (N=118)		1-17 years (N=143)		18-44 years (N=125)		45-64 years (N=257)		65-84 years (N=333)		85+ years (N=98)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Stenotrophomonas maltophilia	***7***	***0.7%***	2	1.7%	0	0%	0	0%	1	0.4%	4	1.2%	0	0%
AMR Genes														
CTX-M	***46***	***4.3%***	3	2.5%	1	0.7%	5	4.0%	9	3.5%	20	6.0%	8	8.2%
IMP	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	***4***	***0.4%***	0	0%	0	0%	0	0%	2	0.8%	1	0.3%	1	1.0%
NDM	***1***	***0.1%***	0	0%	0	0%	0	0%	1	0.4%	0	0%	0	0%
OXA-48-like	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
VIM	***4***	***0.4%***	1	0.8%	0	0%	0	0%	2	0.8%	1	0.3%	0	0%
mecA/C	***195***	***18.2%***	34	28.8%	19	13.3%	25	20.0%	44	17.1%	64	19.2%	9	9.2%
mecA/C and MREJ (MRSA)	***54***	***5.0%***	3	2.5%	9	6.3%	8	6.4%	12	4.7%	14	4.2%	8	8.2%
mcr-1	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
vanA/B	***23***	***2.1%***	0	0%	0	0%	3	2.4%	5	1.9%	13	3.9%	2	2.0%
Yeast														
Candida albicans	***13***	***1.2%***	2	1.7%	1	0.7%	0	0%	2	0.8%	6	1.8%	2	2.0%
Candida auris	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Candida glabrata	***11***	***1.0%***	0	0%	0	0%	1	0.8%	4	1.6%	5	1.5%	1	1.0%
Candida krusei	***2***	***0.2%***	0	0%	0	0%	0	0%	0	0%	2	0.6%	0	0%
Candida parapsilosis	***9***	***0.8%***	0	0%	1	0.7%	1	0.8%	4	1.6%	3	0.9%	0	0%
Candida tropicalis	***5***	***0.5%***	0	0%	0	0%	0	0%	2	0.8%	3	0.9%	0	0%
Cryptococcus neoformans/gattii	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%

In addition, the observed multiple detections (as determined by the BIOFIRE BCID2 Panel) during the prospective clinical evaluation are presented in Table 15. At least one analyte was detected in a total of 976 PBC specimens (90.9% positivity rate; 976/1074). Polymicrobial detections of up to four organisms were observed.

Table 14. Expected Value (as determined by the BIOFIRE BCID2 Panel) Summary by Site for PBC Specimens Collected during the BIOFIRE BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BIOFIRE BCID2 Panel Result	Overall (N=1074)		Site 1 (N=117)		Site 2 (N=98)		Site 3 (N=191)		Site 4 (N=84)		Site 5 (N=106)		Site 6 (N=118)		Site 7 (N=146)		Site 8 (N=104)		Site 9 (N=110)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria																				
Enterococcus faecalis	***32***	***3.0%***	2	1.7%	1	1.0%	3	1.6%	5	6.0%	7	6.6%	6	5.1%	2	1.4%	5	4.8%	1	0.9%
Enterococcus faecium	***30***	***2.8%***	0	0%	4	4.1%	5	2.6%	9	10.7%	0	0%	4	3.4%	0	0%	2	1.9%	6	5.5%
Listeria monocytogenes	***3***	***0.3%***	0	0%	1	1.0%	0	0%	1	1.2%	0	0%	0	0%	0	0%	1	1.0%	0	0%
Staphylococcus spp.	***484***	***45.1%***	57	48.7%	29	29.6%	93	48.7%	31	36.9%	54	50.9%	58	49.2%	85	58.2%	43	41.3%	34	30.9%
Staphylococcus aureus	***151***	***14.1%***	17	14.5%	9	9.2%	14	7.3%	14	16.7%	19	17.9%	22	18.6%	24	16.4%	18	17.3%	14	12.7%
Staphylococcus epidermidis	***250***	***23.3%***	30	25.6%	14	14.3%	59	30.9%	12	14.3%	27	25.5%	28	23.7%	43	29.5%	23	22.1%	14	12.7%
Staphylococcus lugdunensis	***7***	***0.7%***	0	0%	0	0%	2	1.0%	1	1.2%	1	0.9%	2	1.7%	1	0.7%	0	0%	0	0%
Streptococcus spp.	***123***	***11.5%***	23	19.7%	12	12.2%	8	4.2%	6	7.1%	18	17.0%	8	6.8%	26	17.8%	9	8.7%	13	11.8%
Streptococcus agalactiae (Group B)	***9***	***0.8%***	0	0%	1	1.0%	2	1.0%	0	0%	3	2.8%	0	0%	1	0.7%	2	1.9%	0	0%
Streptococcus pneumoniae	***26***	***2.4%***	9	7.7%	1	1.0%	0	0%	0	0%	3	2.8%	3	2.5%	4	2.7%	5	4.8%	1	0.9%

BIOFIRE BCID2 Panel Result	Overall (N=1074)		Site 1 (N=117)		Site 2 (N=98)		Site 3 (N=191)		Site 4 (N=84)		Site 5 (N=106)		Site 6 (N=118)		Site 7 (N=146)		Site 8 (N=104)		Site 9 (N=110)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Streptococcus pyogenes (Group A)	***13***	***1.2%***	7	6.0%	1	1.0%	0	0%	0	0%	2	1.9%	0	0%	2	1.4%	0	0%	1	0.9%
Gram-Negative Bacteria																				
Acinetobacter calcoaceticus-baumannii complex	***13***	***1.2%***	0	0%	0	0%	10	5.2%	0	0%	0	0%	1	0.8%	0	0%	2	1.9%	0	0%
Bacteroides fragilis	***9***	***0.8%***	0	0%	0	0%	2	1.0%	1	1.2%	1	0.9%	1	0.8%	0	0%	0	0%	4	3.6%
Enterobacterales	***323***	***30.1%***	19	16.2%	33	33.7%	50	26.2%	32	38.1%	34	32.1%	35	29.7%	44	30.1%	43	41.3%	33	30.0%
Enterobacter cloacae complex	***16***	***1.5%***	0	0%	4	4.1%	4	2.1%	1	1.2%	0	0%	1	0.8%	1	0.7%	3	2.9%	2	1.8%
Escherichia coli	***160***	***14.9%***	14	12.0%	20	20.4%	26	13.6%	8	9.5%	9	8.5%	17	14.4%	12	8.2%	27	26.0%	27	24.5%
Klebsiella aerogenes	***2***	***0.2%***	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.8%	0	0%	0	0%	1	0.9%
Klebsiella oxytoca	***8***	***0.7%***	1	0.9%	0	0%	1	0.5%	3	3.6%	0	0%	1	0.8%	1	0.7%	1	1.0%	0	0%
Klebsiella pneumoniae group	***55***	***5.1%***	1	0.9%	4	4.1%	13	6.8%	7	8.3%	6	5.7%	12	10.2%	1	0.7%	5	4.8%	6	5.5%
Proteus spp.	***15***	***1.4%***	0	0%	3	3.1%	4	2.1%	0	0%	3	2.8%	0	0%	0	0%	5	4.8%	0	0%
Salmonella spp.	***5***	***0.5%***	2	1.7%	1	1.0%	0	0%	1	1.2%	0	0%	0	0%	1	0.7%	0	0%	0	0%
Serratia marcescens	***11***	***1.0%***	1	0.9%	1	1.0%	1	0.5%	0	0%	1	0.9%	0	0%	2	1.4%	3	2.9%	2	1.8%
Haemophilus influenzae	***8***	***0.7%***	4	3.4%	1	1.0%	0	0%	0	0%	1	0.9%	0	0%	2	1.4%	0	0%	0	0%
Neisseria meningitidis	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Pseudomonas aeruginosa	***31***	***2.9%***	1	0.9%	2	2.0%	5	2.6%	1	1.2%	2	1.9%	7	5.9%	4	2.7%	6	5.8%	3	2.7%
Stenotrophomonas maltophilia	***7***	***0.7%***	1	0.9%	0	0%	2	1.0%	2	2.4%	0	0%	1	0.8%	1	0.7%	0	0%	0	0%
AMR Genes																				
CTX-M	***46***	***4.3%***	2	1.7%	7	7.1%	8	4.2%	7	8.3%	1	0.9%	3	2.5%	2	1.4%	10	9.6%	6	5.5%
IMP	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	***4***	***0.4%***	0	0%	0	0%	4	2.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
NDM	***1***	***0.1%***	0	0%	0	0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
OXA-48-like	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
VIM	***4***	***0.4%***	0	0%	0	0%	4	2.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
mecA/C	***195***	***18.2%***	23	19.7%	10	10.2%	50	26.2%	9	10.7%	19	17.9%	24	20.3%	30	20.5%	19	18.3%	11	10.0%
mecA/C and MREJ (MRSA)	***54***	***5.0%***	3	2.6%	4	4.1%	9	4.7%	5	6.0%	5	4.7%	8	6.8%	11	7.5%	2	1.9%	7	6.4%
mcr-1	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
vanA/B	***23***	***2.1%***	0	0%	3	3.1%	2	1.0%	9	10.7%	1	0.9%	4	3.4%	0	0%	0	0%	4	3.6%
Yeast																				
Candida albicans	***13***	***1.2%***	1	0.9%	3	3.1%	5	2.6%	0	0%	0	0%	0	0%	1	0.7%	2	1.9%	1	0.9%
Candida auris	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Candida glabrata	***11***	***1.0%***	0	0%	3	3.1%	0	0%	3	3.6%	0	0%	1	0.8%	0	0%	0	0%	4	3.6%
Candida krusei	***2***	***0.2%***	0	0%	0	0%	2	1.0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Candida parapsilosis	***9***	***0.8%***	1	0.9%	0	0%	4	2.1%	0	0%	1	0.9%	0	0%	0	0%	2	1.9%	1	0.9%
Candida tropicalis	***5***	***0.5%***	0	0%	1	1.0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	3	2.9%	0	0%
Cryptococcus neoformans/gattii	***0***	***0%***	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%

Table 15. Expected Values (multiple detections as determined by the BIOFIRE BCID2 Panel) for the BIOFIRE BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BIOFIRE BCID2 Panel Organism Result	Expected Value (as determined by testing of 1074 prospective PBC specimens)	
	Number Detected and Reported	% of Total (% of Positives)
Detected (at least one organism result)	976[a]	90.9% (100%)
One organism result	851	79.2% (87.2%)
Two organism results	109	10.1% (11.2%)
Three organism results	13	1.2% (1.3%)
Four organism results	3	0.3% (0.3%)

[a] Removing the FP results due to the presence of nucleic acid from non-viable *E. coli* in specific lots of blood culture bottles results in 968 Detected (at least one organism result; 90.1% of total), 884 with one organism result (82.3% of total, 91.3% of positives), 72 with two organism results (6.7% of total, 7.4% of positives), nine with three organism results (0.8% of total, 0.9% of positives), and three with four organism results (0.3% of total, 0.3% of positives).

The BIOFIRE BCID2 Panel reported a total of 125 prospective specimens with discernible multiple organism detections (11.6% of all specimens, 125/1074; and 12.8% of positive specimens, 125/976). When omitting the 53 false positive (FP) results due to the presence of nucleic acid from non-viable *E. coli* in specific lots of blood culture bottles, the BIOFIRE BCID2 Panel reported a total of 84 prospective specimens with discernible multiple organism detections (7.8% of all specimens, 84/1074; and 8.7% of positive specimens, 84/968). The different types of multiple detections (categorized by gram stain classification) as reported by the BIOFIRE BCID2 Panel are presented in Table 16. The resulting co-detection analyte combinations are presented in Table 17. This table also indicates the number of prospective specimens with FP results for each co-detection combination, as well as the specific analytes that were discrepant. FP results were determined by comparison only to the primary comparator method (e.g. bacterial culture for organisms, and molecular methods for the antimicrobial resistance (AMR) genes, irrespective of host organism bacterial culture results).

Table 16. Expected Values (multiple detection types as determined by the BIOFIRE BCID2 Panel) for the BIOFIRE BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BIOFIRE BCID2 Panel Co-Detection Type	Positive Specimens (N=976)[a]	
	#	EV
Gram Positive + Gram Positive	26	2.7%
Gram Positive + Gram Negative	71	7.3%
Gram Positive + Yeast	8	0.8%
Gram Negative + Gram Negative	13	1.3%
Gram Negative + Yeast	5	0.5%
Yeast + Yeast	1	0.1%
Gram Positive + Gram Negative + Yeast	1	0.1%

[a] Removing the FP results due to the presence of nucleic acid from non-viable *E. coli* in specific lots of bioMérieux blood culture bottles results in 968 Positive Specimens; 34 Gram Positive + Gram Negative (3.5%), 11 Gram Negative + Gram Negative (1.1%), three Gram Negative + Yeast (0.3%), and one Gram Positive + Gram Negative + Yeast (0.1%).

Table 17. Multiple Detection Combinations as Determined by the BIOFIRE BCID2 Panel, Prospective Study

BIOFIRE BCID2 Panel Distinct Co-Detection Combinations					Total Specimens with Co-Detections	Number of Specimens with False Positive Co-Detections[a]	False Positive Analyte(s) [False Positive AMR Gene(s)]
Analyte 1	**Analyte 2**	**Analyte 3**	**Analyte 4**	**AMR Gene(s)**			
E. faecalis	*Staphylococcus* spp., *S. aureus*	*Staphylococcus* spp., *S. epidermidis*	*Enterobacterales*, *E. coli*	*mecA/C*	1	0	-
E. faecalis	*Staphylococcus* spp., *S. aureus*	*Staphylococcus* spp., *S. lugdunensis*	*Enterobacterales*, *Proteus* spp.	CTX-M, *mecA/C*, *mecA/C* and MREJ (MRSA)	1	1	*S. aureus, S. lugdunensis*
E. faecalis	*Staphylococcus* spp., *S. aureus*	*Enterobacterales*, *E. coli*	*Enterobacterales*, *Proteus* spp.	*mecA/C* and MREJ (MRSA)	1	1	*Staphylococcus/S. aureus, Proteus* spp.
E. faecalis	*Staphylococcus* spp., *S. epidermidis*	*Streptococcus* spp.		*mecA/C*	1	1	*Staphylococcus/S. epidermidis, Streptococcus* spp.
E. faecalis	*Staphylococcus* spp., *S. epidermidis*	*Enterobacterales*		*mecA/C, vanA/B*	1	1	*Enterobacterales*[b]
E. faecalis	*Enterobacterales*	*C. parapsilosis*		-	1	1	*C. parapsilosis*
E. faecium	*Staphylococcus* spp., *S. epidermidis*	ACB complex		*mecA/C, vanA/B*	1	1	*Staphylococcus/S. epidermidis*
E. faecium	*Staphylococcus* spp., *S. epidermidis*	*Enterobacterales*, *Proteus* spp.		*mecA/C*	1	1	*Staphylococcus/S. epidermidis*
Staphylococcus spp.	*Streptococcus* spp.	*Enterobacterales*		-	1	1	*Enterobacterales*[b]
Staphylococcus spp.	ACB complex	*Enterobacterales*, *K. pneumoniae* group		CTX-M	1	1	*Staphylococcus* spp.
Staphylococcus spp., *S. aureus*	*Streptococcus* spp., *S. agalactiae*	*Enterobacterales*, *Proteus* spp.		-	1	0	-
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp.	*Enterobacterales*		*mecA/C*	1	1	*S. epidermidis, Enterobacterales*[b]
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp.	*C. glabrata*		*mecA/C*	1	1	*C. glabrata*
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp., *S. pneumoniae*	*Enterobacterales*		*mecA/C*	1	1	*Enterobacterales*[b]
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*, *K. pneumoniae* group	*P. aeruginosa*		CTX-M, NDM, VIM, *mecA/C*	1	0	-
Streptococcus spp.	*Enterobacterales*, *E. coli*	*Enterobacterales*, *K. pneumoniae* group		-	1	0	-
E. faecalis	*Staphylococcus* spp., *S. epidermidis*			*mecA/C*	1	1	*S. epidermidis*
E. faecalis	*Enterobacterales*			-	1	1	*Enterobacterales*[b]
E. faecalis	*Enterobacterales*, *K. oxytoca*			-	1	0	-
E. faecalis	*P. aeruginosa*			-	1	0	-
E. faecium	*Staphylococcus* spp., *S. epidermidis*			*mecA/C, vanA/B*	2	2	*Staphylococcus/S. epidermidis* (2)
E. faecium	*Staphylococcus* spp., *S. epidermidis*			*mecA/C*	1	1	*E. faecium*
E. faecium	*Streptococcus* spp.			*vanA/B*	1	0	-
E. faecium	*Enterobacterales*			*vanA/B*	4	4	*Enterobacterales* (4)[b]
E. faecium	*Enterobacterales*, *E. cloacae* complex			-	1	1	*E. faecium*

BIOFIRE BCID2 Panel Distinct Co-Detection Combinations					Total Specimens with Co-Detections	Number of Specimens with False Positive Co-Detections[a]	False Positive Analyte(s) [False Positive AMR Gene(s)]
Analyte 1	**Analyte 2**	**Analyte 3**	**Analyte 4**	**AMR Gene(s)**			
E. faecium	*Enterobacterales*, *E. coli*			CTX-M	1	0	-
E. faecium	*Enterobacterales*, *K. pneumoniae* group			CTX-M, *vanA/B*	1	1	*E. faecium*
L. monocytogenes	*Enterobacterales*			-	1	1	*Enterobacterales*[b]
Staphylococcus spp.	*Streptococcus* spp.			-	4	1	*Staphylococcus* spp. (1)
Staphylococcus spp.	*Enterobacterales*			-	6	6	*Enterobacterales* (6)[b]
Staphylococcus spp.	*Enterobacterales*, *E. coli*			CTX-M	1	1	*Staphylococcus* spp.
Staphylococcus spp.	*Enterobacterales*, *E. coli*			-	1	1	*Staphylococcus* spp.
Staphylococcus spp.	*Enterobacterales*, *K. oxytoca*			-	1	0	-
Staphylococcus spp.	*C. parapsilosis*			-	1	0	-
Staphylococcus spp., *S. aureus*	*Staphylococcus* spp., *S. epidermidis*			*mecA/C*, *mecA/C* and MREJ (MRSA)	2	2	*S. epidermidis* (2)
Staphylococcus spp., *S. aureus*	*Staphylococcus* spp., *S. epidermidis*			*mecA/C*	3	2	*S. epidermidis* (2)
Staphylococcus spp., *S. aureus*	*Staphylococcus* spp., *S. epidermidis*			-	1	1	*S. epidermidis*
Staphylococcus spp., *S. aureus*	*Streptococcus* spp.			*mecA/C* and MREJ (MRSA)	1	0	-
Staphylococcus spp., *S. aureus*	*Enterobacterales*			*mecA/C* and MREJ (MRSA)	3	2	*Enterobacterales* (2)[b]
Staphylococcus spp., *S. aureus*	*Enterobacterales*			-	4	4	*Enterobacterales* (4)[b]
Staphylococcus spp., *S. epidermidis*	*Staphylococcus*, *S. lugdunensis*			*mecA/C*	2	2	*S. lugdunensis* (2)
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp.			*mecA/C*	4	3	*Staphylococcus/S. epidermidis* (1), *S. epidermidis* (1), *Streptococcus* spp. (1)
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp.			-	1	0	-
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp., *S. pneumoniae*			*mecA/C*	1	0	-
Staphylococcus spp., *S. epidermidis*	*Streptococcus* spp., *S. pneumoniae*			-	1	0	-
Staphylococcus spp., *S. epidermidis*	ACB complex			*mecA/C*	1	0	-
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*			*mecA/C*	10	10	*S. epidermidis* (2), *Enterobacterales* (10)[b]
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*			-	3	3	*Enterobacterales* (3)[b]
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*, *E. coli*			*mecA/C*	1	1	*Enterobacterales*/*E. coli*[b]

BIOFIRE BCID2 Panel Distinct Co-Detection Combinations					Total Specimens with Co-Detections	Number of Specimens with False Positive Co-Detections[a]	False Positive Analyte(s) [False Positive AMR Gene(s)]
Analyte 1	**Analyte 2**	**Analyte 3**	**Analyte 4**	**AMR Gene(s)**			
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*, *E. coli*			-	1	1	*Staphylococcus/S. epidermidis*
Staphylococcus spp., *S. epidermidis*	*Enterobacterales*, *K. pneumoniae* group			CTX-M, *mecA/C*	1	0	-
Staphylococcus spp., *S. epidermidis*	*H. influenzae*			-	1	0	-
Staphylococcus spp., *S. epidermidis*	*P. aeruginosa*			*mecA/C*	2	1	*P. aeruginosa* (1)
Staphylococcus spp., *S. epidermidis*	*C. albicans*			*mecA/C*	2	0	-
Staphylococcus spp., *S. epidermidis*	*C. parapsilosis*			*mecA/C*	1	1	*S. epidermidis*
Staphylococcus spp., *S. epidermidis*	*C. tropicalis*			*mecA/C*	2	0	-
Streptococcus spp.	*B. fragilis*			-	2	2	*B. fragilis* (2)
Streptococcus spp.	*Enterobacterales*			-	2	2	*Enterobacterales* (2)[b]
Streptococcus spp.	*Enterobacterales*, *E. coli*			-	2	1	*Enterobacterales*/*E. coli* (1)[b]
Streptococcus spp.	*Enterobacterales*, *K. pneumoniae* group			-	1	0	-
Streptococcus spp., *S. agalactiae*	*C. krusei*			-	1	0	-
Streptococcus spp., *S. pneumoniae*	*Enterobacterales*			-	3	3	*Enterobacterales* (3)[b]
Streptococcus spp., *S. pneumoniae*	*H. influenzae*			-	1	0	-
ACB complex	*Enterobacterales*, *K. pneumoniae* group			-	1	1	ACB complex
ACB complex	*C. krusei*			-	1	0	-
B. fragilis	*Enterobacterales*, *E. coli*			-	1	1	*B. fragilis*
Enterobacterales	*H. influenzae*			-	1	1	*Enterobacterales*[b]
Enterobacterales	*P. aeruginosa*			-	2	1	*Enterobacterales* (1)[b]
Enterobacterales	*C. glabrata*			-	2	2	*Enterobacterales* (2)[b]
Enterobacterales, *E. cloacae* complex	*Enterobacterales*, *E. coli*			-	1	0	-
Enterobacterales, *E. cloacae* complex	*Enterobacterales*, *K. oxytoca*			-	1	0	-
Enterobacterales, *E. coli*	*Enterobacterales*, *K. aerogenes*			CTX-M	1	0	-
Enterobacterales, *E. coli*	*Enterobacterales*, *K. pneumoniae* group			-	2	0	-
Enterobacterales, *E. coli*	*P. aeruginosa*			CTX-M	1	0	-
Enterobacterales, *E. coli*	*P. aeruginosa*			-	1	1	*P. aeruginosa*

BIOFIRE BCID2 Panel Distinct Co-Detection Combinations					Total Specimens with Co-Detections	Number of Specimens with False Positive Co-Detections[a]	False Positive Analyte(s) [False Positive AMR Gene(s)]
Analyte 1	**Analyte 2**	**Analyte 3**	**Analyte 4**	**AMR Gene(s)**			
Enterobacterales, *E. coli*	*C. tropicalis*			-	1	0	-
Enterobacterales, *K. pneumoniae* group	*P. aeruginosa*			-	1	0	-
Enterobacterales, *K. pneumoniae* group	*C. albicans*			CTX-M, VIM	1	0	-
C. albicans	*C. tropicalis*			-	1	1	*C. albicans*
Total Co-Detections					**125**	**82**	**88/269[c]**
Total Double Detections					**109**	**70**	**72/218**
Total Triple Detections					**13**	**10**	**12/39**
Total Quadruple Detections					**3**	**2**	**4/12**

[a] Determined by comparison to bacterial culture for organisms, and molecular methods for AMR genes, irrespective of host organism bacterial culture results.

[b] Forty-five (45) of the forty-six (46) FP results were due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

[c] Of the 88 discrepant analytes (out of 269 total analytes), all 88 (100%) were confirmed as being present in the specimen during discrepancy investigation; 45/88 (51.1%) were attributed to non-viable *E. coli* nucleic acid in bioMérieux BacT/ALERT blood culture media, and an additional 43/88 (48.9%) were confirmed using an independent molecular method.

PERFORMANCE CHARACTERISTICS

Clinical Performance

The clinical performance of the BIOFIRE BCID2 Panel was established during a prospective multi-center study that was further supplemented with archived and seeded PBC specimens.

Blood culture bottle types evaluated in the prospective clinical study included 11 different media from two different manufacturers as shown in Table 18. Equivalent overall performance was observed when results from the different media were compared; therefore, the data collected from all media types are combined for all analyses. One exception was the detection of 53 false positive *Enterobacterales* results from a limited number of lots of media identified to contain nucleic acid from non-viable *E. coli;* tables containing these data are footnoted.

Table 18. Blood Culture Media Types Evaluated in the BIOFIRE BCID2 Panel Prospective Clinical Evaluation

Blood Culture Media Type	Manufacturer and Product Name	Prospective Study			Seeded Study		
		N	Overall Performance[a]		N	Overall Performance[a]	
			Sensitivity/PPA	Specificity/NPA		Sensitivity/PPA	Specificity/NPA
Aerobic	BD Bactec Plus Aerobic/F	344	98.8%	99.8%	354	99.2%	100%
	BD Standard 10 Aerobic/F	3	100%	100%	0	-	-
	bioMérieux BacT/ALERT FA plus	264	98.8%	99.0%	168	99.0%	100%
	bioMérieux BacT/ALERT SA	21	100%	99.5%	0	-	-
Anaerobic	BD Bactec Plus Anaerobic/F	86	99.1%	99.9%	15[b]	100%	100%
	BD Bactec Standard Anaerobic/F	1	100%	-	0	-	-
	BD Bactec Lytic/10 Anaerobic/F	187	99.6%	99.9%	0	-	-
	bioMérieux BacT/ALERT FN plus	40	100%	99.8%	15	100%	100%
	bioMérieux BacT/ALERT SN	83	97.9%	100%	0	-	-
Pediatric/Low Volume	BD Bactec Peds Plus/F	13	100%	99.6%	0	-	-
	bioMérieux BacT/ALERT PF plus	32	95.8%	98.8%	0	-	-

[a] Note that these calculations do not include the performance for the individual *Staphylococcus* species, individual *Streptococcus* species, or individual *Enterobacterales* interpretations, as the grouped *Staphylococcus* spp., *Streptococcus* spp., and *Enterobacterales* interpretations are included instead.

[b] *Bacteroides fragilis* only.

Nine geographically distinct study sites (seven in the US and two in the EU) participated in the prospective clinical evaluation from October 2018 to May 2019. A total of 11 pouch lots were used for testing.

A total of 1093 residual PBC specimens were acquired for the prospective clinical study. At two of the US sites, 69 specimens enrolled between October 2018 and February 2019 were collected and immediately frozen for later testing at the source laboratory. The remaining 1024 specimens were collected and tested fresh. No difference in performance was observed when fresh and frozen specimen results were compared. Therefore, the data collected from 69 valid frozen specimens are combined with data from the valid 1005 fresh specimens for all analyses.

Nineteen (19) specimens were excluded from the final data analysis. The most common reason for specimen exclusion was that the specimen was found to not meet the inclusion criteria after the specimen was enrolled, most often due to the specimen being tested with the BIOFIRE BCID2 Panel outside of the 24-hour window following positive indication by the continuous monitoring blood culture system.

For the prospective study, the performance of the BIOFIRE BCID2 Panel was evaluated by comparing the test result for each analyte with the appropriate comparator/reference methods shown in Table 19.

