BIOMÉRIEUX

BIOFIRE® FILMARRAY®
LIS INTERFACE MAPPING GUIDE

BIOFIRE FILMARRAY 2.0 &
BIOFIRE FILMARRAY TORCH SYSTEMS

PIONEERING DIAGNOSTICS

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Document Revision History

Document Number	Revision Description	Release Date
BFR0001-2530-01	Initial release of the document.	2021-08-02
BFR0001-2530-02	Additional mapping instructions added for the BIOFIRE GI Panel Pouch due to availability of two different GI Panel v2.1 Pouch Modules. Example XML and HL7 test result messages added for each panel.	2022-02-16
BFR0001-2530-03	Mapping instructions plus example XML and HL7 test result messages added for the BIOFIRE JI Panel. Added note about HL7 escape character used in Pneumonia and Pneumonia *plus* panel results.	2022-06-30
BFR0001-2530-04	The BIOFIRE GI Panel v2.0.1 Pouch Module has been replaced with the BIOFIRE GI Panel v2.0.3 Pouch Module in Section 4 and in affected example XML and HL7 files. The BIOFIRE GI-NoCdiff Panel v2.0.100 Pouch Module has been replaced with the BIOFIRE GI-NoCdiff Panel v2.0.200 Pouch Module in Section 4 and in affected example XML and HL7 files.	2023-02-27
BFR0001-2530-05	Additional mapping instructions and example test result messages added for the BIOFIRE GI Panel Pouch due to availability of three different GI Panel v2.1 Pouch Modules. Specifically, the addition is for the GI Select Pouch Module. Additional observation type of run status and corresponding test results, as well as additional example test results messages, were added for each panel. Removed Respiratory Panel 1.7, Respiratory 2 Panel, and Respiratory 2 *plus* Panel.	2023-10-30
BFR0001-2530-06	Added mapping instructions for the GI Panel Mid v2.1. Updated mapping instructions for the BCID2 Panel section 2.7. Removed BCID Panel section.	2025-03-21
BFR0001-2530-07	Added mapping instructions for the TF Panel v1.0	2025-04-022

1. Using this Document

1.1. Purpose

The purpose of this document is to provide details on how information obtained from sample testing using a BIOFIRE Pouch is electronically reported to a connected information system. This document details codes applicable to all currently released BIOFIRE IVD tests, as relevant to the interface type supported.

1.2. Interface Overview

As an add-on to the system, the BIOFIRE® FILMARRAY® Link Software provides the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems with the ability to interface with a data manager (i.e., a laboratory information system or middleware) to electronically transfer test information. There are two supported implementations:

1. A unidirectional XML flat-file transfer or transfer of structured text from the BIOFIRE System to a data manager, referred to as the XML interface throughout this document, and
2. A unidirectional or bidirectional transfer of structured data sets from the BIOFIRE System to a data manager utilizing HL7 v2.5.1 based on the CLSI AUTO16 standard, referred to as the HL7 interface throughout this document.

Note that some of the information in this document may only directly apply to one interface, which will be indicated in the corresponding section.

Warning: In order to interface a BIOFIRE test with a data manager, the corresponding test Electronic Report Module (ERM) must be installed. ERM installation instructions can be found within the user guides associated with the BIOFIRE Link Software (refer to FLM2-PRT-0230: *BIOFIRE® FILMARRAY® 2.0 System LIS Interfacing User Guide* if using BIOFIRE 2.0 or HTFA-PRT-0057: *BIOFIRE® FILMARRAY® TORCH System LIS Interfacing User Guide* if using TORCH). The key code for downloading the ERM from the BIOFIRE e-labeling website can be found within the corresponding test section in this document.

1.3. Mapping by BIOFIRE Pouch Type

A BIOFIRE Pouch is a disposable testing pack allowing for sample testing on a specific BIOFIRE® FILMARRAY® Panel(s). Each BIOFIRE Panel is associated with a unique universal order identifier, a unique set of observations and results, and is cleared for use with a specific sample type(s).

The unique information associated with each currently released BIOFIRE Pouch can be found in the corresponding section for that pouch within this document. For each currently released pouch, the following information is provided within the section:

- Subsection 1 provides the name of the associated disposable testing pack (BIOFIRE Pouch).
- Subsection 2 provides the universal ID order codes for the associated BIOFIRE Panel(s) on the pouch.
- Subsection 3 provides the unique sample type(s) the BIOFIRE Pouch is cleared for use with.
- Subsection 4 provides the possible results that may be associated with each observation on the BIOFIRE Panel(s). Each result is associated with a result number, which is used to indicate if that

result is a possible result for the specific observations on the BIOFIRE Panel(s) (detailed in subsections 5 and 6).

For reference, all possible results and their corresponding result numbers are provided in Table

1.3.1. Note that not every possible result may be used by a BIOFIRE Pouch. Users should refer to subsections 5 and 6 for the respective BIOFIRE Pouch to see which possible results the observations on a BIOFIRE Pouch may be associated with.

Table 1.3.1: All Possible Observation Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
EQUIVOC	Equivocal	**3**
NOT_APPLICABLE	N/A	**4**
DETECT_BIN_10^4	Detected Bin 10^4 copies/mL	**5**
DETECT_BIN_10^5	Detected Bin 10^5 copies/mL	**6**
DETECT_BIN_10^6	Detected Bin 10^6 copies/mL	**7**
DETECT_BIN_10^7	Detected Bin >= 10^7 copies/mL	**8**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**
Conditionality		
		Result Number
Observation is conditionally reported, and may therefore not be present in the electronic report (*see relevant subsection 6 for conditional reporting conditions, if applicable*)		**150**

- Subsection 5 provides all of the possible observations for the panel(s), and which possible results each observation can be associated with. This includes observations of the following type:
    - **Targets**:
      The pathogens that the sample is being tested for.
    - **Run Status***:*
      An observation used to inform the status (success or failure) of the panel test.

- Subsection 6 provides any conditional reporting rules that may apply to the observations on the panel(s).
- Subsection 7 includes any notes that are associated with each panel. Each panel may be associated with warnings or notes that give additional information to help with interpretation of information on the report or indicate relevant actions a user should take.

1.4. Interpreting the Table Headers

Throughout this document, tables are used to indicate the properties for the information described in section 1.3. The types of header information that are used and their meanings are:

- **Code:** A unique string used to identify the property
- **Display Name:** A string used to identify the full name of the property, correlating to