Table 19. Comparator Methods for the Prospective BIOFIRE BCID2 Panel Clinical Evaluation

BIOFIRE BCID2 Panel Result	Reference / Comparator Method(s)
Bacteria and *Cryptococcus*	Standard manual and automated microbiological/biochemical identification methods (performed for SOC and abstracted from the subject medical chart)
Candida species	SOC identification for genus level followed by PCR & sequencing of isolates for species identification
AMR Genes	Method 1 – Assessment of BIOFIRE BCID2 Panel performance (i) One PCR assay performed directly from PBC followed by sequencing of PCR amplicon (CTX-M, IMP, KPC, NDM, OXA-48 like, VIM, and *mcr-1*) (ii) Commercially available FDA-cleared and CE-marked molecular IVD assays performed on PBC (*mecA/C*, *mecA/C* and MREJ (MRSA), KPC, and *vanA/B*) Method 2 – Assessment of genotype concordance PCR & sequencing for specific resistance gene from applicable cultured isolates Method 3 – Assessment of phenotype concordance Phenotypic AST of applicable cultured isolates

To supplement the prospective study for low prevalence analytes, a total of 427 frozen archived PBC specimens were collected from 12 external laboratories and retrospectively tested. Of these, 395 were evaluable. Prior to testing with the BIOFIRE BCID2 Panel, the composition/integrity of the specimens was first confirmed with confirmatory molecular methods; 370 specimens contained confirmed analytes of interest.

Table 20 provides a summary of demographic information for the 1074 specimens included in the prospective study and the 370 specimens included in the archived study.

Table 20. Demographic Data for Prospective and Archived Studies

		Prospective	Archived
Sex	Male	573 (53%)	205 (55%)
	Female	501 (47%)	156 (42%)
	Unknown	0 (0%)	9 (2%)
Age	<1 year	118 (11%)	22 (6%)
	1-17 years	143 (13%)	32 (9%)
	18-44 years	125 (12%)	44 (12%)
	45-64 years	257 (24%)	112 (30%)
	65-84 years	333 (31%)	132 (36%)
	85+ years	98 (9%)	27 (7%)
	Unknown	0 (0%)	1 (<1%)
Total		**1074**	**370**

A total of 552 seeded blood culture specimens were also evaluated to further supplement the prospective and archived studies for low prevalence analytes (including AMR genes) and to assess performance in seeded polymicrobial specimens. Seeded PBC specimens were prepared by inoculating human whole blood with a variety of different isolates/strains for each analyte at low concentrations and growing to positivity in a continuous monitoring blood culture system. The number of analytes tested, and the purpose of including each analyte in the seeded study is presented in Table 21 and Table 22.

Table 21. Seeded Specimen Analyte Composition

Purpose	Analyte	Number Tested[a]
Low Prevalence Analyte	*Listeria monocytogenes*	36
	Staphylococcus lugdunensis	30
	Bacteroides fragilis	30

Purpose	Analyte	Number Tested[a]
	Klebsiella aerogenes	42
	Neisseria meningitidis	35
	Salmonella spp.	37
	Stenotrophomonas maltophilia	30
	Candida auris	30
	Candida krusei	33
	Candida tropicalis	35
	Cryptococcus neoformans/gattii	30
	IMP	30
	KPC	45
	NDM	30
	OXA-48-like	30
	VIM	30
	mcr-1	30
Evaluation of Polymicrobial Specimens	*E. faecalis*	10
	E. faecium	10
	S. aureus	10
	mecA/C and MREJ	5
	C. albicans	10
AMR Gene Host and Evaluation of Polymicrobial Specimens	*A. calcoaceticus-baumannii* complex	19
	K. pneumoniae group	92
	E. coli	44
	P. aeruginosa	26
AMR Gene Host	*E. cloacae* complex	8
	K. oxytoca	6
	Proteus	9
Present in Host with other Rare AMR Genes	CTX-M	63

[a] 552 seeded specimens total including some with polymicrobial composition or Detected results reporting both an AMR gene and host organism.

Table 22. Strains and Replicates Tested in Seeded Specimens

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
Acinetobacter baumannii	---	2 Individual clinical isolates	5 each (10)
	NDM-1	AR-BANK #0083	3
	NDM-1	AR-BANK #0088	3
	IMP-4	Individual clinical isolate	3
***Acinetobacter baumannii* total**			**19**
Bacteroides fragilis	---	ATCC 29771	3
	---	ATCC 23745	3
	---	ATCC 25285	3
	---	ATCC 29768	3
	---	ATCC 43858	3
	---	ATCC 43860	3
	---	ATCC 43936	3
	---	ATCC 43937	3
	---	ATCC BAA-2283	3
	---	Individual clinical isolate	3
***Bacteroides fragilis* total**			**30**
Candida albicans	---	2 Individual clinical isolates	5 each (10)
***Candida albicans* total**			**10**
Candida auris	---	AR-BANK #0381	3
	---	AR-BANK #0382	3
	---	AR-BANK #0383	3
	---	AR-BANK #0384	3
	---	AR-BANK #0385	3
	---	AR-BANK #0386	3
	---	AR-BANK #0387	3
	---	AR-BANK #0388	3
	---	AR-BANK #0389	3
	---	AR-BANK #0390	3
***Candida auris* total**			**30**

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
Candida krusei	---	ATCC 14243	15
	---	ATCC 6258	3
	---	15 Individual clinical isolates	1 each (15)
***Candida krusei* total**			**33**
Candida tropicalis	---	35 Individual clinical isolates	1 each (35)
***Candida tropicalis* total**			**35**
Cryptococcus gattii	---	Individual clinical isolate	3
	---	ATCC 56989	3
	---	ATCC 56992	3
	---	ATCC 64062	3
	---	ATCC MYA-4560	3
***Cryptococcus gattii* total**			**15**
Cryptococcus neoformans	---	4 Individual clinical isolates	3 each (12)
	---	ATCC 13690	3
***Cryptococcus neoformans* total**			**15**
Enterobacter cloacae	NDM-1, CTX-M-15	AR-BANK #0038	3
	VIM-1	AR-BANK #0154	3
	KPC	2 Individual clinical isolates	1 each (2)
***Enterobacter cloacae* total**			**8**
Enterococcus faecalis	---	2 Individual clinical isolates	5 each (10)
***Enterococcus faecalis* total**			**10**
Enterococcus faecium	---	2 Individual clinical isolates	5 each (10)
***Enterococcus faecium* total**			**10**
Escherichia coli	NDM-1	AR-BANK #0069	3
	CTX-M-55, *mcr-1*	AR-BANK #0346	4
	CTX-M-14, CTX-M-55, *mcr-1*	AR-BANK #0349	4
	mcr-1	AR-BANK #0350	3
	mcr-1	AR-BANK #0493	4
	mcr-1	AR-BANK #0494	4
	CTX-M, *mcr-1*	AR-BANK #0495	3
	NDM-1	ATCC BAA-2452	3
	IMP-4	Individual clinical isolate	3
	IMP-3	Individual clinical isolate	3
	IMP-9	Individual clinical isolate	3
	VIM-7	Individual clinical isolate	3
	KPC	Individual clinical isolate	4
***Escherichia coli* total**			**44**
Klebsiella aerogenes	---	10 Individual clinical isolates	3 each (30)
	---	2 Individual clinical isolates	1 each (2)
	OXA-48	AR-BANK #0074	3
	IMP-4	AR-BANK #0161	4
	CTX-M	Individual clinical isolate	3
***Klebsiella aerogenes* total**			**42**
Klebsiella oxytoca	KPC-3	AR-BANK #0147	3
	CTX-M	Individual clinical isolate	3
***Klebsiella oxytoca* total**			**6**
Klebsiella pneumoniae	---	2 Individual clinical isolates	5 each (10)
	IMP-4	AR-BANK #0034	3
	OXA-181; CTX-M-15	AR-BANK #0039	3
	VIM-27; CTX-M-15	AR-BANK #0040	3
	VIM-27; CTX-M-15	AR-BANK #0046	3
	OXA-181, CTX-M-15	AR-BANK #0051	3
	OXA232; CTX-M-15	AR-BANK #0066	3
	OXA-232; CTX-M-15	AR-BANK #0075	3
	IMP-4	AR-BANK #0080	3
	VIM-1	AR-BANK #0135	3
	NDM-7; CTX-M-15	AR-BANK #0138	3
	OXA-181; CTX-M-15	AR-BANK #0140	3

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
	OXA-181; CTX-M-15	AR-BANK #0141	3
	OXA-181; CTX-M-15	AR-BANK #0142	3
	NDM-1; OXA-232; CTX-M-15	AR-BANK #0153	3
	OXA-48	AR-BANK #0160	3
	mcr-1	AR-BANK #0497	4
	NDM-1; CTX-M	ATCC BAA-2146	3
	KPC	Individual clinical isolate	8
	KPC	22 Individual clinical isolates	1 each (22)
***Klebsiella pneumoniae* total**			**92**
Listeria monocytogenes	---	ATCC 19115	8
	---	ATCC 35152	1
	---	ATCC 43248	5
	---	ATCC 51779	5
	---	Individual clinical isolate	2
	---	7 Individual clinical isolates	1 each (7)
	---	NCTC 10890	8
***Listeria monocytogenes* total**			**36**
Neisseria meningitidis	---	ATCC 13077	10
	---	ATCC 13090	10
	---	ATCC 13102	4
	---	ATCC 13103	1
	---	ATCC 35561	4
	---	6 Individual clinical isolates	1 each (6)
***Neisseria meningitidis* total**			**35**
Proteus mirabilis	KPC-6	AR-BANK #0155	3
	NDM-1	AR-BANK #0159	3
	CTX-M	Individual clinical isolate	3
***Proteus mirabilis* total**			**9**
Pseudomonas aeruginosa	VIM-4	AR-BANK #0054	3
	KPC-5	AR-BANK #0090	3
	IMP-14	AR-BANK #0092	4
	VIM-2	AR-BANK #0100	3
	IMP-1	AR-BANK #0103	4
	VIM-2	AR-BANK #0108	3
	VIM-2	AR-BANK #0110	3
	VIM-2	AR-BANK #0111	3
***Pseudomonas aeruginosa* total**			**26**
Salmonella sp.	---	3 Individual clinical isolates	3 each (9)
Salmonella enterica serogroup C	---	Individual clinical isolate	3
Salmonella enterica ser. Berta	---	Individual clinical isolate	3
Salmonella enterica ser. Enteritidis	---	Individual clinical isolate	3
	mcr-1	AR-BANK #0496	4
Salmonella enterica ser. Javiana	---	Individual clinical isolate	3
Salmonella enterica ser. Newport	---	Individual clinical isolate	3
Salmonella enterica ser. Senftenberg	NDM-1	AR-BANK #0127	3
Salmonella enterica ser.Typhi	---	Individual clinical isolate	3
Salmonella enterica ser. Typhimurium	---	Individual clinical isolate	3
***Salmonella* sp. total**			**37**
Staphylococcus aureus	---	Individual clinical isolate	5
	mecA & MREJ	Individual clinical isolate	5
***Staphylococcus aureus* total**			**10**
Staphylococcus lugdunensis	---	5 Individual clinical isolates	3 each (15)
	---	ATCC 43809	3
	---	ATCC 49576	3
	---	ATCC 700328	3
	---	ATCC 700582	3
	---	NCTC 7990	3
***Staphylococcus lugdunensis* total**			**30**

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
Stenotrophomonas maltophilia	---	10 Individual clinical isolates	3 each (30)
***Stenotrophomonas maltophilia* total**			**30**

Table 23. Carbapenem AST Results for Strains with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	Carbapenem AST				
			Doripenem	Ertapenem	Imipenem	Meropenem	Drug Not Specified
CLSI M100 ED30:2020 Used for Breakpoints							
Individual clinical isolate	IMP-4	*Acinetobacter baumannii*	-	-	S	S	-
Individual clinical isolate	IMP-4	*Escherichia coli*	-	R	R	R	-
CLSI 2018 M100 S28 Used for Breakpoints							
AR-BANK #0103	IMP-1	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0161	IMP-4	*Klebsiella aerogenes*	R	R	I	I	-
AR-BANK #0034	IMP-4	*Klebsiella pneumoniae*	I	R	S	I	-
AR-BANK #0080	IMP-4	*Klebsiella pneumoniae*	R	R	I	R	-
AR-BANK #0092	IMP-14	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0147	KPC-3	*Klebsiella oxytoca*	I	R	R	I	-
AR-BANK #0090	KPC-5	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0155	KPC-6	*Proteus mirabilis*	I	R	R	I	-
AR-BANK #0083	NDM-1	*Acinetobacter baumannii*	R	-	R	R	-
AR-BANK #0088	NDM-1	*Acinetobacter baumannii*	R	-	R	R	-
AR-BANK #0038[a]	NDM-1	*Enterobacter cloacae*	R	R	R	R	-
AR-BANK #0069	NDM-1	*Escherichia coli*	R	R	R	R	-
AR-BANK #0159	NDM-1	*Proteus mirabilis*	R	R	R	R	-
AR-BANK #0127	NDM-1	*Salmonella enterica* ser. Senftenberg	R	R	R	R	-
AR-BANK #0153[a]	NDM-1, OXA-232	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0138[a]	NDM-7	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0074	OXA-48	*Klebsiella aerogenes*	I	R	R	I	-
AR-BANK #0160	OXA-48	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0039[a]	OXA-181	*Klebsiella pneumoniae*	R	R	R	I	-
AR-BANK #0051[a]	OXA-181	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0140[a]	OXA-181	*Klebsiella pneumoniae*	R	R	I	R	-
AR-BANK #0141[a]	OXA-181	*Klebsiella pneumoniae*	R	R	I	R	-
AR-BANK #0142[a]	OXA-181	*Klebsiella pneumoniae*	I	R	R	I	-
AR-BANK #0066[a]	OXA-232	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0075[a]	OXA-232	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0154	VIM-1	*Enterobacter cloacae*	R	R	R	I	-
AR-BANK #0135	VIM-1	*Klebsiella pneumoniae*	R	R	R	R	-

Strain	AMR Gene(s)	Organism	Carbapenem AST				
			Doripenem	Ertapenem	Imipenem	Meropenem	Drug Not Specified
AR-BANK #0100	VIM-2	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0108	VIM-2	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0110	VIM-2	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0111	VIM-2	*Pseudomonas aeruginosa*	R	-	R	R	-
AR-BANK #0054	VIM-4	*Pseudomonas aeruginosa*	I	-	R	R	-
AR-BANK #0040[a]	VIM-27	*Klebsiella pneumoniae*	R	R	R	R	-
AR-BANK #0046[a]	VIM-27	*Klebsiella pneumoniae*	R	R	R	R	-
CLSI 2012 M100 S22 Used for Breakpoints							
Individual clinical isolate	KPC	*Enterobacter cloacae*	-	-	-	-	R
Individual clinical isolate	KPC	*Enterobacter cloacae*	-	-	-	-	R
Individual clinical isolate	KPC	*Escherichia coli*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	I
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Individual clinical isolate	KPC	*Klebsiella pneumoniae*	-	-	-	-	R
Unknown Source for Breakpoints or No AST Information Available							

Strain	AMR Gene(s)	Organism	Carbapenem AST				
			Doripenem	Ertapenem	Imipenem	Meropenem	Drug Not Specified
Individual clinical isolate	IMP-3	*Escherichia coli*	-	-	-	-	-
Individual clinical isolate	IMP-9	*Escherichia coli*	-	-	-	-	-
ATCC BAA-2452	NDM-1	*Escherichia coli*	-	R	R	-	-
ATCC BAA-2146[a,b]	NDM-1	*Klebsiella pneumoniae*	-	-	-	-	-
Individual clinical isolate	VIM-7	*Escherichia coli*	-	-	-	-	-

[a] Also carries CTX-M gene.

[b] Presence of CTX-M gene verified by independent molecular method.

Table 24. ESBL AST Results for Strains with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	ESBL AST							
			Ampicillin	Aztreonam	Cefazolin	Cefepime	Cefotaxime	Cefoxitin	Ceftazidime	Ceftriaxone
CLSI M100 ED30:2020 Used for Breakpoints										
Individual clinical isolate	CTX-M	*Klebsiella aerogenes*	R	R	-	S	R	R	R	R
Individual clinical isolate	CTX-M	*Klebsiella oxytoca*	R	R	-	S	R	S	S	R
Individual clinical isolate	CTX-M	*Proteus mirabilis*	R	S	-	S	R	S	S	R
CLSI 2018 M100 S28 Used for Breakpoints										
AR-BANK #0495[a,e]	CTX-M	*Escherichia coli*	R	R	R	R	R	S	R	R
AR-BANK #0497[a,e]	CTX-M	*Klebsiella pneumoniae*	R	R	R	R	R	I	R	R
AR-BANK #0349[a]	CTX-M-14, CTX-M-55	*Escherichia coli*	R	R	R	R	R	I	R	R
AR-BANK #0038[b]	CTX-M-15	*Enterobacter cloacae*	R	R	R	R	R	R	R	R
AR-BANK #0039[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0040[d]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0046[d]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0051[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0066[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0075[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0138[b]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0140[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0141[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	I	R	R
AR-BANK #0142[c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0153[b,c]	CTX-M-15	*Klebsiella pneumoniae*	R	R	R	R	R	R	R	R
AR-BANK #0346[a]	CTX-M-55	*Escherichia coli*	R	R	R	R	R	R	R	R
No AST Information Available										

ATCC BAA-2146[b,e]	CTX-M	*Klebsiella pneumoniae*	-	-	-	-	-	-	-	-

[a] Also carries *mcr-1* gene.
[b] Also carries NDM gene.
[c] Also carries OXA-48-like gene.
[d] Also carries VIM gene.
[e] Presence of CTX-M gene verified by independent molecular method.

Table 25. Colistin MIC for Strains with *mcr-1* Gene Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	Colistin MIC (µg/ml)
AR-BANK #0346[a]	*mcr-1*	*Escherichia coli*	4
AR-BANK #0349[a]	*mcr-1*	*Escherichia coli*	2-4
AR-BANK #0350	*mcr-1*	*Escherichia coli*	4
AR-BANK #0493	*mcr-1*	*Escherichia coli*	8
AR-BANK #0494	*mcr-1*	*Escherichia coli*	8
AR-BANK #0495[a,b]	*mcr-1*	*Escherichia coli*	4
AR-BANK #0497[a,b]	*mcr-1*	*Klebsiella pneumoniae*	8
AR-BANK #0496	*mcr-1*	*Salmonella* sp.	8

[a] Also carries CTX-M gene.
[b] Presence of CTX-M gene verified by independent molecular method.
[c] As of February 2020, the United States Food and Drug Administration has not established or recognized minimum inhibitory concentration (MIC) breakpoints for colistin antimicrobial susceptibility testing (AST) related to *mcr-1*.

Table 26. Methicillin AST Result for Strain with *mecA* and MREJ Genes Used in Seeded Specimens

Strain	Organism	AMR Gene(s)	Methicillin AST
Individual clinical isolate[a]	*Staphylococcus aureus*	*mecA* & MREJ	R

[a] CLSI 2012 M100 S22 used for breakpoints.

The results from all three clinical studies are summarized for each organism in Table 27 through Table 39. Performance is based on a comparison of the BIOFIRE BCID2 Panel results to the results from comparator methods for prospective specimens (Table 19), the confirmed analyte of interest for archived specimens, and to the known analyte composition for seeded specimens. Positive Percent Agreement (PPA) or Sensitivity for each analyte was calculated as 100% × (TP / (TP + FN)). True positive (TP) indicates that both the BIOFIRE BCID2 Panel and the comparator method (or known analyte composition) had a positive result for the specific analyte, and false negative (FN) indicates that the BIOFIRE BCID2 Panel was negative while the comparator result was positive. Negative Percent Agreement (NPA) or Specificity was calculated as 100% × (TN / (TN + FP)). True negative (TN) indicates that both the BIOFIRE BCID2 Panel and the comparator method (or known analyte composition) had negative results, and false positive (FP) indicates that the BIOFIRE BCID2 Panel was positive while the comparator result was negative. The exact binomial two-sided 95% confidence interval (95%CI) was calculated. Investigations of discrepant results are summarized in the footnotes.

Table 27. BIOFIRE BCID2 Panel Clinical Performance Summary, *Enterococcus* spp.

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Enterococcus faecalis	Prospective	31/33	93.9	80.4-98.3%	1040/1041	99.9	99.5-100%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	***41/43***[b]	***95.3***	***84.5-98.7%***	***1582/1583***[c]	***99.9***	***99.6-100%***
Enterococcus faecium	Prospective	27/27	100	87.5-100%	1044/1047	99.7	99.2-99.9%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	***37/37***	***100***	***90.6-100%***	***1586/1589***[d]	***99.8***	***99.4-99.9%***

[a] Archived testing not performed for *E. faecalis* or *E. faecium.*
[b] *E. faecalis* was detected in both FN specimens using an additional molecular method.
[c] The single FP specimen was negative for *E. faecalis* when tested with additional molecular methods.
[d] *E. faecium* was detected in all three FP specimens using an additional molecular method.

Table 28. BIOFIRE BCID2 Panel Clinical Performance Summary, *Listeria monocytogenes*

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Listeria monocytogenes	Prospective	3/3	100	43.9-100%	1071/1071	100	99.6-100%
	Archived	5/5	100	56.6-100%	231/231	100	98.4-100%
	Seeded	36/36	100	90.4-100%	516/516	100	99.3-100%
	Overall	***44/44***	***100***	***92.0-100%***	***1818/1818***	***100***	***99.8-100%***

Table 29. BIOFIRE BCID2 Panel Clinical Performance Summary, *Staphylococcus* spp.

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Staphylococcus spp.	Prospective	471/472	99.8	98.8-100%	589/602	97.8	96.3-98.7%
	Seeded	40/40	100	91.2-100%	512/512	100	99.3-100%
	Overall	***511/512***	***99.8***	***98.9-100%***	***1101/1114***[b]	***98.8***	***98.0-99.3%***
Staphylococcus aureus	Prospective	149/149	100	97.5-100%	923/925	99.8	99.2-99.9%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	***159/159***	***100***	***97.6-100%***	***1465/1467***[c]	***99.9***	***99.5-100%***
Staphylococcus epidermidis	Prospective	221/229	96.5	93.3-98.2%	816/845	96.6	95.1-97.6%
	Overall	***221/229***[d]	***96.5***	***93.3-98.2%***	***816/845***[e]	***96.6***	***95.1-97.6%***
Staphylococcus lugdunensis	Prospective	4/4	100	51.0-100%	1067/1070	99.7	99.2-99.9%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	***50/50***	***100***	***92.9-100%***	***1714/1717***[f]	***99.8***	***99.5-99.9%***

[a] Archived testing not performed for *Staphylococcus* spp., *S. aureus*, or *S. epidermidis*; seeded testing not performed for *S. epidermidis.*
[b] *Staphylococcus* spp. was detected in all 13 FP specimens using an additional molecular method.
[c] *S. aureus* was detected in both FP specimens using an additional molecular method.
[d] *S. epidermidis* was detected in 3/8 FN specimens using an additional molecular method; sequencing of the remaining five FN specimens and their isolates identified them as other *Staphylococcus* spp.
[e] *S. epidermidis* was detected in all 29 FP specimens using an additional molecular method.
[f] *S. lugdunensis* was detected in all three FP specimens using an additional molecular method.

Table 30. BIOFIRE BCID2 Panel Clinical Performance Summary, *Streptococcus* spp.

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Streptococcus spp.	Prospective	121/123	98.4	94.3-99.6%	949/951	99.8	99.2-99.9%
	Overall	***121/123***[b]	***98.4***	***94.3-99.6%***	***949/951***[c]	***99.8***	***99.2-99.9%***
Streptococcus agalactiae (Group B)	Prospective	9/9	100	70.1-100%	1065/1065	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	***25/25***	***100***	***86.7-100%***	***1285/1285***	***100***	***99.7-100%***
Streptococcus pneumoniae	Prospective	26/26	100	87.1-100%	1048/1048	100	99.6-100%
	Overall	***26/26***	***100***	***87.1-100%***	***1048/1048***	***100***	***99.6-100%***
Streptococcus pyogenes (Group A)	Prospective	13/14	92.9	68.5-98.7%	1060/1060	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	***29/30***	***96.7***	***83.3-99.4%***	***1280/1280***	***100***	***99.7-100%***

[a] Archived testing not performed for *Streptococcus* spp. or *S. pneumoniae*; seeded testing not performed for *Streptococcus* spp., *S. agalactiae*, *S. pneumoniae*, or *S. pyogenes.*
[b] *Streptococcus* spp. was detected in 1/2 FN specimens using an additional molecular method.
[c] *Streptococcus* spp. was detected in both FP specimens using an additional molecular method.

Table 31. BIOFIRE BCID2 Panel Clinical Performance Summary, *Acinetobacter calcoaceticus-baumannii* complex

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Acinetobacter calcoaceticus-baumannii complex	Prospective	12/13	92.3	66.7-98.6%	1060/1061	99.9	99.5-100%
	Archived	34/35	97.1	85.5-99.5%	102/103	99.0	94.7-99.8%
	Seeded	19/19	100	83.2-100%	533/533	100	99.3-100%
	Overall	***65/67***[a]	***97.0***	***89.8-99.2%***	***1695/1697***[b]	***99.9***	***99.6-100%***

[a] ACB complex was detected in both FN specimens; one was detected using an additional molecular method and one was detected upon BIOFIRE BCID2 Panel retest.
[b] ACB complex was detected in both FP specimens using an additional molecular method.

Table 32. BIOFIRE BCID2 Panel Clinical Performance Summary, *Bacteroides fragilis*

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Bacteroides fragilis	Prospective	6/6	100	61.0-100%	1065/1068	99.7	99.2-99.9%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	***52/52***	***100***	***93.1-100%***	***1712/1715***[a]	***99.8***	***99.5-99.9%***

[a] *B. fragilis* was detected in all three FP specimens using an additional molecular method.

Table 33. BIOFIRE BCID2 Panel Clinical Performance Summary, *Enterobacterales*

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Enterobacterales	Prospective	269/270	99.6	97.9-99.9%	750/804	93.3	91.3-94.8%
	Seeded	228/228	100	98.3-100%	324/324	100	98.8-100%
	Overall	***497/498***	***99.8***	***98.9-100%***	***1074/1128***[b]	***95.2***	***93.8-96.3%***
Enterobacter cloacae complex	Prospective	16/16	100	80.6-100%	1058/1058	100	99.6-100%
	Archived	16/16	100	80.6-100%	219/219	100	98.3-100%
	Seeded	8/8	100	67.6-100%	544/544	100	99.3-100%
	Overall	***40/40***	***100***	***91.2-100%***	***1821/1821***	***100***	***99.8-100%***
Escherichia coli	Prospective	158/159	99.4	96.5-99.9%	913/915	99.8	99.2-99.9%
	Seeded	44/44	100	92.0-100%	508/508	100	99.2-100%
	Overall	***202/203***[c]	***99.5***	***97.3-99.9%***	***1421/1423***[d]	***99.9***	***99.5-100%***
Klebsiella aerogenes	Prospective	2/2	100	34.2-100%	1072/1072	100	99.6-100%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	42/42	100	91.6-100%	510/510	100	99.3-100%
	Overall	***60/60***	***100***	***94.0-100%***	***1707/1707***	***100***	***99.8-100%***
Klebsiella oxytoca	Prospective	8/8	100	67.6-100%	1066/1066	100	99.6-100%
	Archived	16/16	100	80.6-100%	219/219	100	98.3-100%
	Seeded	6/6	100	61.0-100%	546/546	100	99.3-100%
	Overall	***30/30***	***100***	***88.6-100%***	***1831/1831***	***100***	***99.8-100%***
Klebsiella pneumoniae group	Prospective	55/56	98.2	90.6-99.7%	1018/1018	100	99.6-100%
	Seeded	92/92	100	96.0-100%	460/460	100	99.2-100%
	Overall	***147/148***[e]	***99.3***	***96.3-99.9%***	***1478/1478***	***100***	***99.7-100%***
Proteus spp.	Prospective	14/14	100	78.5-100%	1059/1060	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	208/208	100	98.2-100%
	Seeded	9/9	100	70.1-100%	543/543	100	99.3-100%
	Overall	***39/39***	***100***	***91.0-100%***	***1810/1811***[f]	***99.9***	***99.7-100%***
Salmonella spp.	Prospective	5/5	100	56.6-100%	1069/1069	100	99.6-100%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	37/37	100	90.6-100%	515/515	100	99.3-100%
	Overall	***58/58***	***100***	***93.8-100%***	***1709/1709***	***100***	***99.8-100%***
Serratia marcescens	Prospective	11/11	100	74.1-100%	1063/1063	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	***27/27***	***100***	***87.5-100%***	***1283/1283***	***100***	***99.7-100%***

[a] Archived testing not performed for *Enterobacterales*, *E. coli,* or *K. pneumoniae* group; seeded testing not performed for *S. marcescens.*

[b] Fifty-three (53) of 54 FP *Enterobacterales* results were attributed to the presence of nucleic acid from non-viable *E. coli* in specific lots of blood culture bottles. The remaining FP specimen was observed in a blood culture bottle from a different manufacturer; an *Enterobacterales* organism (*E. coli*) was detected in this specimen using an additional molecular method.

[c] The single FN specimen was negative for *E. coli* when tested with Luminex Verigene BC-GN test.

[d] The two FP specimens were attributed to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

[e] *K. pneumoniae* group was detected in the single FN specimen using an additional molecular method.

[f] *Proteus* spp. was detected in the single FP specimen using an additional molecular method.

Table 34. BIOFIRE BCID2 Panel Clinical Performance Summary, *Haemophilus influenzae*

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Haemophilus influenzae	Prospective	8/8	100	67.6-100%	1066/1066	100	99.6-100%
	Archived	24/25	96.0	80.5-99.3%	211/211	100	98.2-100%
	Overall	***32/33***[b]	***97.0***	***84.7-99.5%***	***1277/1277***	***100***	***99.7-100%***

[a] Seeded testing not performed for *H. influenzae.*

[b] The single FN specimen was determined to contain a novel deletion in the BIOFIRE BCID2 Panel assay target gene region.

Table 35. BIOFIRE BCID2 Panel Clinical Performance Summary, *Neisseria meningitidis*

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Neisseria meningitidis	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	3/3	100	43.9-100%	233/233	100	98.4-100%
	Seeded	35/35	100	90.1-100%	517/517	100	99.3-100%
	Overall	***38/38***	***100***	***90.8-100%***	***1824/1824***	***100***	***99.8-100%***

Table 36. BIOFIRE BCID2 Panel Clinical Performance Summary, *Pseudomonas aeruginosa*

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Pseudomonas aeruginosa	Prospective	29/29	100	88.3-100%	1043/1045	99.8	99.3-99.9%
	Seeded	24/26	92.3	75.9-97.9%	526/526	100	99.3-100%
	Overall	***53/55***[b]	***96.4***	***87.7-99.0%***	***1569/1571***[c]	***99.9***	***99.5-100%***

[a] Archived testing not performed for *P. aeruginosa.*
[b] 16/16 single seeded specimens were TP, and 8/10 specimens that were co-seeded with *E. faecalis* were detected. *E. faecalis* was detected in 10/10 of the co-seeded specimens.
[c] *P. aeruginosa* was detected in both FP specimens using an additional molecular method.

Table 37. BIOFIRE BCID2 Panel Clinical Performance Summary, *Stenotrophomonas maltophilia*

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Stenotrophomonas maltophilia	Prospective	7/8	87.5	52.9-97.8%	1066/1066	100	99.6-100%
	Archived	22/23	95.7	79.0-99.2%	116/116	100	96.8-100%
	Seeded	25/30[a]	83.3	66.4-92.7%	522/522	100	99.3-100%
	Overall	***54/61***[b]	***88.5***	***78.2-94.3%***	***1704/1704***	***100***	***99.8-100%***

[a] 20/20 single seeded specimens were TP, and 5/10 specimens that were co-seeded with *S. aureus* were detected. *S. aureus* was detected in 10/10 of the co-seeded specimens.
[b] *S. maltophilia* was detected in 2/7 FN specimens: one was detected using an additional molecular method and one was detected upon BIOFIRE BCID2 Panel retest; the remaining five FN specimens were polymicrobial seeded specimens.

Table 38. BIOFIRE BCID2 Panel Clinical Performance Summary, *Candida* spp.

Analyte	Study[a]	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Candida albicans	Prospective	12/12	100	75.8-100%	1061/1062	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	218/218	100	98.3-100%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	***38/38***	***100***	***90.8-100%***	***1821/1822***[b]	***99.9***	***99.7-100%***
Candida auris	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	1/1	100	-	13/13	100	77.2-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	***31/31***	***100***	***89.0-100%***	***1609/1609***	***100***	***99.8-100%***
Candida glabrata	Prospective	10/10	100	72.2-100%	1063/1064	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	217/218	99.5	97.4-99.9%
	Overall	***26/26***	***100***	***87.1-100%***	***1280/1282***[c]	***99.8***	***99.4-100%***
Candida krusei	Prospective	2/2	100	34.2-100%	1072/1072	100	99.6-100%
	Archived	9/9	100	70.1-100%	227/227	100	98.3-100%
	Seeded	33/33	100	89.6-100%	519/519	100	99.3-100%
	Overall	***44/44***	***100***	***92.0-100%***	***1818/1818***	***100***	***99.8-100%***
Candida parapsilosis	Prospective	8/8	100	67.6-100%	1065/1066	99.9	99.5-100%
	Archived	22/23	95.7	79.0-99.2%	211/211	100	98.2-100%
	Overall	***30/31***[d]	***96.8***	***83.8-99.4%***	***1276/1277***[e]	***99.9***	***99.6-100%***
Candida tropicalis	Prospective	5/5	100	56.6-100%	1069/1069	100	99.6-100%
	Archived	15/15	100	79.6-100%	219/220	99.5	97.5-99.9%
	Seeded	35/35	100	90.1-100%	517/517	100	99.3-100%
	Overall	***55/55***	***100***	***93.5-100%***	***1805/1806***[f]	***99.9***	***99.7-100%***

[a] Seeded testing was not performed for *C. glabrata* or *C. parapsilosis.*
[b] *C. albicans* was detected in the single FP specimen using an additional molecular method.
[c] *C. glabrata* was detected in both FP specimens using an additional molecular method.

[d] The single FN specimen was misidentified as *C. parapsilosis* by the source laboratory; molecular testing of the specimen identified it as *C. orthopsilosis.*
[e] *C. parapsilosis* was detected in the single FP specimen using an additional molecular method.
[f] The single FP specimen was identified as a cross-reactivity between the BIOFIRE BCID2 Panel Ctropicalis assay and high titer *C. parapsilosis* (refer to Analytical Specificity section for additional information regarding this cross-reactivity).

Table 39. BIOFIRE BCID2 Panel Clinical Performance Summary, *Cryptococcus neoformans/gattii*

Analyte	Study	Sensitivity			Specificity		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Cryptococcus neoformans/gattii	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	6/6	100	61.0-100%	135/135	100	97.2-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	***36/36***	***100***	***90.4-100%***	***1731/1731***	***100***	***99.8-100%***

BIOFIRE BCID2 Panel assay performance stratified by species for *Staphylococcus* spp., *Streptococcus* spp., *Enterobacterales, Enterobacter cloacae* complex, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Cryptococcus neoformans/gattii*. BIOFIRE BCID2 Panel genus and group level organism results are presented in Table 40 through Table 43. Note: multiple organisms from a group may be detected in a single specimen, therefore the "Total" values in these tables may not match the performance values presented above, which are reported per specimen.

Table 40. Stratification of *Staphylococcus* spp. Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
S. aureus	149/149 (100%)	-	10/10 (100%)
S. auricularis	1/1 (100%)	-	-
S. capitis	19/19 (100%)	-	-
S. caprae	4/4 (100%)	-	-
S. epidermidis	229/229 (100%)	-	-
S. haemolyticus	24/24 (100%)	-	-
S. hominis	52/53 (98.1%)	-	-
S. lentus	1/1 (100%)	-	-
S. lugdunensis	4/4 (100%)	16/16 (100%)	30/30 (100%)
S. pettenkoferi	10/10 (100%)	-	-
S. simulans	3/3 (100%)	-	-
S. warneri	2/2 (100%)	-	-
Total *Staphylococcus* spp.	**498/499 (99.8%) 95%CI: 98.9-100%**	**16/16 (100%) 95%CI: 80.6-100%**	**40/40 (100%) 95% CI: 91.2-100%**

Table 41. Stratification of *Streptococcus* spp. Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
Group A (Pyogenic)			
S. pyogenes	13/14 (92.9%)	16/16 (100%)	-
Group B (Pyogenic)			
S. agalactiae	9/9 (100%)	16/16 (100%)	-
Group C/G (Pyogenic)			
S. canis	1/1 (100%)	-	-
S. dysgalactiae	5/5 (100%)	-	-
Group D (Bovis)			
S. bovis group	2/2 (100%)	-	-
S. gallolyticus	2/2 (100%)	-	-
S. lutetiensis	1/1 (100%)	-	-
Group F (Anginosus)			
S. anginosus	3/4 (75.0%)	-	-
S. anginosus group	3/3 (100%)	-	-
S. constellatus	2/2 (100%)	-	-
S. intermedius	2/2 (100%)	-	-
S. vestibularis	2/2 (100%)	-	-
Mitis Group			
S. gordonii	1/1 (100%)	-	-
S. mitis	10/10 (100%)	-	-
S. mitis/oralis	7/7 (100%)	-	-
S. oralis	1/1 (100%)	-	-
S. parasanguinis	6/6 (100%)	-	-
S. pneumoniae	26/26 (100%)	-	-

Species	Sensitivity		
	Prospective	Archived	Seeded
Mutans Group			
S. mutans	2/2 (100%)	-	-
Salivarius Group			
S. salivarius	8/8 (100%)	-	-
Other			
Viridans streptococci	19/19 (100%)	-	-
Total *Streptococcus* spp.	**125/127 (98.4%) 95%CI: 94.4-99.6%**	**32/32 (100%) 95%CI: 89.3-100%**	**-**

Table 42. Stratification of *Enterobacterales* Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
***Enterobacter cloacae* complex**			
Enterobacter cloacae	10/10 (100%)	14/14 (100%)	8/8 (100%)
Enterobacter cloacae complex	3/3 (100%)	2/2 (100%)	-
Enterobacter hormaechei	2/2 (100%)	-	-
Enterobacter kobei	1/1 (100%)	-	-
Total	**16/16 (100%) 95%CI: 80.6-100%**	**16/16 (100%) 95%CI: 80.6-100%**	**8/8 (100%) 95%CI: 67.6-100%**
***Klebsiella pneumoniae* group**			
Klebsiella pneumoniae	51/51 (100%)	-	92/92 (100%)
Klebsiella pneumoniae group	3/3 (100%)	-	-
Klebsiella variicola	2/2 (100%)	-	-
Total	**56/56 (100%) 95%CI: 93.6-100%**	**-**	**92/92 (100%) 95%CI: 96.0-100%**
***Proteus* spp.**			
Proteus mirabilis	13/13 (100%)	14/14 (100%)	9/9 (100%)
Proteus penneri	1/1 (100%)	-	-
Proteus vulgaris	-	1/1 (100%)	-
Proteus sp.	-	1/1 (100%)	-
Total	**14/14 (100%) 95%CI: 78.5-100%**	**16/16 (100%) 95%CI: 80.6-100%**	**9/9 (100%) 95%CI: 70.1-100%**
***Salmonella* spp.**			
Salmonella enterica sv. Berta	-	-	3/3 (100%)
Salmonella enterica sv. Enteritidis	-	-	7/7 (100%)
Salmonella enterica sv. Javiana	-	-	3/3 (100%)
Salmonella enterica sv. Newport	-	1/1 (100%)	3/3 (100%)
Salmonella enterica sv. Paratyphi	-	1/1 (100%)	-
Salmonella enterica sv. Senftenberg	-	-	3/3 (100%)
Salmonella enterica sv. Tel-el-kebir	1/1 (100%)	-	-
Salmonella enterica sv. Typhi	-	1/1 (100%)	3/3 (100%)
Salmonella enterica sv. Typhimurium	-	-	3/3 (100%)
Salmonella enterica serogroup B	-	1/1 (100%)	-
Salmonella enterica serogroup C	-	-	3/3 (100%)
Salmonella enterica	2/2 (100%)	-	-
Salmonella spp.	2/2 (100%)	12/12 (100%)	9/9 (100%)
Total	**5/5 (100%) 95%CI: 56.6-100%**	**16/16 (100%) 95%CI: 80.6-100%**	**37/37 (100%) 95%CI: 90.6-100%**
Other			
Citrobacter amalonaticus	1/1 (100%)	-	-
Citrobacter freundii	1/1 (100%)	-	-
Enterobacter amnigenus	1/1 (100%)	-	-
Escherichia coli	159/159 (100%)	-	44/44 (100%)
Hafnia alvei	1/1 (100%)	-	-
Klebsiella aerogenes	2/2 (100%)	16/16 (100%)	42/42 (100%)
Klebsiella oxytoca	8/8 (100%)	16/16 (100%)	6/6 (100%)
Pantoea septica/agglomerans	1/1 (100%)	-	-
Providencia stuartii	2/3 (66.7%)	-	-
Serratia liquefaciens complex	1/1 (100%)	-	-
Serratia marcescens	11/11 (100%)	16/16 (100%)	-
Total *Enterobacterales*	**279/280 (99.6%) 95%CI: 98.0-99.9%**	**96/96 (100%) 95%CI: 96.2-100%**	**238/238 (100%) 95%CI: 98.4-100%**

Table 43. Stratification of *Cryptococcus neoformans/gattii* Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
C. gattii	-	-	15/15 (100%)
C. neoformans	-	6/6 (100%)	15/15 (100%)
Total *Cryptococcus neoformans/gattii*	**-**	**6/6 (100%) 95%CI: 61.0-100%**	**30/30 (100%) 95%CI: 88.6-100%**

Antimicrobial resistance (AMR) gene results are reported only when one or more applicable bacteria that may carry the gene are also detected in the sample. If no applicable bacteria are detected, the AMR gene results are reported as Not Applicable (N/A). The results are summarized for each AMR gene in Table 44 through Table 73. Note: the "Performance Summary" tables below do not include specimens for which a potential host organism was not reported (i.e. the AMR gene was reported as N/A); these specimens are instead accounted for in the "Distribution of Clinical Specimens" tables below.

Table 44. BIOFIRE BCID2 Panel Clinical Performance Summary, CTX-M

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
CTX-M	Prospective	46/47	97.9	88.9-99.6%	312/312	100	98.8-100%
	Seeded	63/63	100	94.3-100%	198/198	100	98.1-100%
	Overall	***109/110***	***99.1***	***95.0-99.8%***	***510/510***	***100***	***99.3-100%***

[a] Archived testing was not performed for CTX-M.

Table 45. Distribution of CTX-M in Prospective Clinical Specimens

CTX-M		SOC: any associated organism PCR/seq: CTX-M			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	46	0	0	*46*
	Org+ / Res-	1	258	54[a]	*313*
	Org -	0	2	713	*715*
	Total	*47*	*260*	*767*	*1074*
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	46/47	97.9	88.9-99.6%
		Org+ / Res-	258/260	99.2	97.2-99.8%
		Org -	713/767[a]	93.0	90.9-94.6%

[a] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 46. Stratification of CTX-M Clinical Performance by Associated Host Organism

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	46/47	97.9	88.9-99.6%	312/312	100	98.8-100%
	Seeded	63/63	100	94.3-100%	198/198	100	98.1-100%
	Overall	***109/110***	***99.1***	***95.0-99.8%***	***510/510***	***100***	***99.3-100%***
Acinetobacter calcoaceticus-baumannii complex	Prospective	1/1	100	-	12/12	100	75.8-100%
	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	***1/1***	***100***	***-***	***31/31***	***100***	***89.0-100%***
Enterobacterales	Prospective	46/47	97.9	88.9-99.6%	276/276	100	98.6-100%
	Seeded	63/63	100	94.3-100%	165/165	100	97.7-100%
	Overall	***109/110***	***99.1***	***95.0-99.8%***	***441/441***	***100***	***99.1-100%***
Enterobacter cloacae complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	***3/3***	***100***	***43.9-100%***	***21/21***	***100***	***84.5-100%***
Escherichia coli	Prospective	30/30	100	88.6-100%	130/130	100	97.1-100%
	Seeded	11/11	100	74.1-100%	33/33	100	89.6-100%
	Overall	***41/41***	***100***	***91.4-100%***	***163/163***	***100***	***97.7-100%***
Klebsiella aerogenes	Prospective	1/1	100	-	1/1	100	-

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
	Seeded	3/3	100	43.9-100%	39/39	100	91.0-100%
	Overall	***4/4***	***100***	***51.0-100%***	***40/40***	***100***	***91.2-100%***
Klebsiella oxytoca	Prospective	0/0	-	-	8/8	100	67.6-100%
	Seeded	3/3	100	43.9-100%	3/3	100	43.9-100%
	Overall	***3/3***	***100***	***43.9-100%***	***11/11***	***100***	***74.1-100%***
Klebsiella pneumoniae group	Prospective	12/12	100	75.8-100%	43/43	100	91.8-100%
	Seeded	40/40	100	91.2-100%	52/52	100	93.1-100%
	Overall	***52/52***	***100***	***93.1-100%***	***95/95***	***100***	***96.1-100%***
Proteus spp.	Prospective	4/4	100	51.0-100%	11/11	100	74.1-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	***7/7***	***100***	***64.6-100%***	***17/17***	***100***	***81.6-100%***
Salmonella spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	***0/0***	***-***	***-***	***42/42***	***100***	***91.6-100%***
Serratia marcescens	Prospective	0/1	0	-	10/10	100	72.2-100%
	Overall	***0/1***	***0***	***-***	***10/10***	***100***	***72.2-100%***
Pseudomonas aeruginosa	Prospective	2/2	100	34.2-100%	29/29	100	88.3-100%
	Seeded	0/0	-	-	24/24	100	86.2-100%
	Overall	***2/2***	***100***	***34.2-100%***	***53/53***	***100***	***93.2-100%***

[a] Archived testing not performed for CTX-M; seeded testing not performed for CTX-M with *S. marcescens.*

Table 47. BIOFIRE BCID2 Panel Clinical Performance Summary, IMP

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
IMP	Prospective	0/0	-	-	359/359	100	98.9-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	***29/29***	***100***	***88.3-100%***	***591/591***	***100***	***99.4-100%***

[a] Archived testing not performed for IMP.

Table 48. Distribution of IMP in Prospective Clinical Specimens

IMP		SOC: any associated organism PCR/seq: IMP			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	0	0	0	*0*
	Org+ / Res-	0	305	54[a]	*359*
	Org -	0	2	713	*715*
	Total	*0*	*307*	*767*	*1074*
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/0	-	-
		Org+ / Res-	305/307	99.3	97.7-99.8%
		Org -	713/767[a]	93.0	90.9-94.6%

[a] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 49. Stratification of IMP Clinical Performance by Associated Host Organism, Seeded study[a]

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	***29/29***	***100***	***88.3-100%***	***232/232***	***100***	***98.4-100%***
Acinetobacter calcoaceticus-baumannii complex	3/3	100	43.9-100%	16/16	100	80.6-100%
Enterobacterales	19/19	100	83.2-100%	209/209	100	98.2-100%
Enterobacter cloacae complex	0/0	-	-	8/8	100	67.6-100%
Escherichia coli	9/9	100	70.1-100%	35/35	100	90.1-100%
Klebsiella aerogenes	4/4	100	51.0-100%	38/38	100	90.8-100%
Klebsiella oxytoca	0/0	-	-	6/6	100	61.0-100%
Klebsiella pneumoniae group	6/6	100	61.0-100%	86/86	100	95.7-100%
Proteus spp.	0/0	-	-	9/9	100	70.1-100%
Salmonella spp.	0/0	-	-	37/37	100	90.6-100%
Pseudomonas aeruginosa	7/7	100	64.6-100%	17/17	100	81.6-100%

[a] No observations for IMP in the prospective evaluation; archived testing not performed; seeded testing not performed for IMP with *S. marcescens*.

Table 50. BIOFIRE BCID2 Panel Clinical Performance Summary, KPC

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
KPC	Prospective[a]	4/4	100	51.0-100%	328/328	100	98.8-100%
	Archived	14/14	100	78.5-100%	5/5	100	56.6-100%
	Seeded	45/45	100	92.1-100%	216/216	100	98.3-100%
	Overall	***63/63***	***100***	***94.3-100%***	***549/549***	***100***	***99.3-100%***

[a] Twenty-seven (27) specimens were FN for an associated host organism by the molecular comparator method, thus providing an "N/A" result for KPC.

Table 51. Distribution of KPC in Prospective Clinical Specimens

KPC		SOC: any associated organism FDA-cleared test: KPC			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	4	0	0	*4*
	Org+ / Res-	0	298	54[a]	*352*
	Org -	0	0	713	*713*
	Total	*4*	*298*	*767*	*1069*[b]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	4/4	100	51.0-100%
		Org+ / Res-	298/298	100	98.7-100%
		Org -	713/767[a]	93.0	90.9-94.6%

[a] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.
[b] Five specimens were FN for the associated host organism by the molecular comparator method, thus providing an "N/A" result for KPC.

Table 52. Stratification of KPC Clinical Performance by Associated Host Organism

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	4/4	100	51.0-100%	328/328	100	98.8-100%
	Archived	14/14	100	78.5-100%	5/5	100	56.6-100%
	Seeded	45/45	100	92.1-100%	216/216	100	98.3-100%
	Overall	***63/63***	***100***	***94.3-100%***	***549/549***	***100***	***99.3-100%***
Acinetobacter calcoaceticus-baumannii complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	***0/0***	***-***	***-***	***37/37***	***100***	***90.6-100%***
Enterobacterales	Prospective	4/4	100	51.0-100%	292/292	100	98.7-100%
	Archived	14/14	100	78.5-100%	0/0	-	-

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
	Seeded	42/42	100	91.6-100%	186/186	100	98.0-100%
	Overall	***60/60***	***100***	***94.0-100%***	***478/478***	***100***	***99.2-100%***
Enterobacter cloacae complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Archived	2/2	100	34.2-100%	0/0	-	-
	Seeded	2/2	100	34.2-100%	6/6	100	61.0-100%
	Overall	***4/4***	***100***	***51.0-100%***	***22/22***	***100***	***85.1-100%***
Escherichia coli	Prospective	0/0	-	-	159/159	100	97.6-100%
	Seeded	4/4	100	51.0-100%	40/40	100	91.2-100%
	Overall	***4/4***	***100***	***51.0-100%***	***199/199***	***100***	***98.1-100%***
Klebsiella aerogenes	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	***0/0***	***-***	***-***	***44/44***	***100***	***92.0-100%***
Klebsiella oxytoca	Prospective	0/0	-	-	8/8	100	67.6-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	3/3	100	43.9-100%	3/3	100	43.9-100%
	Overall	***4/4***	***100***	***51.0-100%***	***11/11***	***100***	***74.1-100%***
Klebsiella pneumoniae group	Prospective	4/4	100	51.0-100%	51/51	100	93.0-100%
	Archived	11/11	100	74.1-100%	0/0	-	-
	Seeded	30/30	100	88.6-100%	62/62	100	94.2-100%
	Overall	***45/45***	***100***	***92.1-100%***	***113/113***	***100***	***96.7-100%***
Proteus spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	***3/3***	***100***	***43.9-100%***	***21/21***	***100***	***84.5-100%***
Salmonella spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	***0/0***	***-***	***-***	***42/42***	***100***	***91.6-100%***
Serratia marcescens	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	***0/0***	***-***	***-***	***11/11***	***100***	***74.1-100%***
Pseudomonas aeruginosa	Prospective	0/0	-	-	31/31	100	89.0-100%
	Seeded	3/3	100	43.9-100%	21/21	100	84.5-100%
	Overall	***3/3***	***100***	***43.9-100%***	***52/52***	***100***	***93.1-100%***

[a] Archived testing not performed for KPC with *E. coli, K. aerogenes, Proteus* spp., *Salmonella* spp., *S. marcescens,* or *P. aeruginosa*; seeded testing not performed for KPC with *S. marcescens.*

Table 53. BIOFIRE BCID2 Panel Clinical Performance Summary, NDM

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
NDM	Prospective	1/1	100	-	358/358	100	98.9-100%
	Archived	5/5	100	56.6-100%	5/5	100	56.6-100%
	Seeded	30/30	100	88.6-100%	231/231	100	98.4-100%
	Overall	***36/36***	***100***	***90.4-100%***	***594/594***	***100***	***99.4-100%***

Table 54. Distribution of NDM in Prospective Clinical Specimens

NDM		SOC: any associated organism PCR/seq: NDM			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	1	0	0	*1*
	Org+ / Res-	0	304	54[a]	*358*
	Org -	0	2	713	*715*
	Total	*1*	*306*	*767*	*1074*

NDM	SOC: any associated organism PCR/seq: NDM			
	Org+ / Res+	Org+ / Res-	Org -	*Total*
	Performance	**Agreement**	**%**	**95%CI**
Org+ / Res+		1/1	100	-
Org+ / Res-		304/306	99.3	97.6-99.8%
Org -		713/767[a]	93.0	90.9-94.6%

[a] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 55. Stratification of NDM Clinical Performance by Associated Host Organism

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	1/1	100	-	358/358	100	98.9-100%
	Archived	5/5	100	56.6-100%	5/5	100	56.6-100%
	Seeded	30/30	100	88.6-100%	231/231	100	98.4-100%
	Overall	***36/36***	***100***	***90.4-100%***	***594/594***	***100***	***99.4-100%***
Acinetobacter calcoaceticus-baumannii complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	6/6	100	61.0-100%	13/13	100	77.2-100%
	Overall	***6/6***	***100***	***61.0-100%***	***31/31***	***100***	***89.0-100%***
Enterobacterales	Prospective	1/1	100	-	322/322	100	98.8-100%
	Archived	5/5	100	56.6-100%	0/0	-	-
	Seeded	24/24	100	86.2-100%	204/204	100	98.2-100%
	Overall	***30/30***	***100***	***88.6-100%***	***526/526***	***100***	***99.3-100%***
Enterobacter cloacae complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	***3/3***	***100***	***43.9-100%***	***21/21***	***100***	***84.5-100%***
Escherichia coli	Prospective	0/0	-	-	160/160	100	97.7-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	6/6	100	61.0-100%	38/38	100	90.8-100%
	Overall	***7/7***	***100***	***64.6-100%***	***198/198***	***100***	***98.1-100%***
Klebsiella aerogenes	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	***0/0***	***-***	***-***	***44/44***	***100***	***92.0-100%***
Klebsiella oxytoca	Prospective	0/0	-	-	8/8	100	67.6-100%
	Seeded	0/0	-	-	6/6	100	61.0-100%
	Overall	***0/0***	***-***	***-***	***14/14***	***100***	***78.5-100%***
Klebsiella pneumoniae group	Prospective	1/1	100	-	54/54	100	93.4-100%
	Archived	4/4	100	51.0-100%	0/0	-	-
	Seeded	9/9	100	70.1-100%	83/83	100	95.6-100%
	Overall	***14/14***	***100***	***75.8-100%***	***137/137***	***100***	***97.3-100%***
Proteus spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	***3/3***	***100***	***43.9-100%***	***21/21***	***100***	***84.5-100%***
Salmonella spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	3/3	100	43.9-100%	34/34	100	89.8-100%
	Overall	***3/3***	***100***	***43.9-100%***	***39/39***	***100***	***91.0-100%***
Serratia marcescens	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	***0/0***	***-***	***-***	***11/11***	***100***	***74.1-100%***
Pseudomonas aeruginosa	Prospective	1/1	100	-	30/30	100	88.6-100%
	Seeded	0/0	-	-	24/24	100	86.2-100%
	Overall	***1/1***	***100***	***-***	***54/54***	***100***	***93.4-100%***

[a] Archived testing not performed for NDM with *E. cloacae* complex, *K. aerogenes, K. oxytoca, Proteus* spp., *Salmonella* spp., *S. marcescens,* or *P. aeruginosa*; seeded testing not performed for NDM with *S. marcescens.*

Table 56. BIOFIRE BCID2 Panel Clinical Performance Summary, OXA-48-like

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
OXA-48-like	Prospective	0/0	-	-	323/323	100	98.8-100%
	Seeded	30/30	100	88.6-100%	198/198	100	98.1-100%
	Overall	***30/30***	***100***	***88.6-100%***	***521/521***	***100***	***99.3-100%***

[a] Archived testing not performed for OXA-48-like.

Table 57. Distribution of OXA-48-like in Prospective Clinical Specimens

OXA-48-like		SOC: any associated organism PCR/seq: OXA-48-like			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	0	0	0	*0*
	Org+ / Res-	0	269	54[a]	*323*
	Org -	0	1	750	*751*
	Total	*0*	*270*	*804*	*1074*
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/0	-	-
		Org+ / Res-	269/270	99.6	97.9-99.9%
		Org -	750/804[a]	93.3	91.3-94.8%

[a] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 58. Stratification of OXA-48-like Clinical Performance by Associated Host Organism, Seeded study[a]

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	***30/30***	***100***	***88.6-100%***	***198/198***	***100***	***98.1-100%***
Enterobacterales	30/30	100	88.6-100%	198/198	100	98.1-100%
Enterobacter cloacae complex	0/0	-	-	8/8	100	67.6-100%
Escherichia coli	0/0	-	-	44/44	100	92.0-100%
Klebsiella aerogenes	3/3	100	43.9-100%	39/39	100	91.0-100%
Klebsiella oxytoca	0/0	-	-	6/6	100	61.0-100%
Klebsiella pneumoniae group	27/27	100	87.5-100%	65/65	100	94.4-100%
Proteus spp.	0/0	-	-	9/9	100	70.1-100%
Salmonella spp.	0/0	-	-	37/37	100	90.6-100%

[a] No observations for OXA-48-like in prospective evaluation; archived testing not performed; seeded testing not performed for OXA-48-like with *S. marcescens*.

Table 59. BIOFIRE BCID2 Panel Clinical Performance Summary, VIM

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
VIM	Prospective	4/4	100	51.0-100%	355/355	100	98.9-100%
	Archived	1/1	100	-	5/5	100	56.6-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	***34/34***	***100***	***89.8-100%***	***592/592***	***100***	***99.4-100%***

Table 60. Distribution of VIM in Prospective Clinical Specimens

VIM		SOC: any associated organism PCR/seq: VIM			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
	Org+ / Res+	4[a]	0	0	*4*
	Org+ / Res-	0	301	54[b]	*355*

VIM		SOC: any associated organism PCR/seq: VIM			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org -	0	2	713	*715*
	Total	*4*	*303*	*767*	*1074*
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	4/4	100	51.0-100%
		Org+ / Res-	301/303	99.3	97.6-99.8%
		Org -	713/767[b]	93.0	90.9-94.6%

[a] One specimen had co-detection of *Klebsiella pneumoniae* group with *Pseudomonas aeruginosa.*
[b] Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 61. Stratification of VIM Clinical Performance by Associated Host Organism

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	4/4[b]	100	51.0-100%	355/355	100	98.9-100%
	Archived	1/1	100	-	5/5	100	56.6-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	***34/34***	***100***	***89.8-100%***	***592/592***	***100***	***99.4-100%***
Acinetobacter calcoaceticus-baumannii complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	***0/0***	***-***	***-***	***37/37***	***100***	***90.6-100%***
Enterobacterales	Prospective	2/2	100	34.2-100%	321/321	100	98.8-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	15/15	100	79.6-100%	213/213	100	98.2-100%
	Overall	***18/18***	***100***	***82.4-100%***	***534/534***	***100***	***99.3-100%***
Enterobacter cloacae complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	***3/3***	***100***	***43.9-100%***	***21/21***	***100***	***84.5-100%***
Escherichia coli	Prospective	0/0	-	-	160/160	100	97.7-100%
	Seeded	3/3	100	43.9-100%	41/41	100	91.4-100%
	Overall	***3/3***	***100***	***43.9-100%***	***201/201***	***100***	***98.1-100%***
Klebsiella aerogenes	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	***0/0***	***-***	***-***	***44/44***	***100***	***92.0-100%***
Klebsiella oxytoca	Prospective	0/0	-	-	8/8	100	67.6-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	0/0	-	-	6/6	100	61.0-100%
	Overall	***1/1***	***100***	***-***	***14/14***	***100***	***78.5-100%***
Klebsiella pneumoniae group	Prospective	2/2	100	34.2-100%	53/53	100	93.2-100%
	Seeded	9/9	100	70.1-100%	83/83	100	95.6-100%
	Overall	***11/11***	***100***	***74.1-100%***	***136/136***	***100***	***97.3-100%***
Proteus spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	0/0	-	-	9/9	100	70.1-100%
	Overall	***0/0***	***-***	***-***	***24/24***	***100***	***86.2-100%***
Salmonella spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	***0/0***	***-***	***-***	***42/42***	***100***	***91.6-100%***
Serratia marcescens	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	***0/0***	***-***	***-***	***11/11***	***100***	***74.1-100%***
Pseudomonas aeruginosa	Prospective	3/3	100	43.9-100%	28/28	100	87.9-100%
	Seeded	14/14	100	78.5-100%	10/10	100	72.2-100%
	Overall	***17/17***	***100***	***81.6-100%***	***38/38***	***100***	***90.8-100%***

[a] Archived testing not performed for VIM with *E. cloacae* complex, *E. coli, K. aerogenes, K. pneumoniae* group, *Proteus* spp., *Salmonella* spp., *S. marcescens,* or *P. aeruginosa*; seeded testing not performed for VIM with *S. marcescens.*
[b] One specimen had co-detection of *Klebsiella pneumoniae* group with *Pseudomonas aeruginosa.*

Table 62. BIOFIRE BCID2 Panel Clinical Performance Summary, *mecA/C*, Prospective study[a]

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
mecA/C	195/195	100	98.1-100%	60/60	100	94.0-100%

[a] Archived and seeded testing not performed for *mecA/C*.

Table 63. Distribution of *mecA/C* in Prospective Clinical Specimens

mecA/C		SOC: any associated organism FDA-cleared test: *mecA*			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	171[a]	0	24	*195*
	Org+ / Res-	0	54	6	*60*
	Org -	4	3	811	*818*
	Total	*175*	*57*	*841*	*1073*[b]
		Performance	Agreement	%	95%CI
		Org+ / Res+	171/175	97.7	94.3-99.1%
		Org+ / Res-	54/57	94.7	85.6-98.2%
		Org -	811/841	96.4	95.0-97.5%

[a] Two specimens had co-detections of *Staphylococcus epidermidis* with *Staphylococcus lugdunensis*.
[b] One specimen was FN for the associated host organism by the molecular comparator method, thus providing an "N/A" result for *mecA/C*.

Table 64. Stratification of *mecA/C* Clinical Performance by Associated Host Organism, Prospective study[a]

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	***195/195***[b]	***100***	***98.1-100%***	***60/60***	***100***	***94.0-100%***
Staphylococcus epidermidis	194/194	100	98.1-100%	56/56	100	93.6-100%
Staphylococcus lugdunensis	3/3[c]	100	43.9-100%	4/4	100	51.0-100%

[a] Archived and seeded testing not performed for *mecA/C*.
[b] Two specimens had co-detections *of Staphylococcus epidermidis* with *Staphylococcus lugdunensis*.
[c] All three specimens were identified as mixed cultures with *mecA* present in a different *Staphylococcus* species.

Table 65. BIOFIRE BCID2 Panel Clinical Performance Summary, *mecA/C* and MREJ (MRSA)

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
mecA/C and MREJ (MRSA)	Prospective	52/57	91.2	81.1-96.2%	92/94	97.9	92.6-99.4%
	Seeded	5/5	100	56.6-100%	5/5	100	56.6-100%
	Overall	***57/62***[b]	***91.9***	***82.5-96.5%***	***97/99***[c]	***98.0***	***92.9-99.4%***

[a] Archived testing not performed for *mecA/C* and MREJ (MRSA).
[b] Isolates recovered from the five FN specimens were identified as MSSA by SOC phenotypic AST methods.
[c] Isolates recovered from the two FP specimens were identified as MRSA by SOC phenotypic AST methods.

Table 66. Distribution of *mecA/C* and MREJ (MRSA) in Prospective Clinical Specimens

mecA/C and MREJ (MRSA)		SOC: any associated organism FDA-cleared test: MRSA			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BCID2 Panel Result	Org+ / Res+	50	2	2	*54*
	Org+ / Res-	5	92	0	*97*
	Org -	0	0	923	*923*
	Total	*55*	*94*	*925*	*1074*

mecA/C and MREJ (MRSA)	SOC: any associated organism FDA-cleared test: MRSA			
	Org+ / Res+	Org+ / Res-	Org -	*Total*
	Performance	**Agreement**	**%**	**95%CI**
	Org+ / Res+	50/55	90.9	80.4-96.1%
	Org+ / Res-	92/94	97.9	92.6-99.4%
	Org -	923/925	99.8	99.2-99.9%

The nature of the seven discrepant results for *mecA/C* and MREJ (MRSA) between the BIOFIRE BCID2 Panel and the reference method (Cepheid Xpert® MRSA/SA BC) was investigated using various methods. As shown in Table 67, all *S. aureus* isolates recovered from the five false negative (FN) specimens were negative for the *mecA/C* genes by PCR/sequencing and had a methicillin-sensitive antimicrobial susceptibility testing (AST) phenotype, indicating MSSA rather than MRSA. From three of these specimens, the laboratory also isolated a coagulase-negative *Staphylococcus* (CoNS) that was methicillin resistant (i.e. carrying the *mecA* or *mecC* gene). Three of the five FN specimens were reported as SA (negative for MRSA) by the Cepheid Xpert® MRSA/SA BC test when residual specimen was retested.

Similarly, *S. aureus* isolates from both false positive (FP) specimens were positive for the *mecA/C* genes by PCR/sequencing and had a methicillin-resistant AST phenotype. Additionally, one of the specimens had a result of MRSA when retested by the Cepheid Xpert® MRSA/SA BC test (Table 67).

In all cases, the BIOFIRE BCID2 Panel *mecA/C* and MREJ (MRSA) results (Detected or Not Detected) were concordant with the AST phenotype of the *S. aureus* isolated from the blood culture, including instances where methicillin-resistant CoNS were also present in the specimen.

Table 67. Investigation of Specimens with Discrepant *mecA/C* and MREJ (MRSA) Results

Discrepancy Type[a]	Laboratory Information	BIOFIRE BCID2 Panel	Cepheid Xpert® MRSA/SA BC	Investigation Summary		
	Additional Staphylococci Isolated	*mecA/C and* MREJ (MRSA) Results (associated with TP *S. aureus*)[b]	MRSA/SA Results[c]	Cepheid Xpert® MRSA/SA BC Retest[c]	*mecA/C* Isolate PCR/sequencing Result	SOC Isolate AST Result (methicillin resistance phenotype)[d]
FN	-	Not Detected	MRSA	SA	Negative	MSSA
FN	*S. haemolyticus* (methicillin resistant)	Not Detected	MRSA	SA	Negative	MSSA
FN	*S. epidermidis* (methicillin resistant)	Not Detected	MRSA	MRSA	Negative	MSSA
FN	-	Not Detected	MRSA	SA	Negative	MSSA
FN	*S. epidermidis* (methicillin resistant)	Not Detected	MRSA	MRSA	Negative	MSSA
FP	-	Detected	SA	MRSA	Positive	MRSA
FP	-	Detected	SA	SA	Positive	MRSA

[a] FN = false negative; FP = false positive
[b] TP = true positive
[c] MRSA = methicillin resistant *Staphylococcus aureus*; SA = *Staphylococcus aureus*
[d] SOC = standard of care; MSSA = methicillin sensitive *Staphylococcus aureus*; MRSA = methicillin resistant *Staphylococcus aureus*

Table 68. BIOFIRE BCID2 Panel Clinical Performance Summary, *mcr-1*

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
mcr-1	Prospective	0/0	-	-	240/240	100	98.4-100%
	Seeded	30/30	100	88.6-100%	189/189	100	98.0-100%
	Overall	***30/30***	***100***	***88.6-100%***	***429/429***	***100***	***99.1-100%***

[a] Archived testing not performed for *mcr-1*.

Table 69. Distribution of *mcr-1* in Prospective Clinical Specimens

Mcr-1		SOC: any associated organism PCR/seq: *mcr-1*			
		Org+ / Res+	**Org+ / Res-**	**Org -**	***Total***
BCID2 Panel Result	**Org+ / Res+**	0	0	0	*0*
	Org+ / Res-	0	238	2	*240*
	Org -	0	0	834	*834*
	Total	*0*	*238*	*836*	*1074*
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/0	-	-
		Org+ / Res-	238/238	100	98.4-100%
		Org -	834/836	99.8	99.1-99.9%

Table 70. Stratification of *mcr-1* Clinical Performance by Associated Host Organism, Seeded study[a]

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall (any associated organism identified)	***30/30***	***100***	***88.6-100%***	***189/189***	***100***	***98.0-100%***
Enterobacter cloacae complex	0/0	-	-	8/8	100	67.6-100%
Escherichia coli	22/22	100	85.1-100%	22/22	100	85.1-100%
Klebsiella aerogenes	0/0	-	-	42/42	100	91.6-100%
Klebsiella oxytoca	0/0	-	-	6/6	100	61.0-100%
Klebsiella pneumoniae group	4/4	100	51.0-100%	88/88	100	95.8-100%
Salmonella spp.	4/4	100	51.0-100%	33/33	100	89.6-100%

[a] No observations for *mcr-1* in prospective evaluation; no archived testing performed.

Table 71. BIOFIRE BCID2 Panel Clinical Performance Summary, *vanA/B*

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
vanA/B	Prospective	23/24	95.8	79.8-99.3%	38/38	100	90.8-100%
	Archived	16/16	100	80.6-100%	0/0	-	-
	Overall	***39/40[b]***	***97.5***	***87.1-99.6%***	***38/38***	***100***	***90.8-100%***

[a] Seeded testing not performed for *vanA/B*.
[b] *vanA/B* was detected in the single FN specimen upon BIOFIRE BCID2 Panel retest; the isolate recovered from this specimen was vancomycin resistant by SOC phenotypic AST methods.

Table 72. Distribution of *vanA/B* in Prospective Clinical Specimens

vanA/B		SOC: any associated organism FDA-cleared test: *vanA/B*			
		Org+ / Res+	**Org+ / Res-**	**Org -**	***Total***
BCID2 Panel Result	**Org+ / Res+**	22	0	1	*23*
	Org+ / Res-	1	35	3	*39*
	Org -	0	0	1010	*1010*
	Total	*23*	*35*	*1014*	*1072*[a]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	22/23	95.7	79.0-99.2%
		Org+ / Res-	35/35	100	90.1-100%
		Org -	1010/1014	99.6	99.0-99.8%

[a]Two specimens were FN for the associated host organism by the molecular comparator method, thus providing an "N/A" result for *vanA/B*.

Table 73. Stratification of *vanA/B* Clinical Performance by Associated Host Organism

Analyte	Study[a]	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	23/24	95.8	79.8-99.3%	38/38	100	90.8-100%
	Archived	16/16	100	80.6-100%	0/0	-	-
	Overall	***39/40***	***97.5***	***87.1-99.6%***	***38/38***	***100***	***90.8-100%***
Enterococcus faecalis	Prospective	1/1	100	-	31/31	100	89.0-100%
	Archived	2/2	100	34.2-100%	0/0	-	-
	Overall	***3/3***	***100***	***43.9-100%***	***31/31***	***100***	***89.0-100%***
Enterococcus faecium	Prospective	22/23	95.7	79.0-99.2%	7/7	100	64.6-100%
	Archived	14/14	100	78.5-100%	0/0	-	-
	Overall	***36/37***	***97.3***	***86.2-99.5%***	***7/7***	***100***	***64.6-100%***

[a] Seeded testing not performed for *vanA/B.*

For prospective specimens only, the correlation of the AMR gene results reported in the specimen by the BIOFIRE BCID2 Panel to the identification of the gene in the cultured isolates from that particular specimen was assessed using one polymerase chain reaction (PCR) assay followed by bidirectional sequencing, performed directly on the isolate. The results are shown only for isolates recovered from specimens with true positive results (i.e. concordant results between BIOFIRE BCID2 Panel and culture), and further stratified by each applicable host organism recovered from that specimen. There were no observations by either the BIOFIRE BCID2 Panel or the reference/comparator methods for IMP, OXA-48-like, and *mcr-1*; therefore, performance tables are not shown for these analytes. Performance for the remaining analytes is presented in Table 74 through Table 77.

Table 74. CTX-M and Select Carbapenem Resistance Genes Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BIOFIRE BCID2 Panel	N	CTX-M		KPC		NDM		VIM		*Overall* (any resistance gene)	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall *(any associated organism identified)*	**317**	**46/46 (100%)**	**267/271 (98.5%)**	**4/4 (100%)**	**313/313 (100%)**	**1/1 (100%)**	**315/316 (99.7%)**	**4/4 (100%)**	**312/313 (99.7%)**	**53/53 (100%) [93.2-100%]**	**261/264 (98.9%) [96.7-99.6%]**
Acinetobacter calcoaceticus-baumannii complex	12	0/0 (-)	11/12 (91.7%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	11/12 (91.7%)
Enterobacterales	276	46/46 (100%)	229/230 (99.6%)	4/4 (100%)	272/272 (100%)	1/1 (100%)	275/275 (100%)	1/1 (100%)	274/275 (99.6%)	50/50[a] (100%)	225/226 (99.6%)
Enterobacter cloacae complex	16	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)
Escherichia coli	158	30/30 (100%)	128/128 (100%)	0/0 (-)	158/158 (100%)	0/0 (-)	158/158 (100%)	0/0 (-)	158/158 (100%)	30/30 (100%)	128/128 (100%)
Klebsiella aerogenes	2	0/0 (-)	1/2 (50.0%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	1/2 (50.0%)
Klebsiella oxytoca	8	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)

Organism Identified by SOC and Detected by the BIOFIRE BCID2 Panel	N	CTX-M		KPC		NDM		VIM		*Overall* *(any resistance gene)*	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Klebsiella pneumoniae group	55	12/12 (100%)	43/43 (100%)	4/4 (100%)	51/51 (100%)	1/1 (100%)	54/54 (100%)	1/1 (100%)	53/54 (98.1%)	16/16[a] (100%)	39/39 (100%)
Proteus spp.	14	4/4 (100%)	10/10 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	4/4 (100%)	10/10 (100%)
Salmonella spp.	5	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)
Serratia marcescens	11	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)
Pseudomonas aeruginosa	29	0/0 (-)	27/29 (93.1%)	0/0 (-)	29/29 (100%)	0/0 (-)	28/29 (96.6%)	3/3 (100%)	26/26 (100%)	3/3 (100%)	25/26 (96.2%)

[a] Two *K. pneumoniae* group isolates had the presence of dual AMR genes as determined by PCR (one CTX-M and NDM; one CTX-M and VIM).

Table 75. *mecA/C* Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any associated organism identified)*	***162/165***	***98.2***	***94.8-99.4%***	***51/60***	***85.0***	***73.9-91.9%***
Staphylococcus epidermidis	162/165	98.2	94.8-99.4%	47/56	83.9	72.2-91.3%
Staphylococcus lugdunensis	0/0	-	-	4/4	100	51.0-100%

Table 76. *mecA/C* and MREJ (MRSA) Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Staphylococcus aureus	52/52	100	93.1-100%	97/97	100	96.2-100%

Table 77. *vanA/B* Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any associated organism identified)*	***22/23***	***95.7***	***79.0-99.2%***	***35/35***	***100***	***90.1-100%***
Enterococcus faecalis	1/1	100	-	30/30	100	88.6-100%
Enterococcus faecium	21/22	95.5	78.2-99.2%	5/5	100	56.6-100%

For prospective specimens, the BIOFIRE BCID2 Panel AMR gene reporting in the specimen was also compared to phenotypic antimicrobial susceptibility testing (AST) methods performed on organism isolates recovered from those specimens. The results presented in Table 78 through Table 83 are only for specimens with concordant (true positive) results and are further stratified by each applicable host organism recovered from that specimen. Note that antimicrobial resistance, particularly extended-spectrum β-lactamase (ESBL) activity and carbapenem resistance, may be due to mechanisms other than the presence of the AMR genes detected by the BIOFIRE BCID2 Panel. Conversely, the detection of these genes may not always confer an antimicrobial resistance phenotype. Additionally, discordant results between *mecA/C* detection in a blood culture specimen by the BIOFIRE BCID2 Panel and the observed methicillin (oxacillin/cefoxitin) resistance of cultured *Staphylococcus* isolates may be due to polymicrobial *Staphylococcus* cultures containing a mixture of resistant and sensitive organisms.

Table 78. CTX-M Performance Table (as compared to phenotypic AST methods for ESBL activity on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	ESBL	Non-ESBL	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any associated organism identified)*	***313*** ***46***	***267***	***43/46***	***93.5***	***82.5-97.8%***	***260/267***	***97.4***	***94.7-98.7%***
Acinetobacter calcoaceticus-baumannii complex	12 0	12	0/0	-	-	11/12	91.7	64.6-98.5%
Enterobacterales	273 46	227	43/46	93.5	82.5-97.8%	223/227	98.2	95.6-99.3%
Enterobacter cloacae complex	16 0	16	0/0	-	-	16/16	100	80.6-100%
Escherichia coli	157 30	127	30/30	100	88.6-100%	127/127	100	97.1-100%
Klebsiella aerogenes	2 0	2	0/0	-	-	1/2	50.0	-
Klebsiella oxytoca	8 1	7	0/1	0	-	7/7	100	64.6-100%
Klebsiella pneumoniae group	54 11	43	10/11	90.9	62.3-98.4%	41/43	95.3	84.5-98.7%

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	ESBL	Non-ESBL	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Proteus spp.	4	10 (14)	3/4	75.0	30.1-95.4%	9/10	90.0	59.6-98.2%
Salmonella spp.	0	5 (5)	0/0	-	-	5/5	100	56.6-100%
Serratia marcescens	0	11 (11)	0/0	-	-	11/11	100	74.1-100%
Pseudomonas aeruginosa	0	28 (28)	0/0	-	-	26/28	92.9	77.4-98.0%

Table 79. Carbapenem Resistance Genes Performance Table (as compared to phenotypic AST methods for carbapenem resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by BIOFIRE BCID2 Panel	N		IMP		KPC		NDM		OXA-48-like		VIM		*Overall* *(any resistance gene)*	
	R	S	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall *(any associated organism identified)*	**313**		**0/25 (0%)**	**288/288 (100%)**	**4/25 (16.0%)**	**288/288 (100%)**	**2/25 (8.0%)**	**288/288 (100%)**	**0/6 (0%)**	**267/267 (100%)**	**4/25 (16.0%)**	**287/288 (99.7%)**	**8/25 (32.0%) [17.2-51.6%]**	**287/288 (99.7%) [98.1-99.9%]**
	25	***288***												
Acinetobacter calcoaceticus-baumannii complex	12		0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)	N/A	N/A	0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)
	12	0												
Enterobacterales	273		0/6 (0%)	267/267 (100%)	4/6 (66.7%)	267/267 (100%)	1/6 (16.7%)	267/267 (100%)	0/6 (0%)	267/267 (100%)	1/6 (16.7%)	266/267 (99.6%)	5/6[a] (83.3%)	266/267 (99.6%)
	6	267												
Enterobacter cloacae complex	16		0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)
	0	16												
Escherichia coli	157		0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)
	0	157												
Klebsiella aerogenes	2		0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)
	0	2												
Klebsiella oxytoca	8		0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)
	0	8												
Klebsiella pneumoniae group	54		0/6 (0%)	48/48 (100%)	4/6 (66.7%)	48/48 (100%)	1/6 (16.7%)	48/48 (100%)	0/6 (0%)	48/48 (100%)	1/6 (16.7%)	47/48 (97.9%)	5/6[a] (83.3%)	47/48 (97.9%)
	6	48												
Proteus spp.	14		0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)
	0	14												
Salmonella spp.	5		0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)
	0	5												
Serratia marcescens	11		0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)
	0	11												
Pseudomonas aeruginosa	28		0/7 (0%)	21/21 (100%)	0/7 (0%)	21/21 (100%)	1/7 (14.3%)	21/21 (100%)	N/A	N/A	3/7 (42.9%)	21/21 (100%)	3/7[b] (42.9%)	21/21 (100%)
	7	21												

[a] One *K. pneumoniae* group isolate had the presence of dual AMR genes as determined by the BCID2 Panel (NDM and VIM).
[b] One *P. aeruginosa* isolate had the presence of dual AMR genes as determined by the BCID2 Panel (NDM and VIM).

Table 80. *mecA/C* Performance Table (as compared to phenotypic AST methods for methicillin (oxacillin/cefoxitin) resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any associated organism identified)*	***225*** ***164***	***61***	***160/164***	***97.6***	***93.9-99.0%***	***50/61***	***82.0***	***70.5-89.6%***
Staphylococcus epidermidis	221 163	58	160/163	98.2	94.7-99.4%	47/58	81.0	69.1-89.1%
Staphylococcus lugdunensis	4 1	3	0/1	0	-	3/3	100	43.9-100%

Table 81. *mecA/C* and MREJ (MRSA) Performance Table (as compared to phenotypic AST methods for methicillin (oxacillin/cefoxitin) resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Staphylococcus aureus	149 52	97	52/52	100	93.1-100%	97/97	100	96.2-100%

Table 82. *mcr-1* Performance Table (as compared to phenotypic AST methods for colistin on cultured isolate(s) from prospective PBC specimens)[a]

Organism Identified by SOC and Detected by BIOFIRE BCID2 Panel	MIC[b] (µg/mL)	N
Overall *(any associated organism identified)*	***0.25***	***242***
	0.5	***241***
	1	***112***
	2	***21***
	4	***8***
	>4	***6***
Enterobacter cloacae complex	0.25	16
	0.5	15
	1	12
	2	5
	4	2
	>4	2
Escherichia coli	0.25	157
	0.5	157
	1	60
	2	7
	4	3
	>4	2
Klebsiella aerogenes	0.25	2
	0.5	2
	1	1
	2	1
	4	0
	>4	0
Klebsiella oxytoca	0.25	8
	0.5	8
	1	5
	2	1
	4	1
	>4	1
Klebsiella pneumoniae group	0.25	54
	0.5	54
	1	29
	2	6
	4	1
	>4	1
Salmonella spp.	0.25	5
	0.5	5
	1	5
	2	1

Organism Identified by SOC and Detected by BIOFIRE BCID2 Panel	MIC[b] (µg/mL)	N
	4	1
	>4	0

[a] No *mcr-1* specimens were identified by the BIOFIRE BCID2 Panel in the prospective clinical evaluation.

[b] Minimum inhibitory concentration (MIC) values were determined using microbroth dilution. As of February 2020, the United States Food and Drug Administration has not established or recognized MIC breakpoints for colistin antimicrobial susceptibility testing (AST) related to *mcr-1*.

Table 83. *vanA/B* Performance Table (as compared to phenotypic AST methods for vancomycin resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any associated organism identified)*	***58***		***21/22***	***95.5***	***78.2-99.2%***	***35/36***	***97.2***	***85.8-99.5%***
	22	***36***						
Enterococcus faecalis	31		1/1	100	-	30/30	100	88.6-100%
	1	30						
Enterococcus faecium	27		20/21	95.2	77.3-99.2%	5/6	83.3	43.6-97.0%
	21	6						

The overall success rate for initial specimen tests in all three clinical studies was 99.4% (2042/2055). Eight tests (8/2055; 0.4%) did not complete on the initial test attempt, resulting in an instrument success rate of 99.6% (2047/2055) for initial specimen tests. Seven of the eight specimens were able to be retested and valid results were produced after a single retest. Of the 2047 tests that successfully produced a completed run on the initial test, 2042 had valid pouch controls. This represents a 99.8% (2042/2047) success rate for pouch controls in completed runs in the initial specimen tests. The five specimens with invalid control(s) were able to be retested and valid results were produced on the first retest.

Evaluation of Blood Culture Bottle Types

The BIOFIRE BCID2 Panel was tested for compatibility with thirteen different blood culture bottles types. Over 35 different bacterial or yeast isolates were each mixed with human whole blood (acid citrate dextrose anticoagulant), seeded directly into a blood culture bottle (≤300 CFU/bottle), and incubated for growth in a continuous monitoring blood culture system (or standard incubator for the VersaTREK bottles) until indicated as positive for growth. For each positive bottle (note that some isolates did not grow to positivity in every bottle type), the sample was tested with the BIOFIRE BCID2 Panel and was plate enumerated to determine the concentration of organism in the bottle. Samples were collected, tested, and enumerated within one hour of positive bottle indication and 24 hours after positive bottle indication (+24h).

The correct organism (and AMR gene) detection was reported by the BIOFIRE BCID2 Panel for every positive bottle tested at the positive bottle indication and 24 hours after positivity (815/815 = 100%; Table 84) for all bottle types evaluated.

Table 84. Compatibility of the BIOFIRE BCID2 Panel with Different Blood Culture Bottle Types

Manufacturer System	Bottle Type		Time Point	Seeded Organism		
				Gram-positive Bacteria	Gram-negative Bacteria	Yeast
bioMérieux BACT/ALERT® VIRTUO®	**Aerobic**	**BACT/ALERT® SA**	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
		BACT/ALERT® FA Plus	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
	Anaerobic	**BACT/ALERT® SN**	Bottle Positive	11/11	19/19	7/7
			Positive +24h	11/11	19/19	7/7
		BACT/ALERT® FN Plus	Bottle Positive	10/10	15/15	2/2
			Positive +24h	10/10	15/15	3/3
	Pediatric	**BACT/ALERT® PF Plus**	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
Becton	**Aerobic**	**BACTEC™ Standard**	Bottle Positive	11/11	18/18	7/7

Manufacturer System	Bottle Type		Time Point	Seeded Organism		
				Gram-positive Bacteria	Gram-negative Bacteria	Yeast
Dickinson BACTEC™ FX40			Positive +24h	11/11	18/18	7/7
		BACTEC™ Plus+	Bottle Positive	10/10	18/18	8/8
			Positive +24h	10/10	18/18	8/8
	Anaerobic	BACTEC™ Standard	Bottle Positive	9/9	13/13	1/1
			Positive +24h	9/9	13/13	1/1
		BACTEC™ Plus+	Bottle Positive	10/10	13/13	1/1
			Positive +24h	10/10	13/13	1/1
	Pediatric	BACTEC™ Peds Plus+	Bottle Positive	10/10	18/18	8/8
			Positive +24h	11/11	18/18	8/8
	Lytic	BACTEC™ Lytic	Bottle Positive	10/10	12/12	1/1
			Positive +24h	10/10	12/12	1/1
Thermo[a] Scientific VersaTREK™	Aerobic	VersaTREK™ REDOX 1™	Bottle Positive	9/9	18/18	4/4
			Positive +24h	9/9	18/18	4/4
	Anaerobic	VersaTREK™ REDOX 2™	Bottle Positive	9/9	13/13	0/0
			Positive +24h	9/9	13/13	1/1
# Correct Detected Results/Total Positive Bottles				**265/265 100%**	**422/422 100%**	**128/128 100%**
				815/815 100%		

[a] A VersaTREK system was not available for the evaluation. Seeded VersaTREK bottles were placed in a standard incubator (37°C, with or without agitation) for the average time to positivity required for the same isolate in the other bottles/systems.

The concentrations of each organism enumerated from bottles at the time of positivity and 24 hours after positivity are shown in Table 85; representing the approximate range of concentrations expected in a clinical setting for a mono-microbial blood culture.

Table 85. Concentration of Organism in a Blood Culture at Positivity and 24 Hours After Positivity (+24h)

BIOFIRE BCID2 Panel Analyte	Organism [AMR Gene]	Isolate ID	Concentration [a]	
			Positive Bottle (CFU/mL)	+24h (CFU/mL)
Gram Positive Bacteria				
Enterococcus faecalis	*Enterococcus faecalis [vanA/B]*	ATCC 51299	3.88E+08	1.16E+09
Enterococcus faecium	*Enterococcus faecium [vanA/B]*	ATCC 700221	1.37E+08	7.48E+08
Listeria monocytogenes	*Listeria monocytogenes*	ATCC 15313	9.28E+07	3.36E+08
***Staphylococcus* spp.**	*Staphylococcus hominis*	ATCC 25615	3.02E+06	6.52E+07
Staphylococcus aureus	*Staphylococcus aureus* [*mecA/C and* MREJ]	ATCC BAA-38	2.88E+07	3.76E+08
Staphylococcus epidermidis	*Staphylococcus epidermidis*	ATCC 12228	1.34E+07	6.19E+08
Staphylococcus lugdunensis	*Staphylococcus lugdunensis*	ATCC 43809	7.05E+07	7.90E+08
***Streptococcus* spp.**	*Streptococcus mitis*	ATCC 49456	2.29E+07	1.36E+08
Streptococcus agalactiae	*Streptococcus agalactiae*	ATCC 13813	3.82E+08	5.33E+08
Streptococcus pneumoniae	*Streptococcus pneumoniae*	ATCC 6303	6.86E+07	4.53E+07
Streptococcus pyogenes	*Streptococcus pyogenes*	ATCC 49399	2.04E+08	1.83E+08
Gram Negative Bacteria				
***Acinetobacter calcoaceticus-baumannii* complex**	*Acinetobacter baumannii* [NDM]	CDC FDA AR Bank #0033	2.27E+08	4.22E+08
	Acinetobacter calcoaceticus	ATCC 23055	1.23E+07	5.46E+07
Bacteroides fragilis	*Bacteroides fragilis*	ATCC 25285	1.98E+08	3.00E+09
Enterobacterales	*Citrobacter freundii*	ATCC 8090	1.57E+08	1.07E+09
	Morganella morganii [CTX-M, NDM]	CDC FDA AR Bank #0057	6.73E+08	1.66E+09
	Raoultella ornithinolytica	ATCC 31898	1.83E+08	1.18E+09
***Enterobacter cloacae* complex**	*Enterobacter cloacae* [VIM]	CDC FDA AR Bank #0154	1.20E+08	9.89E+08
Escherichia coli	*Escherichia coli* [*mcr-1*]	CDC FDA AR Bank #0350	1.02E+08	1.25E+09
Haemophilus influenzae	*Haemophilus influenzae*	ATCC 10211	3.54E+08	2.60E+08
Klebsiella aerogenes	*Klebsiella aerogenes* [OXA-48-like]	CDC FDA AR Bank #0074	3.14E+08	1.63E+09
Klebsiella oxytoca	*Klebsiella oxytoca*	ATCC 13182	2.68E+08	1.33E+09
***Klebsiella pneumoniae* group**	*Klebsiella pneumoniae*	CDC FDA AR Bank #0097	1.45E+08	4.31E+08
Neisseria meningitidis	*Neisseria meningitidis*	ATCC 13090	2.07E+08	9.30E+07

BIOFIRE BCID2 Panel Analyte	Organism [AMR Gene]	Isolate ID	Concentration [a]	
			Positive Bottle (CFU/mL)	+24h (CFU/mL)
***Proteus* spp.**	*Proteus mirabilis* [CTX-M]	GRE 1254053	1.26E+08	9.17E+08
Pseudomonas aeruginosa	*Pseudomonas aeruginosa* [IMP]	CDC FDA AR Bank #0092	9.75E+07	5.87E+08
	Pseudomonas aeruginosa	ATCC 10145	3.16E+08	9.00E+08
***Salmonella* spp.**	*Salmonella enterica* [CTX-M]	CDC FDA AR Bank #0407	2.14E+08	1.33E+09
Serratia marcescens	*Serratia marcescens* [KPC]	JMI 697	9.09E+07	1.02E+09
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	ATCC 700475	2.80E+08	1.11E+09
Yeast				
Candida albicans	*Candida albicans*	ATCC 90028	4.28E+05	6.79E+06
Candida auris	*Candida auris*	CDC FDA AR Bank #0381	2.81E+06	2.49E+07
Candida glabrata	*Candida glabrata*	ATCC 15545	1.15E+06	3.68E+07
Candida krusei	*Candida krusei*	ATCC 6258	9.99E+05	1.57E+07
Candida parapsilosis	*Candida parapsilosis*	ATCC 34136	5.96E+05	1.39E+07
Candida tropicalis	*Candida tropicalis*	ATCC 201380	3.77E+05	1.19E+07
Cryptococcus neoformans/gattii	*Cryptococcus gattii*	ATCC MYA-4877	4.72E+05	2.83E+06
	Cryptococcus neoformans	ATCC MYA-4564	1.54E+06	9.24E+06

[a] Mean concentration calculated from bottles cultured in the bioMérieux BACT/ALERT VIRTUO and Becton Dickinson BACTEC FX40 systems (VersaTREK bottle data excluded).

Limit of Detection

A limit of detection (LoD) was established for the bacteria and yeast detected by the BIOFIRE BCID2 Panel. Contrived samples of representative isolates were prepared at a known concentration in a simulated blood culture matrix consisting of human whole blood incubated with blood culture media. LoD was estimated by serial dilution and confirmed by testing at least twenty replicates on the BIOFIRE 2.0 and BIOFIRE Torch systems. Confirmation of LoD required detection in at least 95% of replicates tested and the confirmed LoD concentrations are listed in Table 86. Testing also confirmed that each AMR gene can be detected at the LoD concentration of the applicable bacteria with which it may be reported. LoD concentrations are approximately 30 - 200,000-fold lower than the concentrations measured in positive blood cultures.

Table 86. Limit of Detection (LoD) for Analytes Detected by the BIOFIRE BCID2 Panel

BIOFIRE BCID2 Panel Analyte	Organism [AMR Gene] Tested	Isolate ID	LoD Concentration (CFU/mL)
Gram Positive Bacteria			
Enterococcus faecalis	*Enterococcus faecalis* [*vanB*]	ATCC 51299	1.0E+05
Enterococcus faecium	*Enterococcus faecium* [*vanA*]	ATCC 7002211	1.0E+05
Listeria monocytogenes	*Listeria monocytogenes*	ATCC 15313	1.0E+04
***Staphylococcus* spp.**	*Staphylococcus hominis*	ATCC 25615	1.0E+05
Staphylococcus aureus	*Staphylococcus aureus* [*mecA*]	ATCC BAA-38	1.0E+04[aa]
	Staphylococcus aureus [*mecC*]	ATCC BAA-2313	
Staphylococcus epidermidis	*Staphylococcus epidermidis* [*mecA*]	ATCC 35984	1.0E+05
Staphylococcus lugdunensis	*Staphylococcus lugdunensis*	ATCC 43809	1.0E+04
***Streptococcus* spp.**	*Streptococcus mitis*	ATCC 49456	1.0E+04
Streptococcus agalactiae	*Streptococcus agalactiae*	ATCC 13813	5.0E+04
Streptococcus pneumoniae	*Streptococcus pneumoniae*	ATCC 6303	5.0E+03
Streptococcus pyogenes	*Streptococcus pyogenes*	ATCC 49399	5.0E+03
Gram Negative Bacteria			
***Acinetobacter calcloaceticus-baumannii* complex**	*Acinetobacter baumannii* [NDM]	CDC-FDA AR Bank #0033	5.0E+03
Bacteroides fragilis	*Bacteroides fragilis*	ATCC 25285	1.0E+04
Enterobacterales	*Citrobacter freundii*	ATCC 8090	1.0E+05
	Morganella morganii	ATCC 25830	
	Serratia plymuthica	ATCC 183	
***Enterobacter cloacae* complex**	*Enterobacter cloacae* [VIM]	CDC-FDA AR Bank #0154	1.0E+05
Escherichia coli	*Escherichia coli* [*mcr-1*]	CDC-FDA AR Bank #0350	5.0E+05
Haemophilus influenzae	*Haemophilus influenzae*	ATCC 10211	1.0E+04
Klebsiella aerogenes	*Klebsiella aerogenes* [OXA-48-like]	CDC-FDA AR Bank #0074	1.0E+05

BIOFIRE BCID2 Panel Analyte	Organism [AMR Gene] Tested	Isolate ID	LoD Concentration (CFU/mL)
Klebsiella oxytoca	*Klebsiella oxytoca* [CTX-M]	GRE 1254054	1.0E+05
***Klebsiella pneumoniae* group**	*Klebsiella pneumoniae*	ATCC 13883	5.0E+04
Neisseria meningitidis	*Neisseria meningitidis*	ATCC 13090	1.0E+03
***Proteus* spp.**	*Proteus mirabilis*	ATCC 29906	5.0E+05
Pseudomonas aeruginosa	*Pseudomonas aeruginosa* [IMP]	CDC-FDA AR Bank #0092	1.0E+04
***Salmonella* spp.**	*Salmonella enterica*	ATCC 700720	5.0E+04
Serratia marcescens	*Serratia marcescens* [KPC]	JMI 697	1.0E+05
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	ATCC 700475	1.0E+06
Yeast			
Candida albicans	*Candida albicans*	ATCC 90028	1.0E+03
Candida auris	*Candida auris*	CDC-FDA AR Bank #0381	1.0E+03
Candida glabrata	*Candida glabrata*	ATCC 15545	1.0E+02
Candida krusei	*Candida krusei*	ATCC 28870	5.0E+03
Candida parapsilosis	*Candida parapsilosis*	ATCC 34136	1.0E+04
Candida tropicalis	*Candida tropicalis*	ATCC 201380	1.0E+04
Cryptococcus neoformans/gattii	*Cryptococcus gattii*	ATCC MYA-4877	5.0E+02
	Cryptococcus neoformans	ATCC MYA-4564	

[a] Confirmed LoD concentration for *Staphylococcus aureus* is the higher of the two LoD concentrations observed.

Analytical Reactivity (Inclusivity)

The analytical reactivity of BIOFIRE BCID2 Panel assays was assessed via a combination of *in silico* analysis of sequences available in public databases and testing of over 450 isolates representing the genetic, geographic, and temporal diversity of species, subspecies, and AMR gene types detected by the panel. Isolates were tested in triplicate at concentrations near LoD in simulated blood culture matrix.

Results for each isolate tested as well as *in silico* reactivity predictions for species or AMR gene types that were not tested are shown in Table 87 – Table 98. For isolates that were not detected at the initial near-LoD concentration, additional testing was performed at higher concentrations and the approximate concentration where detection was observed is indicated. In most cases, the detected concentration was equal to or less than the concentration expected in a positive blood culture. Alternately, a Not Detected result is indicated if the isolate was not detected at a concentration equivalent to a positive blood culture level. Additional limitations on reactivity predicted by *in silico* sequence analysis are noted.

Table 87. Results for *Enterococcus faecalis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Enterococcus faecalis	ATCC 19433	Type Strain	***Enterococcus faecalis*** **Detected**
	ATCC 29212	Portland	
	ATCC 49533	UWH/1936	
	ATCC 51299	NJ-3	
	ATCC 700802	V583	
	ATCC BAA-2573	bMx 0502240	
	JMI 12536	MA/2002	

Table 88. Results for *Enterococcus faecium* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Enterococcus faecium	ATCC 19434	Type Strain	***Enterococcus faecium*** **Detected**
	ATCC 27270	X3 [F]	
	ATCC 51858	Vancomycin-dependent #4	
	ATCC 700221	-	
	ATCC BAA-2318	-	
	JMI 475	IN/2003	

Table 89. Results for *Listeria monocytogenes* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Listeria monocytogenes	1/2a	ATCC 15313	Type Strain United Kingdom/1924	***Listeria monocytogenes***

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
		ATCC 19111	Li 20 United Kingdom	**Detected**
	1/2b	ATCC BAA-751	NSB 22072	
	4b	ATCC 13932	1071/53 Germany	
		ATCC 43256	CDC F2380	
	7	NCTC 10890	Li 2482 Germany	

[a] Assay reactivity is not serotype dependent, the assay will react with all serotypes (1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4b, 4c, 4d, 4e, and 7).

Note: The BIOFIRE BCID2 Panel may be able to detect strains of live, attenuated Listeria monocytogenes vaccines used in cancer immunotherapy.

Table 90. Results for *Staphylococcus* spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism		Source ID	Strain/Location/Year	Result
Staphylococcus argensis		*In silico* prediction (not tested)		***Staphylococcus* spp.** **Detected**
Staphylococcus arlettae		ATCC 43957	Type strain	
Staphylococcus auricularis		ATCC 33753	Type strain	
Staphylococcus capitis	**ssp. *capitis***	ATCC 27842	-	
	ssp. *urealyticus*	ATCC 49326	Type strain	
Staphylococcus caprae		ATCC 55133	-	
Staphylococcus carnosus	**ssp. *carnosus***	ATCC 51365	Type strain 1983	
Staphylococcus cohnii	**ssp. *cohnii***	ATCC 29972	-	
	ssp. *urealyticus*	ATCC 49330	Type strain	
Staphylococcus condimenti		CCUG 39902T	Type strain Japan	
Staphylococcus cornubiensis		*In silico* prediction (not tested)		
Staphylococcus delphini		ATCC 49171	Type strain Italy	
Staphylococcus devriesei		CCUG 58238T	Type Strain Belgium	
Staphylococcus edaphicus		*In silico* prediction (not tested)		
Staphylococcus epidermidis		ATCC 35984	Tennessee	
Staphylococcus felis		*In silico* prediction (not tested)		
Staphylococcus gallinarum		ATCC 700401	France	
Staphylococcus haemolyticus		ATCC 29968	-	
Staphylococcus hominis	***ssp. hominis***	ATCC 25615	-	
	ssp. *novobiosepticus*	ATCC 700236	Type strain New Jersey1992	
Staphylococcus hyicus		ATCC 11249	Type strain	
Staphylococcus intermedius		ATCC 29663	Type strain	
Staphylococcus kloosii		ATCC 43959	Type strain USA	
Staphylococcus lugdunensis		ATCC 43809	Type strain France	
Staphylococcus lutrae		ATCC 700373	Type strain	
Staphylococcus massiliensis		CCUG 55927T	Type strain France 2005	
Staphylococcus microti		*In silico* prediction (not tested)		
Staphylococcus nepalensis		CCUG 66326	Sweden 2014	
Staphylococcus pasteuri		ATCC 51127	France	
Staphylococcus petrasii	**ssp. *jettensis***	CCUG 62657T	Type strain Belgium	
Staphylococcus pettenkoferi		CCUG 70234	Sweden 2017	
Staphylococcus piscifermentans		*In silico* prediction (not tested)		
Staphylococcus pseudintermedius		ATCC 49444	-	
Staphylococcus pseudolugdunensis		*In silico* prediction (not tested)		
Staphylococcus saccharolyticus		ATCC 14953	Type strain	
Staphylococcus saprophyticus	**ssp. *saprophyticus***	ATCC 15305	Type strain	

Organism		Source ID	Strain/Location/Year	Result
			1935	
Staphylococcus schleiferi	**ssp. *coagulans***	ATCC 49545	Type strain	
	ssp. *schleiferi*	ATCC 43808	Type strain France	
Staphylococcus sciuri	**ssp. *sciuri***	ATCC 29061	-	
Staphylococcus simiae		GRE 1562010	Type strain Czech Republic	
Staphylococcus simulans		ATCC 27848	Type strain	
Staphylococcus stepanovicii		*In silico* prediction (not tested)		
Staphylococcus warneri		ATCC 25614	-	
Staphylococcus xylosus		ATCC 29966	-	
Staphylococcus agnetis		*In silico* prediction (not tested)		***Staphylococcus* spp. Detected** (≥5.9E+06 CFU/mL)
Staphylococcus argenteus[a]		DSM 28299	Type strain Australia/2006	
Staphylococcus aureus[a]		Multiple isolates	-	
Staphylococcus chromogenes		ATCC 43764	Type strain	
Staphylococcus sciuri	**ssp. *rodentium***	*In silico* prediction (not tested)		
Staphylococcus succinus	**ssp. *succinus***	ATCC 700337	Type strain Dominican Republic	
Staphylococcus schweitzeri[a]		DSM 28300	Type strain Gabon/2010	
Staphylococcus vitulinus		ATCC 51145	Type strain	
Staphylococcus equorum		ATCC 43958	Type strain Belgium	**Not Detected**
Staphylococcus fleurettii		DSM 20047	-	
Staphylococcus lentus		ATCC 29070	Type strain France	
Staphylococcus muscae		*In silico* prediction (not tested)		
Staphylococcus rostri				

[a] Also amplified by the Saureus assay at lower concentrations. Will be reported as *Staphylococcus* spp. Detected and *Staphylococcus aureus* Detected.

Table 91. Results for *Staphylococcus aureus* Isolates Tested

Organism		Source ID [a]	Strain/Location/Year	PFGE Type/ PVL (if known)	Result
Staphylococcus aureus	**ssp. *anaerobius***	ATCC 35844	MVF-7/Spain	unknown	***Staphylococcus aureus* Detected**
	ssp. *aureus*	ATCC 10832	Wood 46	unknown	
		ATCC 12600	Type strain 1935	unknown	
		ATCC 14154	Rose	unknown	
		ATCC 25923	Seattle/1945	unknown	
		ATCC 43300	F182/Kansas	unknown	
Staphylococcus aureus		NARSA NRS705	NY-12	USA 100	
		ATCC BAA-41	New York/1994	USA 100/PVL-	
		NARSA NRS701	MN-082	USA 200	
		ATCC BAA-1720	MRSA252 United Kingdom	USA 200	
		ATCC BAA-1717	TCH1516/Texas	USA 300	
		NARSA NRS683	GA-298 Georgia/2005	USA 300/PVL+	
		NARSA NRS662	CO-34	USA 300/PVL+	
		NARSA NRS707	NY-155 New York/2005	USA 300/PVL+	
		ATCC BAA-1707	MW2 North Dakota/1998	USA 400	
		NARSA NRS691	GA-62	USA 500	
		NARSA NRS385	-	USA 500	
		NARSA NRS648	CA-347	USA 600	
		NARSA NRS689	GA-442	USA 700	
		NARSA NRS668	CO-72	USA 800	

Organism	Source ID [a]	Strain/Location/Year	PFGE Type/ PVL (if known)	Result
		Colorado/2005		
	ATCC BAA-42	HDE288 Portugal/1996	USA 800	
	ATCC BAA-1749	96:308	USA 900	
	ATCC BAA-1759	N7129	USA 900	
	NARSA NRS745	CA-629	USA 1000	
	BEI NR-46081	HIP 12899	USA 1100/PVL+	
	ATCC BAA-1765	102-04	USA 1200	
	ATCC BAA-1700	HFH-33798 Illinois/2004	Not USA 100-1100	
	ATCC BAA-1691	HFH-30137 Michigan/2003	Not USA 100-1100	
	ATCC 29213	Wichita	unknown	
	ATCC BAA-38	E2125/Denmark	unknown	
	ATCC BAA-39	HUSA304 Hungary/1993	unknown	
	ATCC BAA-40	CPS22 Portugal/1994	unknown	
	ATCC BAA-44	HPV107 Portugal/1996	PVL-	
	ATCC BAA-2312	M10/0061 Ireland/2010	unknown	
	ATCC BAA-2313	M10/0148 Ireland/2010	unknown	
	ATCC BAA-2421	Massachusetts/2010	unknown	
	ATCC BAA-2422	Massachusetts/2010	unknown	
	GRE 0759084	-	unknown	
	GRE 1055015	-	unknown	
	GRE 0860042	-	unknown	
	GRE 1052034	-	unknown	
	GRE 1151100	-	unknown	
	GRE 0960006	-	unknown	
	GRE 1055017	-	unknown	
	GRE 0759163	-	unknown	
	GRE 1062373	-	unknown	
	GRE 1057114	-	unknown	
	GRE 1062292	-	unknown	
	NARSA NRS686	-	unknown	
	Rennes 1060728	-	unknown	
	Sunnybrook SUN1	Toronto	unknown	
	GRE 1062264[b]	-	unknown	***Staphylococcus aureus*** **Detected**[b] (≥6.3E+05 CFU/mL)

[a] NARSA and BEI isolates sourced by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH.

[b] Isolate from private collection with variant sequence under assay primer(s). Similar variant sequences represent ~1% of over 10,000 *S. aureus* sequences evaluated.

Table 92. Results for *Staphylococcus epidermidis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Staphylococcus epidermidis	ATCC 35984	RP62A Tennesee	***Staphylococcus epidermidis*** **Detected**
	ATCC 12228	FDA strain/PCl 1200	
	ATCC 29887	255-01B	
	ATCC 35983	RP12 Tennesee	
	ATCC 51625	CCF 15990 Ohio	

Organism	Source ID	Strain/Location/Year	Result
	ATCC 700562	1191 Virginia/1997	

Table 93. Results for *Staphylococcus lugdunensis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Staphylococcus lugdunensis	ATCC 43809	Type strain France	***Staphylococcus lugdunensis*** **Detected**
	NCTC 7990	Kelly United Kingdom/1949	
	ATCC 49576	LRA/260.05.79	
	ATCC 700328	6733	
	ATCC 700582	7829 Virginia/1997	

Table 94. Results for *Streptococcus* spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism		Source ID	Strain/Location/Year	Result
Streptococcus acidominimus		*In silico* prediction (not tested)		***Streptococcus*** **spp.** **Detected**
Streptococcus agalactiae		ATCC 13813	Type Strain	
Streptococcus anginosus		ATCC 33397	Havil	
Streptococcus australis		ATCC 700641	Type strain Australia/1987	
Streptococcus azizii		*In silico* prediction (not tested)		
Streptococcus bovimastitidis		*In silico* prediction (not tested)		
Streptococcus bovis		ATCC 33317	Pearl 11	
Streptococcus caballi		*In silico* prediction (not tested)		
Streptococcus canis		ATCC 43496	Type strain Belgium/1982	
Streptococcus castoreus		*In silico* prediction (not tested)		
Streptococcus constellatus		ATCC 27513	VPI 7712	
Streptococcus criceti		*In silico* prediction (not tested)		
Streptococcus cristatus		ATCC 51100	Type strain United Kingdom	
Streptococcus cuniculi		*In silico* prediction (not tested)		
Streptococcus devriesei		*In silico* prediction (not tested)		
Streptococcus didelphis		*In silico* prediction (not tested)		
Streptococcus downei		*In silico* prediction (not tested)		
Streptococcus dysgalactiae	**ssp. *dysgalactiae***	ATCC 43078	Type strain United Kingdom/1970	
	ssp. *equisimilis*	ATCC 12388	Type strain United Kingdom/1970	
	ssp. *equisimilis*	NCTC 8543	LRA 06 11 76	
Streptococcus equinus		ATCC 9812	Type strain	
Streptococcus ferus		*In silico* prediction (not tested)		
Streptococcus gallolyticus	***ssp. gallolyticus***	ATCC BAA-2069	2001	
	ssp. pasteurianus	ATCC 700338	RG 1996	
Streptococcus gordonii		ATCC 10558	Type strain	
Streptococcus halotolerans		*In silico* prediction (not tested)		
Streptococcus henryi		*In silico* prediction (not tested)		
Streptococcus himalayensis		*In silico* prediction (not tested)		
Streptococcus hongkongensis		*In silico* prediction (not tested)		
Streptococcus hyointestinalis		*In silico* prediction (not tested)		
Streptococcus ictaluri		*In silico* prediction (not tested)		
Streptococcus infantarius	**ssp. *infantarius***	ATCC BAA-102	HDP 90056	
Streptococcus iniae		*In silico* prediction (not tested)		
Streptococcus intermedius		ATCC 27335	1877	
Streptococcus lactarius		*In silico* prediction (not tested)		
Streptococcus lutetiensis		*In silico* prediction (not tested)		
Streptococcus macacae		*In silico* prediction (not tested)		
Streptococcus marimammalium		*In silico* prediction (not tested)		
Streptococcus marmotae		*In silico* prediction (not tested)		

Organism		Source ID	Strain/Location/Year	Result
Streptococcus massiliensis		*In silico* prediction (not tested)		
Streptococcus merionis		*In silico* prediction (not tested)		
Streptococcus milleri		*In silico* prediction (not tested)		
Streptococcus minor[a]		*In silico* prediction (not tested)		
Streptococcus mitis		ATCC 49456	Type strain	
Streptococcus mutans		ATCC 25175	Type Strain	
Streptococcus oligofermentans		*In silico* prediction (not tested)		
Streptococcus oralis[a]	**-**	ATCC 10557	SK2	
	ssp. *tigurinus*	DSM 24864	Type strain Switzerland	
Streptococcus orisasini		*In silico* prediction (not tested)		
Streptococcus orisratti		*In silico* prediction (not tested)		
Streptococcus ovis		*In silico* prediction (not tested)		
Streptococcus parasanguinis		ATCC 31412	Si-1	
Streptococcus parasuis		*In silico* prediction (not tested)		
Streptococcus parauberis		*In silico* prediction (not tested)		
Streptococcus pasteurianus		*In silico* prediction (not tested)		
Streptococcus penaeicida		*In silico* prediction (not tested)		
Streptococcus peroris		ATCC 700780	Type strain Japan/1990	
Streptococcus phocae		*In silico* prediction (not tested)		
Streptococcus pluranimalium		*In silico* prediction (not tested)		
Streptococcus plurextorum		*In silico* prediction (not tested)		
Streptococcus pneumoniae		ATCC 33400	Type strain	
Streptococcus porci		*In silico* prediction (not tested)		
Streptococcus porcinus		*In silico* prediction (not tested)		
Streptococcus pseudopneumoniae		ATCC BAA-960	Type strain Canada/2002	
Streptococcus pseudoporcinus		*In silico* prediction (not tested)		
Streptococcus pyogenes		ATCC 49399	QC A62	
Streptococcus ratti		*In silico* prediction (not tested)		
Streptococcus respiraculi		*In silico* prediction (not tested)		
Streptococcus ruminantium		*In silico* prediction (not tested)		
Streptococcus salivarius	**-**	ATCC 13419	C699	
	ssp. *thermophiles*	ATCC 19258	Type Strain	
Streptococcus sanguinis		ATCC 10556	Type strain	
Streptococcus sinensis		DSM 14990	HKU4 Hong Kong	
Streptococcys sobrinus[a]		ATCC 33478	Type strain	
Streptococcus suis[a]		ATCC 43765	Type strain	
Streptococcus thoraltensis		*In silico* prediction (not tested)		
Streptococcus troglodytae		*In silico* prediction (not tested)		
Streptococcus uberis[a]		*In silico* prediction (not tested)		
Streptococcus urinalis		*In silico* prediction (not tested)		
Streptococcus vestibularis		ATCC 49124	Type strain United Kingdom	
Streptococcus equi	**ssp. *equi***	ATCC 33398	Type strain	***Streptococcus* spp. Detected** (≥7.6E+06 CFU/mL)
	ssp. *zooepidemicus*	ATCC 43079	Type strain United Kingdom	
Streptococcus entericus		*In silico* prediction (not tested)		
Streptococcus halitosis				
Streptococcus hyovaginalis				
Streptococcus pantholopis				
Other *Streptococcus* species		No Sequence (not tested)		**Unknown**

[a] A small percentage of publicly available sequences for this species have sequence variation under assay primer(s) that may have an impact on detection.

Table 95. Results for *Streptococcus agalactiae* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Streptococcus agalactiae	II	ATCC 13813	Type strain	***Streptococcus agalactiae*** **Detected**
	III	ATCC 12403	Type strain	
	V	ATCC BAA-611	2603 V/R	
	VIII	ATCC BAA-2669	5030-08	
	Unknown	ATCC 12386	Grouping strain	
		NCTC 8017	MK 104 P	
		BF CI-2460	-	

[a] Assay reactivity is not serotype-dependent, the assay will react with all serotypes.

Table 96. Results for *Streptococcus pneumoniae* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Streptococcus pneumoniae	3	ATCC 6303	-	***Streptococcus pneumoniae*** **Detected**
	1	ATCC 33400	Type strain	
	5	ATCC BAA-341	SPN1439-106 Columbia/1995	
	14	ATCC 700672	VH14/ Spain	
	11A	NCTC 11900	Gorman	
	19A	ATCC 700673	19A-6 Hungary/1989	
	Non-capsulated	ATCC BAA-255	R6 (non-virulent)	
	unknown	ATCC BAA-1409	62076 Canada/2005	

[a] Assay reactivity is not serotype-dependent, the assay will react with all serotypes.

Table 97. Results for *Streptococcus pyogenes* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Streptococcus pyogenes	unknown	ATCC 49399	QC A62	***Streptococcus pyogenes*** **Detected**
		ATCC 19615	Bruno	
	1	ATCC 12344	Type strain	
		ATCC 700294	SF370/M1 GAS	
		ATCC BAA-947	MGAS 5005 Canada/1996	
	3	ATCC 12384	C203	
		ATCC BAA-595	MGAS 315 Texas 1980's	
	6	ATCC 12348	S43	
	Unknown	Clinical Isolate[b]	Missouri/2019	**Not Detected**

[a] Assay reactivity is not serotype-dependent, the assay will react with all serotypes.

[b] Isolate of *S. pyogenes* with partial gene deletion.

Table 98. Results for *Acinetobacter calcoaceticus-baumannii* complex Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Acinetobacter baumannii	CDC FDA AR BANK #0033	-	***Acinetobacter calcoaceticus-baumannii*** **complex Detected**
	ATCC 9955	6-561/Italy	
	ATCC 19606	Type strain	
	ATCC 17961	CDC 7788	
	GRE 1153064	-	
	GRE 1062081	-	
	ATCC 15308	Biol 1 Maryland/1949	
	ATCC 51432	Pennsylvania	
Acinetobacter calcoaceticus	ATCC 23055	Type strain Netherlands	
	ATCC 14987	HO-1/Iowa	
	ATCC 17903	2210	

Organism	Source ID	Strain/Location/Year	Result
Acinetobacter nosocomialis (formerly genomospecies 13TU)		Rhode Island/1950	
	CCUG 57124	Sweden/2008	
Acinetobacter pittii (formerly genomospecies 3)	ATCC 19004	Type strain United Kingdom/1966	
	ATCC 17922	Pennsylvania	
Acinetobacter seifertii	CCUG 34785	Type strain Denmark	
Acinetobacter nosocomialis	ATCC 700472[a]	France/1989	**Not Detected**
Acinetobacter dijkshoorniae	No sequence (not tested)		**Unknown**

[a] Sequence data from this isolate suggests that it has been mischaracterized. Sequence data are not consistent with other sequences of *A. nosocomialis* nor with sequences from other species within the *Acinetobacter calcoaceticus-baumannii* complex.

Table 99. Results for *Bacteroides fragilis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Bacteroides fragilis	ATCC 25285	Type strain United Kingdom/1955	***Bacteroides fragilis*** **Detected**
	ATCC 29771	2044 Florida/USA	
	ATCC 29768	12256	
	ATCC 43937	F1355	
	ATCC BAA-2283	2-1-56 FAA	

Table 100. Results for *Enterobacterales* Isolates Tested and Predicted Reactivity for Species Not Tested

Genus	Organism	Source ID	Strain/Location/Year	Result
Cedeceae	***Cedeceae davisae***	ATCC 43023	CDC 2819-81 South Carolina	***Enterobacterales*** **Detected**
	Cedeceae neteri	ATCC 33855	Type strain California	
Citrobacter	***Citrobacter amalonaticus***	ATCC 25405	Type strain	
	Citrobacter braakii	ATCC 51113	Type strain France	
	Citrobacter farmeri	ATCC 51112	Type strain New York	
	Citrobacter freundii	ATCC 8090	Type strain	
		CDC FDA AR Bank #0157	-	
	Citrobacter koseri	ATCC 27156	CDC 3613-63	
		ATCC 29223	CDC 1378/74	
	Citrobacter murliniae	ATCC 51118	Type strain	
	Citrobacter sedlakii	ATCC 51115	Type strain France	
	Citrobacter rodentium	*In silico* prediction (not tested)		
	Citrobacter werkmanii	ATCC 51114	Type strain Belgium	
	Citrobacter youngae	ATCC 29935	Type strain South Carolina	
Cosenzaea	***Cosenzaea (Proteus) myxofaciens***	ATCC 19692	Type strain	
Cronobacter	***Cronobacter condimenti***	*In silico* prediction (not tested)		
	Cronobacter dublinensis	DSM 18706	Type strain Switzerland/2004	
	Cronobacter malonaticus	DSM 18702	Type strain New York	
	Cronobacter muytjensii	DSM 51329	Type strain France	
	Cronobacter sakazakii	ATCC 29544	Type strain	
	Cronobacter turicensis	CCUG 55852	Type strain Switzerland 2005	
Edwardsiella	***Edwardsiella anguillarum***	*In silico* prediction (not tested)		
	Edwardsiella hoshinae	*In silico* prediction (not tested)		
	Edwardsiella ictaluri	*In silico* prediction (not tested)		
	Edwardseilla piscicida	*In silico* prediction (not tested)		

Genus	Organism	Source ID	Strain/Location/Year	Result
	Edwardsiella tarda	ATCC 15947	Type strain Kentucky	
Enterobacter	***Enterobacter bugandensis***	DSM 29888	Type strain Tanzania	
	Enterobacter cancerogenus	ATCC 35317	Type strain New York	
	Enterobacter roggenkampii	*In silico* prediction (not tested)		
	Enterobacter soli	ATCC BAA-2102	Type strain Peru	
Escherichia	***Escherichia albertii***	CCUG 46494	Type strain Bangladesh	
	Escherichia fergusonii	ATCC 35469	Type strain Missouri	
	Escherichia hermanii	ATCC 33650	Type strain Louisiana	
Erwinia	***Erwinia billingiae***	*In silico* prediction (not tested)		
Hafnia	***Hafnia alvei***	ATCC 51815	C2 Minnesota	
	Hafnia paralvei	ATCC 29927	Type strain	
Klebsiella	***Klebsiella grimontii***	DSM 105630	06D021	
	Klebsiella michiganensis	ATCC BAA-2403	Type strain Michigan	
Kluyvera	***Kluyvera ascorbate***	CDC FDA AR BANK #0144	-	
	Kluyvera cryocrescens	CCUG 18767T	Type strain	
	Kluyvera georgiana	*In silico* prediction (not tested)		
	Kluyvera intermedia	ATCC 33110	Type strain	
Kosakonia	***Kosakonia cowanii***	CCUG 62758	Sweden/2012	
	Kosakonia oryzae	*In silico* prediction (not tested)		
	Kosakonia radicincitans	*In silico* prediction (not tested)		
Leclercia	***Leclercia adecarboxylata***	ATCC 23216	1783	
Lelliottia	***Lelliottia amnigena***	ATCC 51816	C3	
	Leliottia nimipressuralis	*In silico* prediction (not tested)		
Mixta	***Mixta (Pantoea) gaviniae***	CCUG 66381	-	
Morganella	***Morganella morganii*** ***ssp. morganii***	ATCC 25830	M11	
		CDC FDA AR BANK #0057	-	
	ssp. sibonii	ATCC 49948	CDC 8103-85	
Pantoea	***Pantoea agglomerans***	ATCC 27155	CDC 1461-67	
	Pantoea ananatis	*In silico* prediction (not tested)		
	Pantoea septica	CCUG 67124	-	
Phytobacter	***Phytobacter ursingii***	*In silico* prediction (not tested)		
Plesiomonas	***Plesiomonas shigelloides***	ATCC 51572	CIP 69.35	
Pluralibacter	***Pluralibacter (Enterobacter) gergoviae***	ATCC 33028	CDC 604-77	
Providencia	***Providencia alcalifaciens***	ATCC 51902	GNI 3	
	Providencia rettgeri	ATCC 9250	NCTC 1501	
	Providencia stuartii	CDC FDA AR Bank #0026	-	
Pseudoescherichia	***Pseudoescherichia (Escherichia) vulneris***	ATCC 33821	CDC 875-72	
Rahnella	***Rahnella aquatilis***	ATCC 33071	CUETM 77-115	
Raoultella	***Raoultella ornithinolytica***	ATCC 31898	AST 111-4	
	Raoultella planticola	ATCC 31900	AST 151-7	
	Raoultella terrigena[a]	ATCC 33257	Type strain	
Serratia	***Serratia aquatilis***	DSM 100980	2015-2462-01	
	Serratia entomophila[a]	ATCC 43705	Type strain	
	Serratia ficaria	*In silico* prediction (not tested)		
	Serratia fonticola	ATCC 29844	CUETM 77-165	
	Serratia grimesii	*In silico* prediction (not tested)		
	Serratia liquefaciens	ATCC 27592	CDC 1284-57	
	Serratia odorifera	ATCC 33077	1073	

Genus	Organism	Source ID	Strain/Location/Year	Result
	Serratia plymuthica	ATCC 183	K-7	
	Serratia proteamaculans	*In silico* prediction (not tested)		
	Serratia rubidaea	ATCC 27593	2199-72	
Sodalis	***Sodalis praecaptivus***	*In silico* prediction (not tested)		
Shigella	***Shigella boydii***	ATCC 9207	AMC 43-G-58	
	Shigella dysenteriae	ATCC 13313	Strain Newcastle	
	Shigella flexneri	CDC FDA AR Bank #0421	-	
	Shigella sonnei	ATCC 29930	WRAIR I virulent	
Tatumella	***Tatumella ptyseos***	ATCC 33301	H36	
Trabulsiella	***Trabulsiella guamensis***[a]	ATCC 49490	Type strain	
Yersinia	***Yersinia aldovae***	*In silico* prediction (not tested)		
	Yersinia aleksiciae	*In silico* prediction (not tested)		
	Yersinia enterocolitica	ATCC 9610	33114	
	Yersinia entomophage	*In silico* prediction (not tested)		
	Yersinia frederiksenii	ATCC 33641	CDC 1461-81	
	Yersinia intermedia	ATCC 33647	CDC 870-77	
	Yersinia kristensenii	ATCC 33639	CDC 1459-81	
	Yersinia massiliensis	*In silico* prediction (not tested)		
	Yersinia mollaretii	ATCC 43969	CDC 2465-87	
	Yersinia pestis	*In silico* prediction (not tested)		
	Yersinia rohdei	*In silico* prediction (not tested)		
	Yersinia ruckeri	*In silico* prediction (not tested)		
	Yersinia similis	*In silico* prediction (not tested)		
Yokenella	***Yokenella regensburgei***	ATCC 35313	CDC 3349-72	
Mixta	***Mixta (Pantoea) calida***	CCUG 68064	-	***Enterobacterales*** **Detected** (≥1.1E+07 CFU/mL)
Yersinia	***Yersinia pseudotuberculosis***	ATCC 29833	NCTC 10275	
Photorabdus	***Photorabdus asymbiotica***	ATCC 43950	3265-86	**Not Detected**
Arsenophonus	***Arsenophonus nasoniae***	*In silico* prediction (not tested)		
Providencia	***Providencia heimbachae***	*In silico* prediction (not tested)		
Other *Enterobacterales* species		*In silico* prediction (not tested) or No sequence (not tested)		**Detected or Unknown**

[a] Only tested at high concentration (>1.0E+09 CFU/mL), expected to be detected at positive blood culture levels and lower.

Table 101. Results for *Enterobacter cloacae* complex Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
Enterobacter asburiae		GRE 1753006	-	***Enterobacter cloacae*** **complex Detected**
Enterobacter cloacae	-	CDC FDA AR Bank #0154	-	
		CDC FDA AR Bank #0501	-	
		ATCC 49141	AmMS 204	
		ATCC BAA-2341	1101152	
		NCTC 13464	-	
	ssp. cloacae	ATCC 13047	Type strain	
		ATCC BAA-1143	Entb 55M	
	spp. dissolvens	ATCC 23373D	Type strain	
Enterobacter hormaechei	-	ATCC BAA-2082	-	
	ssp. oharae	CCUG 53905T	Type strain Germany	
	ssp. steigerwalthii	CCUG 53904T	Type strain Belgium	
	ssp. xiangfangensis	DSM 46348	1080M	
Enterobacter kobei		GRE 1753004	-	
Enterobacter ludwigii		CCUG 23050	Sweden	
Enterobacter mori		DSM 26271	Type strain/R18-2	
Enterobacter asburiae		ATCC 35953	CDC 1497-78 Rhode Island	***Enterobacter cloacae*** **complex Detected** (≥1.6E+07 CFU/mL)
		ATCC 35954	Type strain Maryland	
		ATCC 35955	In silico prediction	

Organism		Source ID	Strain/Location/Year	Result
			(not tested)	
		ATCC 35957	CDC 570-83 Hawaii	
		GRE 0758100	-	
Enterobacter hormaechei	***ssp. hormaechei***	ATCC 49162	Type strain California	

Table 102. Results for *Escherichia coli* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Escherichia coli	CDC FDA AR BANK #0061	-	***Escherichia coli* Detected**
	CDC FDA AR BANK #0086	-	
	CDC FDA AR BANK #0137	-	
	CDC FDA AR BANK #0149	-	
	CDC FDA AR BANK #0150	-	
	CDC FDA AR BANK #0346	-	
	CDC FDA AR BANK #0349	-	
	CDC FDA AR BANK #0350	-	
	CDC FDA AR BANK #0495	-	
	ATCC 11775	Type strain	
	ATCC 25922	DA strain Seattle 1946	
	GRE 1062016	-	
	GRE 1256018	-	

Table 103. Results for *Klebsiella aerogenes* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Klebsiella aerogenes	CDC FDA AR Bank #0062	-	***Klebsiella aerogenes*** **Detected**
	CDC FDA AR Bank #0074	-	
	CDC FDA AR Bank #0161	-	
	ATCC 13048	Type strain	
	ATCC 29751	MULB-250	
	GRE 1254066	-	

Table 104. Results for *Klebsiella oxytoca* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Klebsiella oxytoca	CDC FDA AR Bank #0147	-	***Klebsiella oxytoca*** **Detected**
	ATCC 8724	NRRL B-199	
	ATCC 13182	Type strain	
	ATCC 43086	Pasco 201 California	
	ATCC 49131	AmMS 101	
	ATCC 700324	LBM 90.11.033	
	GRE 1254054	-	
	JMI 2523	-	
	JMI 7818	-	

Table 105. Results for *Klebsiella pneumoniae* group Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
Klebsiella pneumoniae	-	GRE 1553001	-	***Klebsiella pneumoniae*** **group Detected**
		CDC FDA AR Bank #0040	-	
		CDC FDA AR Bank #0068	-	
		CDC FDA AR Bank #0076	-	
		CDC FDA AR Bank #0079	-	
		CDC FDA AR Bank #0080	-	
		CDC FDA AR Bank #0107	-	
		CDC FDA AR Bank #0497	-	
		CDC FDA AR Bank #0525	-	
		ATCC BAA-1705	ART 2008133	
		GRE 1062084	-	
		GRE 1355030	-	

Organism		Source ID	Strain/Location/Year	Result
		JMI 766	-	
	ssp. *ozanae*	CDC FDA AR Bank #0051	-	
		CDC FDA AR Bank #0096	-	
		ATCC 11296	Type strain Sumatra/Indonesia	
	ssp. *pneumoniae*	ATCC 13883	Type strain	
	ssp. *rhinoscleromatis*	ATCC 13884	Type strain Sumatra/Indonesia	
Klebsiella quasipneumoniae	ssp. *similipneumoniae*	ATCC 700603	K6	
		DSM 28212	Type strain Germany/1997	
	ssp. *quasipneumoniae*	DSM 28211	Type strain Austria/1997	
Klebsiella variicola		ATCC BAA-830	Type strain Mexico/2001	

Table 106. Results for *Proteus* spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism	Source ID	Strain/Location/Year	Result
Proteus alimentorum	*In silico* prediction (not tested)		*Proteus* spp. Detected
Proteus cibarius	*In silico* prediction (not tested)		
Proteus columbae	*In silico* prediction (not tested)		
Proteus hauseri	ATCC 13315	strain Lehmann	
	ATCC 700826	Type strain Tennessee	
Proteus mirabilis	CDC FDA AR Bank #0155	-	
	CDC FDA AR Bank #0156	-	
	CDC FDA AR Bank #0159	-	
	ATCC 29906	Type strain	
	ATCC 33583	571101	
	GRE 1254053	-	
Proteus penneri	ATCC 33519	Type strain Illinois	
	ATCC 35197	CDC 1655-67 Maryland	
	ATCC 27973	CDC 1787-64-SC1 Connecticut	
Proteus terrae	*In silico* prediction (not tested)		
Proteus vulgaris	ATCC 29905	Type strain	

Table 107. Results for *Salmonella* spp. Isolates Tested

Organism (alternate ssp. designation)		Serotype	Source ID	Strain/Location/Year	Result
Salmonella bongori (V)		Brookfield	NCTC 10946	-	*Salmonella* spp. Detected
		-	SGSC 3100 SARC11	CDC 750-72 1972	
		-	ATCC 43975	Type strain	
Salmonella enterica	ssp. *arizonae* (IIIa)	-	ATCC 13314	Type strain	
	ssp. *diarizonae* (IIIb)	-	SGSC 3069 SARC8	CDC 678-94 California/1984	
	ssp. *enterica* (I)	Concord	CDC FDA AR Bank #0407	-	
		Enteritidis	ATCC BAA-708	-	
		Heidelberg	SGSC 2210 SARA30	Pennsylvania/1987	
		Infantis	ATCC BAA-1675	MZ1479 Senegal	
		Montevideo	ATCC BAA-710	G4639 1993	
		Newport	ATCC 27869	C487-69	
		Senftenberg	CDC FDA AR Bank #0127	-	
		Typhimurium	ATCC 700720	1948	
		Typhimurium	SGSC 3029 SARC1	England/1958	
	ssp. *houtenae* (IV)	45a,b:g, z51:-	SGSC 3074 SARC9	CDC 2584-68 Panama/1968	

Organism (alternate ssp. designation)		Serotype	Source ID	Strain/Location/Year	Result
	ssp. *indica* (VI)	45:a:e,n,x	SGSC 3116 SARC13	CDC 1363-65 India 1965	
	ssp. *salamae* (II)	42:f:g,t:-	SGSC 3047 SARC4	CDC3472-64 1964	

Table 108. Results for *Serratia marcescens* Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
Serratia marcescens	**-**	CDC FDA AR Bank #0517	-	***Serratia marcescens*** **Detected**
		ATCC 27137	CDC 3100-71 Colorado	
		GRE 1659004	-	
		GRE 1659006	-	
		JMI 697	-	
	ssp. *marcescens*	ATCC 13880	Type strain	
		ATCC 43297	3G Belgium	
	ssp. *sakuensis*	ATCC BAA-885	Type strain Japan 1992	

Table 109. Results for *Haemophilus influenzae* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Haemophilus influenzae	Type a	ATCC 9006	AMC 36-A-3	***Haemophilus influenzae*** **Detected**
	Type b	ATCC 10211	AMC 36-A-1	
	Type c	ATCC 49699	C 9007	
	Type d	ATCC 9008	AMC 36-A-6	
	Type e	ATCC 8142	AMC 36-A-7	
	Type f	ATCC 700223	GA1264/Georgia	
	Non-typeable	ATCC 33391	Type strain United Kingdom/1950	
		ATCC 51907	Rd [KW20]	
		ATCC 51997	INT 1 Missouri	
	Unknown	Clinical Isolate[b]	Utah/2012	**Not Detected**

[a] Assay reactivity is not serotype-dependent, the assay will react with all types and non-typeable isolates.

[b] Clinical isolate of *H. influenzae* with partial gene deletion.

Table 110. Results for *Neisseria meningitidis* Isolates Tested

Organism	Serotype[a]	Source ID	Strain/Location/Year	Result
Neisseria meningitidis **(encapsulated)**	A	ATCC 13077	M1027 Chicago/1937	***Neisseria meningitidis*** **Detected**
	B	ATCC 13090	M2092 Massachusetts	
	C	ATCC 13102	M1628 Connecticut/1949	
	D	ATCC 13113	M158/[37A] 1955	
	W-135	ATCC 43744	M-1574 Illinois	
	Y	ATCC 35561	M-112/[BO-6]	

[a] Assay reactivity is not serotype-dependent, the assay will react with all serotypes.

NOTE: Unencapsulated strains of Neisseria meningitidis will not be detected.

Table 111. Results for *Pseudomonas aeruginosa* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Pseudomonas aeruginosa	CDC FDA AR BANK #0092	-	***Pseudomonas aeruginosa*** **Detected**
	CDC FDA AR BANK #0054	-	
	CDC FDA AR BANK #0100	-	
	CDC FDA AR BANK #0103	-	
	CDC FDA AR BANK #0239	-	
	ATCC 10145	Type strain	

Organism	Source ID	Strain/Location/Year	Result
		Czechoslovakia/1963	
	ATCC 19429	Radlett Feb United Kingdom	
	ATCC 27853	41501 Boston	
	CUSM PS28	-	
	NCTC 13437	United Kingdom	
	ATCC 9027	IFO 13275	***Pseudomonas aeruginosa*** **Detected** (3.1E+05 CFU/mL)
	ATCC 25619[a]	-	**Not Detected**[a]

[a] This isolate and a subset of *P. aeruginosa* sequences (<1% of total sequences) have critical mismatches to assay primer(s) and will not be detected.

Table 112. Results for *Stenotrophomonas maltophilia* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Stenotrophomonas maltophilia	ATCC 700475	CIP 104854	***Stenotrophomonas maltophilia*** **Detected**
	ATCC 700269	WW Washington/1993	
	ATCC BAA-84	D457 Spain	
	ATCC 13637	Type strain United States/1961	
	ATCC BAA-2423	K279a	

Table 113. Results for CTX-M Isolates Tested and Predicted Reactivity for CTX-M Types[a]

CTX-M Type	Organism	Source ID	Result
CTX-M-1	*Klebsiella oxytoca*	GRE 1254054	**CTX-M** **Detected**
CTX-M-3	*Shigella flexneri*	CDC FDA AR BANK #0421	
CTX-M-8	*Klebsiella aerogenes*	GRE 1254066	
CTX-M-9	*Enterobacter cloacae*	CDC FDA AR Bank #0501	
CTX-M-14	*Escherichia coli*	CDC FDA AR Bank #0086	
	Klebsiella pneumoniae	CDC FDA AR Bank #0079	
CTX-M-14, -55	*Escherichia coli*	CDC FDA AR Bank #0349	
CTX-M-15	*Escherichia coli*	CDC FDA AR BANK #0137	
	Klebsiella pneumoniae ssp. *ozaenae*	CDC FDA AR Bank #0051	
	Klebsiella pneumoniae	CDC FDA AR Bank #0068	
	Klebsiella pneumoniae	CDC FDA AR Bank #0040	
	Serratia marcescens	CDC FDA AR Bank #0517	
	Salmonella enterica ssp. *enterica*	CDC FDA AR Bank #0407	
	Morganella morganii	CDC FDA AR Bank #0057	
CTX-M-22	*Proteus mirabilis*	GRE 1254053	
	Klebsiella pneumoniae	CDC FDA AR Bank #0107	
CTX-M-25	*Enterobacter cloacae*	NCTC 13464	
CTX-M-55	*Escherichia coli*	CDC FDA AR Bank #0346	
CTX-M-124	*Kluyvera ascorbata*	CDC FDA AR Bank #0144	

***In silico* Reactivity Predictions**				
Detected		**Not Detected**	**Unknown** (no sequence)	
CTX-M-1 – CTX-M-69	CTX-M-141 – CTX-M-142	CTX-M-151	CTX-M-70	CTX-M-140
CTX-M-71 – CTX-M-117	CTX-M-144		CTX-M-119	CTX-M-143
CTX-M-121 – CTX-M-127	CTX-M-146 – CTX-M-148		CTX-M-120	CTX-M-145
CTX-M-129 – CTX-M-132	CTX-M-150		CTX-M-128	CTX-M-149
CTX-M-134	CTX-M-152		CTX-M-133	CTX-M-153
CTX-M-136 – CTX-M-139	CTX-M-155 – CTX-M-229		CTX-M-135	CTX-M-154

[a] Isolates were tested at a concentration near the LoD for CTX-M.

Table 114. Results for IMP Isolates Tested and Predicted Reactivity for IMP Types[a]

IMP Type	Organism	Source ID	Result
IMP-1	*Pseudomonas aeruginosa*	CDC FDA AR Bank #0103	**IMP** **Detected**
IMP-4	*Acinetobacter baumannii*	GRE 1062081	

IMP-4	*Escherichia coli*	GRE 1062016	
IMP-4	*Klebsiella pneumoniae*	CDC FDA AR Bank #0080	
IMP-4	*Klebsiella aerogenes*	CDC FDA AR Bank #0161	
IMP-8	*Klebsiella pneumoniae*	GRE 1062084	
IMP-14	*Pseudomonas aeruginosa*	CDC FDA AR Bank #0092	
***In silico* Reactivity Predictions**			
Detected		**Not Detected**	**Unknown** (no sequences)
IMP-1 – IMP-30[b] IMP-32 – IMP-34 IMP-37 – IMP-45 IMP-48 – IMP-49 IMP-51 – IMP-56	IMP-58 – IMP-62 IMP-64 IMP-66 – IMP-84	IMP-10[b] IMP-31 IMP-35 IMP-46 IMP-63	IMP-36 IMP-47 IMP-50 IMP-57 IMP-65

[a] Isolates were tested at a concentration near the LoD for IMP.

[b] A subset of IMP-10 sequences (1/6) have mismatches to the assay primer(s) that may have an impact on detection.

Table 115. Results for KPC Isolates Tested and Predicted Reactivity for KPC Types[a]

KPC Type	Organism	Source ID	Strain/Location/Year	Result
KPC-2	*Klebsiella oxytoca*	JMI 7818	-	**KPC Detected**
	Klebsiella pneumoniae	ATCC BAA-1705	ART 2008133	
	Proteus mirabilis	CDC FDA AR Bank #0156	-	
	Serratia marcescens	JMI 697	-	
KPC-3	*Escherichia coli*	CDC FDA AR Bank #0061	-	
	Klebsiella pneumoniae ssp. ozaenae	CDC FDA AR Bank #0096	-	
	Klebsiella oxytoca	CDC FDA AR Bank #0147	-	
	Serratia marcescens	CDC FDA AR Bank #0517	-	
	Kluyvera ascorbata	CDC FDA AR Bank #0144	-	
KPC-4	*Klebsiella pneumoniae*	JMI 766	-	
KPC-5	*Pseudomonas aeruginosa*	Creighton University PS28	-	
KPC-6	*Proteus mirabilis*	CDC FDA AR Bank #0155	-	
KPC-11	*Klebsiella pneumoniae*	CDC FDA AR Bank #0525	-	
Unknown	*Enterobacter cloacae*	ATCC BAA-2341	1101152	
	Enterobacter hormaechei	ATCC BAA-2082	-	
	Klebsiella oxytoca	JMI 2523	-	
***In silico* Reactivity Predictions**				
Detected				
KPC-1 – KPC-46				

[a] Isolates were tested at a concentration near the LoD for KPC.

Table 116. Results for *mcr-1* Isolates Tested[a]

Organism	Source ID	Result
Escherichia coli	CDC FDA AR Bank #0346	***mcr-1* Detected**
	CDC FDA AR Bank #0349	
	CDC FDA AR Bank #0350	
	CDC FDA AR Bank #0495	
Klebsiella pneumoniae	CDC FDA AR Bank #0497	

[a] Isolates were tested at a concentration near the LoD for *mcr-1*.

Table 117. Results for *mecA/C* in Methicillin-resistant *Staphylococcus epidermidis* Isolates Tested[a,b]

Organism	Source ID	Strain/Location/Year	Result
***Staphylococcus epidermidis* (MRSE)**	ATCC 29887	255-01B	***mecA/C* Detected**
	ATCC 35983	RP12 Tennessee	
	ATCC 35984	RP62A Tennessee	
	ATCC 51625	CCF 15990 Ohio	
	ATCC 700562	1191 Virginia/1997	

[a] No methicillin-resistant isolates of *Staphylococcus lugdunensis* were available for testing.

[b] Isolates were tested at a concentration near the LoD for *mecA/C*.

Table 118. Results for *mecA/C* and MREJ (MRSA) in *Staphylococcus aureus* Isolates Tested and Predicted Reactivity for MREJ Types[a]

Organism	Source ID[b]	Strain/Location/Year	SCCmec Type/ MREJ Type	Result
Staphylococcus aureus	ATCC BAA-2421[c]	Mass/2010	SCCmec Type II	***mecA/C* and MREJ (MRSA) Detected**
	NARSA NRS705	NY-12	SCCmec Type II	
	NARSA NRS701	MN-082	SCCmec Type II	
	ATCC BAA-1717	TCH1516	SCCmec Type IV	
	NARSA NRS683	GA-298	SCCmec Type IV	
	NARSA NRS662	CO-34	SCCmec Type IV	
	NARSA NRS707	NY-155	SCCmec Type IV	
	ATCC BAA-1707	MW2	SCCmec Type IV	
	NARSA NRS691	GA-62	SCCmec Type IV	
	NARSA NRS648	CA-347	SCCmec Type II or IV	
	NARSA NRS689	GA-442	SCCmec Type IV	
	NARSA NRS668	CO-72	SCCmec Type IV	
	ATCC BAA-1700	HFH-33798	SCCmec Type IV	
	BEI NR-46081 (NARSA NRS484)	HIP12899	SCCmec Type IV	
	ATCC BAA-1691	HFH-30137	SCCmec Type IV	
	ATCC 43300	F182 Kansas	SCCmec Type II	
	ATCC BAA-2422	-	SCCmec Type II	
	ATCC BAA-1720	-	SCCmec Type II	
	NARSA NRS745	CA-629	SCCmec Type IV or V	
	ATCC BAA-38	-	MREJ Type i	
	NARSA NRS686	-		
	ATCC BAA-44	-	MREJ Type ii	
	ATCC BAA-41	-		
	NARSA NRS385	-		
	ATCC BAA-42	-		
	ATCC BAA-39	-	MREJ Type iii	
	ACC BAA-40	-	MREJ Type iv	
	GRE 1062264	-	MREJ Type iv	
	GRE 0759084	-	MREJ Type v	
	GRE 1055015	-	MREJ Type vi	
	GRE 0860042	-	MREJ Type vii	
	GRE 1052034	-	MREJ Type ix	
	GRE 1151100	-	MREJ Type xi	
	GRE 0960006	-	MREJ Type xii	
	GRE 1055017	-	MREJ Type xiii	
	GRE 0759163	-	MREJ Type xiv	
	GRE 1057114	-	MREJ Type xvii	
	ATCC BAA-2313[d]	-	SCCmec Type XI	
	ATCC BAA-2312[d]	-	SCCmec Type XI	
Staphylococcus aureus	Rennes 1060728[e]	-	Empty SCCmec cassette	**Not Detected**
	GRE 1062519[e]	-	MREJ Type xix	
	GRE 1062373[f]	-	MREJ Type xv	
	GRE 1062292[f]	-	MREJ Type xviii	

***In silico* Reactivity Predictions for MREJ Types**				
Detected			**Not Detected**	**Unknown** (no sequence)
MREJ Type i,iα	MREJ Type vi	MREJ Type xiii	MREJ Type ix[g]	MREJ Type viii
MREJ Type ii/xvi	MREJ Type vii	MREJ Type xiv	MREJ Type xv	MREJ Type x
MREJ Type iii	MREJ Type ix[g]	MREJ Type xvi	MREJ Type xviii	MREJ Type xx
MREJ Type iv	MREJ Type xi	MREJ Type xvii	MREJ Type xix	
MREJ Type v	MREJ Type xii	MREJ Type xxi		

[a] Isolates were tested at a concentration near the LoD for *Staphylococcus aureus*.

[b] NARSA/BEI isolates were sourced by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH.

[c] Isolate is characterized as methicillin-sensitive *Staphylococcus aureus* (MSSA) with a non-functional *mecA* variant that is amplified by the mecA/C assay.

[d] Isolate is characterized as methicillin-resistant *Staphylococcus aureus* (MRSA) with the *mecC* gene.

[e] Isolate is characterized as MSSA, which matches the *mecA/C* and MREJ (MRSA) Not Detected result.

[f] Isolate is characterized as MRSA, but the MREJ type is not detected by the assay.

[g] A subset of MREJ Type ix sequences (2/8) have mismatches to the assay primer(s) that may have an impact on detection.

Table 119. Results for NDM Isolates Tested and Predicted Reactivity for NDM Types[a]

NDM Type	Organism	Source ID	Result
NDM-1	*Acinetobacter baumannii*	CDC FDA AR Bank #0033	**NDM Detected**
	Salmonella enterica	CDC FDA AR Bank #0127	
	Klebsiella pneumoniae	CDC FDA AR Bank #0068	
	Proteus mirabilis	CDC FDA AR Bank #0159	
NDM-2	*Acinetobacter baumannii*	GRE 1153064	
NDM-5	*Escherichia coli*	CDC FDA AR Bank #0150	
NDM-6		CDC FDA AR Bank #0137	
NDM-7		CDC FDA AR Bank #0149	

***In silico* Reactivity Predictions**			
Detected		**Not Detected**	
NDM-1 – NDM-24[b,c,d]	NDM-32	NDM-1[b]	NDM-18[d]
NDM-27 – NDM-29	NDM-40	NDM-4[c]	

[a] Isolates were tested at a concentration near the LoD for NDM.

[b] A subset of NDM-1 sequences (5/753) have mismatches to assay primer(s) that may have an impact on detection.

[c] A subset of NDM-4 sequences (1/57) have mismatches to assay primer(s) that may have an impact on detection.

[d] A subset of NDM-18 sequences (1/3) have mismatches to assay primer(s) that may have an impact on detection.

Table 120. Results for OXA-48-like Isolates Tested and Predicted Reactivity for OXA-48-like Types[a]

OXA-48 Like Type	Organism	Source ID	Result
OXA-48	*Klebsiella aerogenes*	CDC FDA AR Bank #0074	**OXA-48-like Detected**
OXA-48-like	*Serratia marcescens*	GRE 1659004	
OXA-162	*Klebsiella pneumoniae*	GRE 1355030	
OXA-181	*Klebsiella pneumoniae*	CDC FDA AR Bank #0051	
OXA-232	*Klebsiella pneumoniae*	CDC FDA AR Bank #0068	

***In silico* Reactivity Predictions**					
Detected			**Not Detected[b]**		
OXA-48	OXA-244	OXA-515	OXA-54[c]	OXA-439[d]	OXA-551[d]
OXA-48-like	OXA-245	OXA-519	OXA-163[d]	OXA-517[d]	OXA-552[d]
OXA-162	OXA-252	OXA-546	OXA-247[d]	OXA-535[d]	OXA-553[d]
OXA-181	OXA-370	OXA-547	OXA-405[d]	OXA-538[d]	OXA-567[d]
OXA-199	OXA-484	OXA-566	OXA-416[c]	OXA-548[d]	OXA-731[d]
OXA-204	OXA-505		OXA-436[d]	OXA-549[d]	
OXA-232	OXA-514		OXA-438[d]	OXA-550[d]	

[a] Isolates were tested at a concentration near the LoD for OXA-48-like.

[b] Non-OXA-48-like types (e.g. OXA-23-like, OXA-40/24-like, OXA-51-like, and OXA-58-like, OXA-143a-like, and OXA-143-like) will not be detected.

[c] OXA-48-like progenitor found in *Shewanella* species. The OXAa assay was designed to exclude these types.

[d] OXA-48-like types with altered carbapenem hydrolysis activity. The OXAa assay was designed to exclude these variants.

Table 121. Results for *vanA/B* in Vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* Isolates Tested[a]

van Gene	Organism	Source ID	Strain/Location/Year	Result
vanA	*Enterococcus faecium*	ATCC 700221	-	***vanA/B* Detected**
		JMI 475	IN/2003	
		ATCC BAA-2318	-	
	Enterococcus faecalis	ATCC BAA-2573	bMx 0502240	
		JMI 12536	MA/2002	
		ATCC 700802	V583	
vanB	*Enterococcus faecalis*	ATCC 51299	NJ-3	
	Enterococcus faecium	ATCC 51858	Vancomycin-dependent #4	

[a] Isolates were tested at a concentration near the LoD for *Enterococcus faecium* and *Enterococcus faecalis.*

Table 122. Results for VIM Isolates Tested and Predicted Reactivity for VIM Types[a]

VIM Type	Organism	Source ID	Result
VIM-1	*Enterobacter cloacae*	CDC FDA AR Bank #0154	

	Klebsiella pneumoniae	CDC FDA AR Bank #0076	**VIM Detected**
	Enterobacter cloacae	CDC FDA AR Bank #0501	
VIM-2	*Pseudomonas aeruginosa*	CDC FDA AR Bank #0100	
VIM-4	*Pseudomonas aeruginosa*	CDC FDA AR-BANK #0054	
VIM-7	*Escherichia coli*	GRE 1256018	
VIM-10	*Pseudomonas aeruginosa*	NCTC 13437	
VIM-11	*Pseudomonas aeruginosa*	CDC FDA AR Bank #0239	
VIM-27	*Klebsiella pneumoniae*	CDC FDA AR Bank #0040	

***In silico* Reactivity Predictions**				
Detected		**Not Detected**		**Unknown** (no sequences)
VIM-1 – VIM-20[b] VIM-23 – VIM-38 VIM-40 – VIM-44	VIM-47 – VIM-64 VIM-66	VIM-2[b] VIM-39 VIM-45	VIM-46 VIM-65 VIM-67	VIM-21 VIM-22

[a] Isolates were tested at a concentration near the LoD for VIM.

[b] A subset of VIM-2 sequences (3/182) have mismatches to assay primer(s) that may have an impact on detection.

Table 123. Results for *Candida albicans* Isolates Tested

Organism	Source ID	Strain	Result
Candida albicans	ATCC 11006	-	***Candida albicans*** **Detected**
	ATCC 14053	NIH 3172	
	ATCC 22972	M 97	
	ATCC 10231	DSM 1386	
	ATCC 90028	NCCLS 11	
	ATCC MYA-2876	SC5314	

Note: The assay for detection of C. albicans amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 124. Results for *Candida auris* Isolates Tested[a]

Organism	Source ID	Strain/Location/Year	Result
Candida auris	CDC FDA AR Bank #0381	-	***Candida auris*** **Detected**
	CDC FDA AR Bank #0383	-	
	CDC FDA AR Bank #0384	-	
	CDC FDA AR Bank #0385	-	
	CDC FDA AR Bank #0388	-	
	NCPF 8971	Strain 10 (non-aggregative) United Kingdom/2016	
	NCPF 8977	Strain 2 (aggregative) United Kingdom/2016	

[a] A subset of *Candida auris* sequences (2/151) has mismatches to assay primer(s) that may have an impact on detection.

Table 125. Results for *Candida glabrata* Isolates Tested

Organism	Source ID	Strain/Year	Result
Candida glabrata	ATCC 2001	Type strain	***Candida glabrata*** **Detected**
	ATCC 15545	-	
	ATCC 15126	Mutant TMAGR-23	
	ATCC 32554	26247-1	
	ATCC MYA-2950	303542	
	Clinical Isolate[a]	2018	**Not Detected**

[a] Isolate characterized as 'petite mutant' with loss of mitochondrial function/mitochondrial DNA.

Note: The assay for detection of C. glabrata amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 126. Results for *Candida krusei* Isolates Tested

Organism	Source ID	Strain	Result
Candida krusei	ATCC 6258	Type strain	***Candida krusei*** **Detected**
	ATCC 14243	-	
	ATCC 28870	CBS 2052	
	ATCC 34135	ST-112	
	ATCC 90878	B74	
	ATCC 201748	89-08-008	

Table 127. Results for *Candida parapsilosis* Isolates Tested

Organism	Source ID	Strain	Result
Candida parapsilosis	ATCC 34136	ST-89	***Candida parapsilosis*** **Detected**
	ATCC 22019	Type strain	
	ATCC 28475	CBS 2915	
	ATCC 90875	B78	
	ATCC 96138	MC0433	

Note: The assay for detection of C. parapsilosis amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 128. Results for *Candida tropicalis* Isolates Tested

Organism	Source ID	Strain/Location	Result
Candida tropicalis	ATCC 750	Type strain	***Candida tropicalis*** **Detected**
	ATCC 66029	AmMS 227	
	ATCC 90874	B79 Germany	
	ATCC 201380	API 90 01 105	
	ATCC MYA-2734	509-12.1	

***Note: The assay for detection of C. tropicalis amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected*.**

Table 129. Results for *Cryptococcus neoformans/gattii* Isolates Tested

Organism	Serotype/Genotype[a]	Source ID	Strain	Result
Cryptococcus gattii	-	ATCC MYA-4071	WM 276	***Cryptococcus neoformans/gattii*** **Detected**
	B/VGIIb	ATCC MYA-4094	R272	
	B/VGI	ATCC MYA-4560	WM179	
	B/VGIII	ATCC MYA-4562	WM161	
	C/VGIV	ATCC MYA-4563	WM779	
	VGIIc	ATCC MYA-4877	A6MR38	
Cryptococcus neoformans	-	ATCC 24067	52	
	-	ATCC 32045	Type strain	
	A/VNII	ATCC MYA-4564	WM148	
	AD/VNIII	ATCC MYA-4566	WM628	
	D/VNIV	ATCC MYA-4567	WM629	
	B	ATCC 24065	112	
	A	ATCC 208821[b]	Type strain	

[a] Assay reactivity is not serotype/genotype-dependent, the assay will react with all serotypes and genotypes.

[b] Described as *Cryptococcus neoformans* var. *grubii*.

Analytical Specificity (Cross-Reactivity and Exclusivity)

The potential for non-specific amplification and detection by the BIOFIRE BCID2 Panel assays was evaluated by *in silico* analysis of available sequences and by testing of high concentrations of on-panel and off-panel organisms. Each organism was tested in triplicate with most bacteria tested at a concentration >1.0E+09 CFU/mL and most yeast tested at a concentration >1.0E+08 CFU/mL. Off-panel fungi, viruses, and parasites were tested at the highest cultured concentration possible.

The on-panel organisms tested to assess the potential for intra-panel cross-reactivity are listed in Table 130, with each observed or predicted cross-reactivity indicated. The off-panel organisms tested are listed in Table 131 and the list includes species genetically related to organisms or AMR genes detected by the panel (same genus or otherwise related) as well as unrelated organisms that may be found in blood and/or blood cultures as pathogens or contaminants (e.g. skin microorganisms, viruses, etc.). Off-panel AMR genes were also evaluated, and all observed or predicted cross-reactivities are indicated. Erroneous results due to cross-reactivity with organisms that were not evaluated or due to cross-reactivity with emerging or novel sequences are also possible.

Table 130. On-Panel Organisms and AMR Genes Tested for Evaluation of BIOFIRE BCID2 Panel Analytical Specificity
A risk of cross-reactivity was confirmed for the species in bold.

ON-PANEL			
Gram Positive Bacteria			
Enterococcus faecalis	*Staphylococcus intermedius*	*Staphylococcus xylosus*	*Streptococcus mitis*
Enterococcus faecium	*Staphylococcus lentus*	*Streptococcus agalactiae*	*Streptococcus mutans*
Listeria monocytogenes	*Staphylococcus lugdunensis*	*Streptococcus anginosus*	*Streptococcus oralis*
Staphylococcus argenteus[a]	*Staphylococcus lutrae*	*Streptococcus australis*	*Streptococcus parasanguinis*
Staphylococcus aureus (MRSA)	*Staphylococcus nepalensis*	*Streptococcus bovis*	*Streptococcus pneumoniae*
Staphylococcus auricularis	*Staphylococcus pasteuri*	*Streptococcus canis*	*Streptococcus pseudopneumoniae*
Staphylococcus capitis	*Staphylococcus pettenkoferi*	*Streptococcus constellatus*	*Streptococcus pyogenes*
Staphylococcus caprae	*Staphylococcus pseudintermedius*	*Streptococcus cristatus*	*Streptococcus salivarius*
Staphylococcus carnosus	*Staphylococcus saprophyticus*	*Streptococcus dysgalactiae*	*Streptococcus sanguinis*
Staphylococcus cohnii	*Staphylococcus schleiferi*	*Streptococcus equi*	*Streptococcus sobrinus*
Staphylococcus epidermidis (MRSE)	***Staphylococcus schweitzeri***[a]	*Streptococcus equinus*	*Streptococcus suis*
Staphylococcus equorum	*Staphylococcus sciuri*	*Streptococcus gallolyticus*	*Streptococcus vestibularis*
Staphylococcus haemolyticus	*Staphylococcus simulans*	*Streptococcus gordonii*	
Staphylococcus hominis	*Staphylococcus warneri*	*Streptococcus intermedius*	
Gram Negative Bacteria			
Acinetobacter baumannii	*Enterobacter mori*	*Metakosakonia massiliensis*	*Salmonella typhimurium*
Acinetobacter calcoaceticus	*Enterobacter soli*	*Mixta calida*	*Serratia entomophila*
Acinetobacter nosocomialis[b]	*Erwinia billingiae*	*Mixta gaviniae*	*Serratia ficaria*
Acinetobacter pittii	***Escherichia albertii***[e]	*Morganella morganii*	*Serratia fonticola*
Acinetobacter seifertii	*Escherichia coli*	*Neisseria meningitidis*	*Serratia liquefaciens*
Bacteroides fragilis	***Escherichia fergusonii***[f]	*Pantoea agglomerans*	*Serratia marcescens*
Cedecea davisae	*Escherichia hermannii*	*Pantoea septica*	*Serratia odorifera*
Citrobacter braakii	*Haemophilus influenzae*	*Photorhabdus asymbiotica*	*Serratia plymuthica*
Citrobacter freundii	*Hafnia alvei*	*Plesiomonas shigelloides*[h]	*Serratia rubidaea*
Citrobacter koseri	*Hafnia paralvei*	*Pluralibacter gergoviae*	***Shigella boydii***[f]
Cosenzaea myxofaciens[c]	*Klebsiella aerogenes*	*Proteus hauseri*	***Shigella dysenteriae***[f]
Cronobacter malonaticus	***Klebsiella grimontii***[g]	*Proteus mirabilis*	***Shigella flexneri***[f]
Cronobacter sakazakii	***Klebsiella michiganensis***[g]	*Proteus penneri*	***Shigella sonnei***[f]
Cronobacter turicensis	*Klebsiella oxytoca*	*Proteus vulgaris*	*Shimwellia blattae*
Edwardsiella tarda	*Klebsiella pneumoniae*	*Providencia stuartii*	*Stenotrophomonas maltophilia*
Enterobacter asburiae	*Klebsiella quasipneumoniae*	*Pseudescherichia vulneris*	*Tatumella ptyseos*
Enterobacter bugandensis[d]	*Klebsiella variicola*	*Pseudomonas aeruginosa*	***Trabulsiella guamensis***[i]
Enterobacter cancerogenus	*Kluyvera ascorbata*	*Rahnella aquatilis*	*Yersinia enterocolitica*
Enterobacter cloacae	*Kluyvera intermedia*	*Raoultella ornithinolytica*	*Yersinia frederiksenii*
Enterobacter hormaechei	*Kosakonia cowanii*	*Raoultella planticola*	*Yersinia pestis*
Enterobacter hormaechei subsp. *xiangfangensis* (*aka Enterobacter xiangfangensis*)	*Leclercia adecarboxylata*	*Raoultella terrigena*	*Yersinia psuedotuberculosis*
Enterobacter kobei	*Lelliottia amnigena*	*Salmonella bongori*	*Yokenella regensburgei*
Enterobacter ludwigii	*Lelliottia nimipressuralis*	*Salmonella enterica*	
Yeast			
Candida albicans	*Candida glabrata*	***Candida parapsilosis***[j]	*Cryptococcus gattii*
Candida auris	*Candida krusei*	***Candida tropicalis***[k]	*Cryptococcus neoformans*
Antimicrobial Resistance Genes			
CTX-M	*mcr-1*	NDM	VIM
IMP	*mecA/C*	OXA-48-like	
KPC	*mecA/C* and MREJ (MRSA)	vanA/B	

[a] Detected as *Staphylococcus aureus* (*mecA/C* and MREJ (MRSA) also detected for *S. argenteus*); members of the *Staphylococcus aureus* complex.

[b] Risk of amplification by KPC assay predicted by sequence analysis; not observed when tested at 8.7E+09 CFU/mL.

[c] Detected as *Proteus* spp. at ≥8.8E+06 CFU/mL. Nonpathogenic bacterium isolated from gypsy moths; formerly classified as *Proteus*.

[d] Detected as *Enterobacter cloacae* complex; newly described species.

[e] Detected as *Escherichia coli* at ≥8.0E+08 CFU/mL.

[f] Detected as *Escherichia coli*.

[g] Detected as *Klebsiella oxytoca*; *Klebsiella grimontii* was formerly classified as *K. oxytoca* phylogroup Ko6.

[h] Risk of amplification by Salmonella assay predicted by sequence analysis; not observed when tested at 7.4E+09 CFU/mL.

[i] Detected as *Enterobacter cloacae* complex at ≥9.0E+07 CFU/mL.

[j] Detected as *Candida tropicalis* at ≥2.8E+07 CFU/mL.

[k] Detected as *Candida parapsilosis* at ≥6.3E+07 CFU/mL.

Table 131. Off-Panel Organisms and AMR Genes Tested for Evaluation of BIOFIRE BCID2 Panel Analytical Specificity

A risk of cross-reactivity was confirmed for the species in bold.

OFF-PANEL			
Gram Positive Bacteria			
Acintomyces naeslundii	*Corynebacterium jeikeium*	*Enterococcus raffinosus*	*Micrococcus luteus*
Actinomyces israelii	*Corynebacterium striatum*	*Gemella morbillorum*	*Mycoplasma hominis*

OFF-PANEL			
Actinomyces odontolyticus	*Corynebacterium urealyticum*	*Granulicatella adiacens*[a]	*Mycoplasma pneumoniae*
Aerococcus viridans[a]	*Cutibacterium acnes*	*Kocuria kristinae*	*Nocardia farcinica*
Arcanobacterium haemolyticum	*Enterococcus avium*	*Lactobacillus acidophilus*	*Peptostreptococcus anaerobius*
Bacillus cereus	*Enterococcus casseliflavus*	*Lactococcus lactis*	*Rhodococcus equi*
Bacillus licheniformis	*Enterococcus cecorum*[a]	*Listeria grayi*	*Rothia mucilaginosa*
Bacillus subtilis	*Enterococcus dispar*	*Listeria innocua*	*Sarcina ventriculi*
Clostridioides difficile	*Enterococcus durans*	*Listeria ivanovii*	*Solibacillus silvestris*
Clostridium perfringens	*Enterococcus gallinarum*	*Listeria seeligeri*	*Ureaplasma parvum*
Clostridium tetani	*Enterococcus hirae*	*Listeria welsimeri*	*Ureaplasma urealyticum*
Corynebacterium diptheria	*Enterococcus mundtii*	*Macrococcus caseolyticus*	*Vagococcus fluvialis*
Gram Negative Bacteria			
Acinetobacter baylyi	*Bacteroides uniformis*	*Kingella kingae*	*Pseudomonas fluorescens*
Acinetobacter bereziniae	*Bacteroides vulgatus*	*Kingella negevensis*	*Pseudomonas luteola*
Acinetobacter guillouiae	*Bordetella bronchiseptica*	*Kingella oralis*	*Pseudomonas nitroreducens*
Acinetobacter haemolyticus	*Bordetella parapertussis*	*Legionella pneumophila*	*Pseudomonas oleovorans*
Acinetobacter johnsonii	*Bordetella pertussis*	*Leptospira interrogans*	*Pseudomonas oryzihabitans*
Acinetobacter junii	*Burkholderia cepacia*	*Moraxella catarrhalis*	*Pseudomonas pertucinogena*
Acinetobacter lwoffii	*Burkholderia mallei*	*Moraxella osloensis*[e]	*Pseudomonas putida*
Acinetobacter parvus	*Burkholderia multivorans*	*Mycobacterium tuberculosis*	*Pseudomonas stutzeri*
Acinetobacter radioresistens	*Burkholderia pseudomallei*	*Neisseria gonorrhoeae*	*Pseudomonas veronii*
Acinetobacter schindleri[b]	*Campylobacter hominis*	*Neisseria lactamica*	*Psychrobacter cryohalolentis*
Acinetobacter soli	*Chlamydia trachomatis*	*Neisseria meningitidis* (unencapsulated)	*Psychrobacter immobilis*
Acinetobacter ursingii	*Chlamydophila pneumoniae*	*Neisseria mucosa*	*Ralstonia mannitolilytica*
Acintobacillus ureae	*Chromobacterium violaceum*	*Neisseria sicca*	*Ralstonia pickettii*
Aggregatibacter actinomycetemcomitans	*Eikenella corrodens*	*Parabacteroides distasonis*	*Stenotrophomonas acidiminiphila*
Actinobacillus hominis	***Haemophilus aegyptius***[d]	*Pasteurella aerogenes*	*Stenotrophomonas nitritireducens*
Aeromonas caviae	*Haemophilus ducreyi*	*Pasteurella canis*	*Stenotrophomonas rhizophila*
Aeromonas hydrophila	*Haemophilus haemolyticus*	*Pasteurella multocida*	*Treponema pallidum*
Aeromonas sobria	*Haemophilus parahaemolyticus*	*Pasteurella stomatis*	*Veillonella parvula*
Aggregatibacter aphrophilus	*Haemophilus parainfluenzae*	*Prevotella melaninogenica*	*Vibrio alginolyticus*
Bacteriodes xylanisolvens[c]	*Haemophilus parasuis*	*Prevotella oralis*	*Vibrio parahaemolyticus*
Bacteroides caccae	*Haemophilus quentini*	*Pseudomonas alcaligenes*	*Vibrio vulnificus*
Bacteroides ovatus[c]	*Haemophilus sputorum*	*Pseudomonas citronellolis*	
Bacteroides thetaiotaomicron	*Kingella denitrificans*	*Pseudomonas mendocina*	
Yeast			
Aspergillus flavus	*Candida kefyr* (*Kluyveromyces marxianus*)	*Coccidioides posadasii*	*Millerozyma farinosa* (*Candida cacaoi*)
Aspergillus fumigatus[f]	*Candida lusitaniae* (*Clavispora lusitaniae*)	***Cryptococcus amylolentus***[j]	*Naganishia albida* (*Cryptococcus albidus*)
Aspergillus niger	*Candida metapsilosis*	*Cryptococcus uniguttulatus*	*Papiliotrema laurentii* (*Cryptococcus laurentii*)
Aspergillus terreus	*Candida multis-gemmis*	*Cutaneotrichosporon curvatum* (*Cryptococcus curvatus*)	*Penicillium chrysogenum*
Blastomyces dermatitidis	***Candida nivariensis***[i]	*Cyberlindnera fabianii* (*Candida fabianii*)	*Rhodotorula mucilaginosa*
Candida dubliniensis	***Candida norvegensis*** (*Pichia norvegensis*)[h]	*Histoplasma capsulatum*	*Saccharomyces cerevisiae*
Candida famata (*Debaryomyces* hansenii)[g]	*Candida orthopsilosis*	*Kluyveromyces lactis*	*Schizosaccharomyces pombe*
Candida guilliermondii (*Meyerozyma guilliermondii, Pichia guilliermondii*)	*Candida sojae*	*Kodameae ohmeri*	*Talaromyces marneffei*
Candida haemulonii	*Candida viswanthii*	*Lodderomyces elongisporus*	*Trichosporon asahii*
Candida inconspicua (*Pichia cactophila*)[h]	*Coccidioides immitis*	*Magnusiomyces capitatus*	*Wickerhamomyces anomalus*
Viruses			
Chikungunya Virus	Hepatitis B virus	Human Herpes Virus-7	Varicella Zoster Virus
Cytomegalovirus	Hepatitis C virus	Measles Virus	West Nile Virus
Dengue Virus	Human Immunodeficiency Virus	Mumps Virus	Zika Virus
Enterovirus	Herpes Simplex Virus Type 1	Parvovirus B19	
Epstein Barr Virus	Herpes Simplex Virus Type 2	Polyoma Virus	
Hepatitis A virus	Human Herpes Virus-6	Rubella Virus	
Parasites			
Plasmodium falciparum		*Trypanosoma cruzi*	

OFF-PANEL			
Antimicrobial Resistance Genes			
AmpC	*mcr-3*	*SHV*	*vanC*
bla$_{RAHN}$[k]	*mcr-4*	*SME*	*vanD*
CMY	*ompK36*	*SPM*	***vanM***[l]
mcr-2	*OXA-24/65*	*TEM*	

[a] Risk of amplification by the Staphylococcus assay predicted by sequence analysis; not detected when tested at 3.0E+08 cells/mL (*G. adiacens*) or >6.0E+09 CFU/mL (*A. viridans* and *E. cecorum*). Similar risk predicted for *Aerococcus christensenii* and *Aerococcus sanguinicola*; not tested.

[b] Risk of amplification by the CTX-M assay at ≥8.1E+09 CFU/mL; will not be detected unless an applicable bacterium is also detected.

[c] Detected as *Bacteroides fragilis* at ≥8.2E+06 cells/mL. Similar risk predicted for *Bacteroides ovatus*.

[d] Detected as *Haemophilus influenzae*; also described as *Haemophilus influenzae* biogroup *aegyptius*.

[e] Risk of amplification by KPC assay predicted by sequence analysis; not observed when tested at 7.8E+09 CFU/mL.

[f] Risk of amplification by the Bfragilis assay predicted by sequence analysis; not observed when tested at 5.0E+08 CFU/mL. Similar risk predicted for *Aspergillus lentulus* and *Aspergillus viridinutans*; not tested.

[g] Risk of amplification by the Ckrusei assay predicted by sequence analysis; not observed when tested at 8.9E+08 CFU/mL. Similar risk predicted for other yeast species; not tested.

[h] Detected as *Candida krusei* at ≥3.7E+05 CFU/mL. Similar risk predicted for *Pichia pseudocactophila* and *Pichia cactophila*; not tested.

[i] Detected as *Candida glabrata* at ≥8.0E+06 CFU/mL. *Candida glabrata* complex species; similar risk predicted for *Candida bracarensis*; not tested.

[j] Detected as *Cryptococcus neoformans/gattii*; nonpathogenic fungus isolated from the frass of beetles.

[k] Risk of amplification by the CTX-M assay predicted by sequence analysis; not observed when *Rahnella aquatilis* was tested at 7.8E+09 CFU/mL. Similar risk predicted for *ampC* in *Leminorella* species, *bla*$_{OXY}$, and *bla*$_{KLUC}$; not tested.

l Not tested; predicted to be detected as vanA/B if an applicable bacterium is also detected.

Reproducibility

A multi-center study was performed to evaluate the reproducibility of analyte detection on the BIOFIRE 2.0 and BIOFIRE Torch systems. The study incorporated potential variation introduced by site (three), day (five), operator (at least two per site), system/module, and reagent kit lot (three). The contrived samples contained representative isolates of aerobic and anaerobic gram-positive and gram-negative bacteria, AMR genes, and yeast in simulated blood culture matrix. Each organism was present in a sample at a concentration consistent with what is observed in a positive blood culture (at positive bottle indication or up to 24 hours after positive bottle indication). Negative results were obtained from samples that were not spiked with the organism or AMR gene.

Each of the three sites tested 20 replicates per sample and system for a total of 120 valid runs per sample and 720 valid runs overall. A summary of the reproducibility of results (percent (%) agreement with the expected Detected, Not Detected or N/A result) for each analyte (by site and system) is provided in Table 132.

Table 132. Reproducibility of the BIOFIRE BCID2 Panel Results on BIOFIRE 2.0 and BIOFIRE Torch Systems

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								
			BIOFIRE 2.0				BIOFIRE Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Gram Positive Bacteria											
Enterococcus faecalis **ATCC 51299**	**7.65E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Enterococcus faecium **ATCC 27270**	**9.19E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Listeria monocytogenes	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
***Staphylococcus* spp.**	**Multiple[a]**	**Detected**	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	**179/180 (99.4%)**	60/60 (100%)	60/60 (100%)	60/60 (100%)	**180/180 (100%)**	**359/360 99.7% [98.5%-99.9%]**
	Negative (no analyte)	**Not Detected**	60/60 (100%)	60/60 (100%)	60/60 (100%)	**180/180 (100%)**	60/60 (100%)	60/60 (100%)	60/60 (100%)	**180/180 (100%)**	**360/360 100% [99.0%-100%]**
Staphylococcus aureus **ATCC BAA-38**	**2.44E+08 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Staphylococcus epidermidis	**2.31E+06 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								All Sites/Systems [95% Confidence Interval]
			BIOFIRE 2.0				BIOFIRE Torch				
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
ATCC 12228	**Negative (no analyte)**	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Staphylococcus lugdunensis **ATCC 43809**	**1.67E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
***Streptococcus* spp.**	**Multiple[b]**	**Detected**	40/40 (100%)	40/40 (100%)	40/40 (100%)	**120/120 (100%)**	40/40 (100%)	40/40 (100%)	40/40 (100%)	**120/120 (100%)**	**240/240 100% [98.4%-100%]**
	Negative (no analyte)	**Not Detected**	80/80 (100%)	80/80 (100%)	80/80 (100%)	**240/240 (100%)**	80/80 (100%)	80/80 (100%)	80/80 (100%)	**240/240 (100%)**	**480/480 100% [99.2%-100%]**
Streptococcus agalactiae	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
Streptococcus pneumoniae **ATCC 6303**	**5.91E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Streptococcus pyogenes **ATCC 49399**	**2.63E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	None (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Gram Negative Bacteria											
***Acinetobacter calcoaceticus-baumannii* complex (*Acinetobacter baumannii*) AR Bank 0033**	**7.36E+07 CFU/mL**	**Detected**	19/20 (95.0%)	19/20 (95.0%)	20/20 (100%)	**58/60 (96.7%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**118/120 98.3% [94.1%-99.8%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Bacteroides fragilis **ATCC 25285**	**8.62E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [99.4%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Enterobacterales	**Multiple[c]**	**Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								All Sites/Systems [95% Confidence Interval]
			BIOFIRE 2.0				BIOFIRE Torch				
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
	Negative (no analyte)	**Not Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
***Enterobacter cloacae* complex**	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
Escherichia coli	**8.79E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-%99.9%]**
CDC-FDA AR Bank #0350	**Negative (no analyte)**	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Klebsiella aerogenes	**9.29E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
CDC-FDA AR Bank #0161	**Negative (no analyte)**	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Klebsiella oxytoca	**2.44E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
CDC-FDA AR Bank #0147	**Negative (no analyte)**	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
***Klebsiella pneumoniae* group**	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
***Proteus* spp. (*Proteus mirabilis*) GRE 1254053**	**1.68E+09 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
***Salmonella* spp. (*Salmonella enterica*) ATCC 700720**	**1.74E+09 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Serratia marcescens	**3.05E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
GRE 1659004	**Negative (no analyte)**	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								All Sites/Systems [95% Confidence Interval]
			BIOFIRE 2.0				BIOFIRE Torch				
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Haemophilus influenzae **ATCC 10211**	**1.32E+08 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [99.4%-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Neisseria meningitidis	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
Pseudomonas aeruginosa **CDC-FDA AR Bank #0054**	**7.22E+07 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Stenotrophomonas maltophilia **ATCC 700475**	**1.13E+09 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Antimicrobial Resistance Genes											
CTX-M (CTX-M-22) (*Proteus mirabilis*) GRE 1254053	**1.68E+09 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-%99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
IMP (IMP-4) (*Klebsiella aerogenes*) CDC-FDA AR Bank #0161	**9.29E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
KPC-3 (*Klebsiella oxytoca*) ATCC 10211	**2.44E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
mcr-1 **(*Escherichia coli*) CDC-FDA AR Bank #0350**	**8.79E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	19/20[d] (95.0%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4%-99.9%]**
	Negative (no analyte)	**Not Detected or N/A**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								All Sites/Systems [95% Confidence Interval]
			BIOFIRE 2.0				BIOFIRE Torch				
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
mecA/C	**Negative (no analyte)**	**Not Detected or N/A**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
mecA/C and MREJ (MRSA) (*Staphylococcus aureus*) ATCC BAA-38	**2.44E+08 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**
	Negative (no analyte)	**N/A**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
NDM (NDM-1) (*Acinetobacter baumannii*) CDC-FDA AR Bank #0033	**7.36E+07 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
OXA-48-*like* (OXA-48) (*Serratia marcescens*) GRE 1659004	**3.05E+07 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4-99.9%]**
	Negative (no analyte)	**Not Detected or N/A**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
vanA/B (*vanB*) (*Enterococcus faecalis*) ATCC 51299	**7.65E+08 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**N/A**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
VIM (VIM-4) (*Pseudomonas aeruginosa*) CDC-FDA AR Bank #0054	**7.22E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [97.0%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Yeast											
Candida albicans ATCC 90028	**1.76E+05 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4%-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Candida auris CDC-FDA AR Bank #0381	**3.49E+07 CFU/mL**	**Detected**	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	**59/60 (98.3%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**119/120 99.2% [95.4%-99.9%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Agreement with Expected Result								
			BIOFIRE 2.0				BIOFIRE Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Candida glabrata **ATCC 15545**	**3.82E+07 CFU/mL**	**Detected**	20/20 (100%)	18/20 (90.0%)	20/20 (100%)	**58/60 (96.7%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**118/120 98.3% [94.1%-99.8%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Candida krusei **ATCC 6258**	**2.48E+05 CFU/mL**	**Detected**	18/20 (90.0%)	20/20 (100%)	20/20 (100%)	**58/60 (96.7%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**118/120 98.3% [94.1%-99.8%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Candida parapsilosis **ATCC 34136**	**2.91E+05 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [99.4%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Candida tropicalis	**Negative (no analyte)**	**Not Detected**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	120/120 (100%)	120/120 (100%)	120/120 (100%)	**360/360 (100%)**	**720/720 100% [99.5%-100%]**
Cryptococcus neoformans/gattii **(*Cryptococcus neoformans*) ATCC MYA-4564**	**1.20E+07 CFU/mL**	**Detected**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	20/20 (100%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**120/120 100% [99.4%-100%]**
	Negative (no analyte)	**Not Detected**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	100/100 (100%)	100/100 (100%)	100/100 (100%)	**300/300 (100%)**	**600/600 100% [99.4%-100%]**
Overall Agreement with the Expected Results (All Analytes/All Test Concentrations) [95% Confidence Interval]			**5148/5160 99.8% [99.6%-99.9%]**	**5157/5160 99.9% [99.8%-99.9%]**	**5157/5160 99.9% [99.8%-99.9%]**	**15461/15480 99.9% [99.8%-99.9%]**	**5160/5160 100% [99.9%-100%]**	**5160/5160 100% [99.9%-100%]**	**5160/5160 100% [99.9%-100%]**	**15480/15480 100% [99.9%-100%]**	**30941/30960 99.94% [99.90%-99.96%]**

[a] *Staphylococcus* spp. data are from samples containing *Staphylococcus aureus, Staphylococcus epidermidis,* and *Staphylococcus lugdunensis* at the concentrations listed in their respective sections.

[b] *Streptococcus* spp. data are from samples containing *Streptococcus pneumoniae* and *Streptococcus pyogenes* at the concentrations listed in their respective sections.

[c] *Enterobacterales* data are from samples containing *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Proteus mirabilis, Salmonella enterica,* and *Serratia marcescens* at the concentrations listed in their respective sections.

[d] One replicate of the *mcr-1* test result was reported as N/A. For this replicate, the MCR-1 assay was positive, but an applicable bacterium was not detected.

Interference

Potentially interfering substances that could be present in blood culture specimens were evaluated for their effect on BIOFIRE BCID2 Panel performance. The substances tested included endogenous blood components (e.g. albumin, gamma-globulin, human genomic DNA), exogenous substances (e.g. prescribed or over-the-counter medications, blood anticoagulants, substances used to decontaminate or disinfect work areas, etc.), potentially competing commensal or infectious microorganisms, and various bottle/culture media.

Each substance was added to contrived samples containing representative panel organisms at concentrations near LoD (at least 10-fold lower than organism concentrations in a positive blood culture). The concentration of the substances or competing microorganisms added to the samples was equal to or greater than the highest level expected be in a blood culture.

Valid and accurate results were obtained for each sample containing endogenous and exogenous substances as well as various anticoagulants and disinfectants at the concentrations indicated in Table 133 (no interference).

Table 133. Endogenous Substances, Exogenous Substances, Anticoagulants, and Disinfectants Tested - No Interference Observed

Substance Tested	Reference Range in Whole Blood[a]	Concentration Expected in Positive Blood Culture[b]	Test Concentration
Endogenous Substances			
Albumin	35 – 52 mg/mL	7.0 – 10.4 mg/mL	15 mg/mL[c]
Bilirubin (unconjugated)	0.0 – 0.2 mg/mL	0.00 – 0.04 mg/mL	0.40 mg/mL
Cholesterol	<2.0 mg/mL	<0.4 mg/mL	4.0 mg/mL
Fibrinogen	1.6 – 4.3 mg/mL[d]	0.32 – 0.86 mg/mL	4.3 mg/mL
Gamma-globulin	7 – 16 mg/mL[e]	1.4 – 3.2 mg/mL	20 mg/mL
D-Glucose	0.74 – 1.00 mg/mL	0.15 – 0.20 mg/mL	10 mg/mL
Hemoglobin	<0.03 mg/mL	<0.006 mg/mL	10 mg/mL
Magnesium ($MgSO_4$)	0.017 – 0.024 mg/mL	0.0034 – 0.0048 mg/mL	0.1 mg/mL
Triglycerides	<1.50 mg/mL	<0.30 mg/mL	15 mg/mL
Human Genomic DNA (e.g. nucleic acids from white blood cells)	4.0E+06 – 1.0E+07 cells/mL	8.0E+05 – 2.0E+06 cells/mL	0.07 mg/mL (1.0E+07 cells/mL)[f]
Exogenous Substances			
Over-the-Counter Medications and Supplements			
Acetaminophen	0.052 mg/mL	0.0104 mg/mL	0.156 mg/mL
Salicylic Acid	9.52 µg/mL	1.90 µg/mL	28.6 µg/mL
Ibuprofen	0.073 mg/mL	0.015 mg/mL	0.219 mg/mL
Biotin (Vitamin B7)	1.71 µg/mL	0.342 µg/mL	3.51 µg/mL
Chemotherapeutics			
Ara-C Triphosphate[g] (active metabolite of Cytarabine)	C_{max} = 13.2 µg/mL[h]	C_{max} = 2.64 µg/mL	2.64 µg/mL[i]

Substance Tested	Test Concentration
Anticoagulants	
Sodium Citrate	4× the vacutainer-specific ratio (anticoagulant:blood)
K_2EDTA	4× the vacutainer-specific ratio (anticoagulant:blood)
K_3EDTA	4× the vacutainer-specific ratio (anticoagulant:blood)
Lithium Heparin	4× the vacutainer-specific ratio (anticoagulant:blood)
Sodium Heparin	4× the vacutainer-specific ratio (anticoagulant:blood)
Acid Citrate Dextrose (ACD)	4× the vacutainer-specific ratio (anticoagulant:blood)
Sodium Polyanetholesulfonate (SPS)	4× the vacutainer-specific ratio (anticoagulant:blood)
Disinfectants	
Bleach	5% v/v (3,000 ppm)
Ethanol	7% v/v
Povidone (iodinated)	1% v/v

[a] EP37: Supplemental Table for Interference Testing in Clinical Chemistry – First Edition (2018), unless otherwise noted.

[b] Calculated as a 5-fold dilution of the whole blood reference range (blood diluted in bottle media).

[c] Albumin testing was performed over a range of concentrations; an effect on detection near LoD was observed at >15 mg/mL.

[d] Wakeman, LJ et al, Fibrinogen reference range in adolescents. *Blood* 112, 4091 (2008).

[e] EP07: Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition (2018); values for IgG.

[f] Cells/mL calculated from mass and human genome size.

[g] Pyrimidine analog that inhibits DNA polymerase activity.

[h] Liston, D.R. & Davis, M. Clinically relevant concentrations of anticancer drugs: a guide for nonclinical studies. *Clin Cancer Research* 23, 3489-3498 (2017).

[i] 20% of C_{max} represents the maximum expected concentration of drug metabolite in blood (McEvoy, G.K. (ed.). American Hospital Formulary Service. AHFS Drug Information. American Society of Health-System Pharmacists, Bethesda, MD. 2007, p. 994).

Valid and accurate results were obtained for each sample spiked with the high concentrations of potentially competing microorganisms indicated in Table 134 (no interference).

Table 134. Competing Microorganisms Tested - No Interference Observed

Substance Tested	Test Concentration
On-Panel	
Staphylococcus epidermidis	8.78E+08 CFU/mL
Escherichia coli	1.38E+08 CFU/mL
Streptococcus mitis	6.95E+08 CFU/mL
Stenotrophomonas maltophilia	7.40E+08 CFU/mL
Bacteroides fragilis	5.40E+07 CFU/mL[a]
Off-Panel	
Corynebacterium jeikeium	8.70E+08 CFU/mL
Bacillus cereus	8.40E+08 CFU/mL
Micrococcus luteus	8.40E+08 CFU/mL
Clostridium perfringens	1.73E+08 cells/mL[a]
Cutibacterium (Propionibacterium) acnes	1.12E+07 cells/mL[a]

[a] Culture concentration in cells/mL determined via optical density (OD_{600}).

Valid and accurate results were obtained for each sample prepared in 1:1 (v/v) ratio with the various bottle/culture media (aerobic, anaerobic, pediatric, and myco media formulations) indicated in Table 135 (no interference).

Table 135. Blood Culture Media Tested - No Interference Observed

Bottle Type/Description		Bottle Media Tested
Aerobic	Standard aerobic	bioMérieux BACT/ALERT® SA
	Aerobic (with adsorbent polymeric beads)	bioMérieux BACT/ALERT® FA Plus
	Aerobic (with activated charcoal)[a]	bioMérieux BACT/ALERT® FA [a]
	Standard aerobic	BD BACTEC™ Standard/10 Aerobic/F
	Aerobic (with resin for antibiotic neutralization)	BD BACTEC™ Plus Aerobic/F
	Aerobic	Thermo Scientific™ VersaTrek™ REDOX™ 1
Anaerobic	Standard anaerobic	bioMérieux BACT/ALERT® SN
	Anaerobic (with adsorbent polymeric beads)	bioMérieux BACT/ALERT® FN Plus
	Anaerobic (with activated charcoal)[a]	bioMérieux BACT/ALERT® FN[a]
	Standard anaerobic	BD BACTEC™ Standard Anaerobic/F
	Anaerobic (with resin for antibiotic neutralization)	BD BACTEC™ Plus Anaerobic/F
	Lytic anaerobic	BD BACTEC™ Lytic/10 Anaerobic/F
	Anaerobic	Thermo Scientific™ VersaTrek™ REDOX™ 2
Pediatric	Pediatric (with adsorbent polymeric beads)	bioMérieux BACT/ALERT® PF Plus
	Pediatric (with activated charcoal)[a]	bioMérieux BACT/ALERT® PF[a]
	Pediatric (with resin for antibiotic neutralization)	BD BACTEC™ Peds Plus/F
Myco	Mycobacteria[b]	bioMérieux BACT/ALERT® MP[b]
	Mycobacteria and fungi	BD BACTEC™ Media Myco/F Lytic

[a] Bottles containing activated charcoal are not recommended for use with the BIOFIRE BCID2 Panel.

[b] Bottle is not intended for use with blood specimens.

NOTE: The BIOFIRE BCID2 Panel is not intended for testing of whole blood samples.

NOTE: The BIOFIRE BCID2 Panel is not intended for use with media containing charcoal or culture bottles containing body fluids/specimens other than blood.

NOTE: Avoid contact between samples and bleach prior to testing (bleach can damage nucleic acids).

APPENDIX A

Symbols Glossary

ISO 15223-1 Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied					
5.1.1 	Manufacturer	5.1.2 	Authorized representative in the European Community	5.1.4 	Use-By date (YYYY-MM-DD)
5.1.5 	Batch Code (Lot Number)	5.1.6 	Catalog Number	5.1.7 	Serial Number
5.2.8 	Do Not Use if Package Is Damaged	5.3.2 	Keep Away from Sunlight	5.3.7 	Temperature Limit
5.4.2 	Do Not Reuse	5.4.3 	Consult Instructions for Use	5.5.1 	In vitro Diagnostic Medical Device
5.5.5 	Contains Sufficient For <n> Tests	5.7.10 	Unique Device Identifier		
Use of Symbols in Labeling – 81 FR 38911, Docket No. (FDA-2013-N-0125)					
Rx Only	Prescription Use Only				
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC.10/30)					
	Serious eye damage, cat. 1		Acute toxicity, cat. 4 & Skin irritation, cat. 2		Acute aquatic hazard, cat.1 & Long-term aquatic hazard, cat.1
European In Vitro Diagnostic Regulation (IVDR 2017/746)			**UK Medical Devices Regulation 2002**		
	European Union Conformity		UKCA – UK Conformity Assessed		
Manufacturer Symbols (BioFire Diagnostics, LLC)					
	BIOFIRE BCID2 Panel		A panel in the BIOFIRE BCID Panel product family		
	European Union Product Importer				

APPENDIX B

Contact and Legal Information

Customer and Technical Support for U.S. Customers	
Reach Us on the Web http://www.biofiredx.com **Reach Us by E-mail** BioFireSupport@biomerieux.com **Reach Us by Mail** 515 Colorow Drive Salt Lake City, UT 84108 USA	**Reach Us by Phone** 1-800-735-6544 – Toll Free 1-801-736-6354 – Utah **Reach Us by Fax** 1-801-588-0507
Customer and Technical Support outside of the U.S.	
Contact the local bioMérieux sales representative or an authorized distributor for technical support.	

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108
USA

EC REP
Qarad EC-REP BV
Pas 257
B-2440 Geel, Belgium

EU
bioMérieux SA
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APPENDIX C

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REVISION HISTORY

Version	Revision Date	Description of Revision(s)
01	April 2020	Initial Release
02	June 2020	Update to: • Minor typographical errors caught after the release of the product • Table 8 to show *Enterobacterales* as Not Detected in last row (this was an error in the first revision) and minor wording changes for consistency and clarity. • Table 10 to show *Staphylococcus aureus* as Detected in last two rows (this was an error in the first revision). Addition of: • The BIOFIRE BCID2 Panel panel-specific pouch module software download link to first page.
03	July 2021	Update to: • Minor typographical errors • CE mark to include Notified Body # 2797 • Safety Precautions section to provide additional information and warnings on the Sample Buffer. Note: This information was previously only contained within the SDS. Addition of: • EUDAMED link to the EU Summary of Safety and Performance required for compliance to the European In Vitro Diagnostic Regulation (IVDR 2017/746) • Note for *Staphylococcus aureus mecA/C* and MREJ interpretation was added
04	June 2022	Additions: • UKCA Symbol to cover and symbols glossary • UKCA Authorized Rep Address added • UDI Symbol to symbols glossary • Additional Sample Buffer ampoule steps Update to: • EC updated to EU in front of importer information • Removal of volumes in materials provided section Removals: • "DO NOT REFRIGERATE" statement from the "Reagent Storage, Handling and Stability" section.
05	July 2023	Additions: • Ingredients statement added to the Materials Provided section Update to: • Updated classification of *Propionibacterium acnes* to *Cutibacterium (Propionbacterium) acnes* in Table 134. • Minor typographical errors • Customer Technical Support email • Branding • Summary of Organisms section updated for *Neisseria meningitidis* to address unencapsulated strains of *N. meningitidis*.

		• Limitations section to further point out that the BIOFIRE BCID2 Panel does not detect unencapsulated strains of *N. meningitidis*. (Previously mentioned as a note in Analytical Reactivity (Inclusivity) section

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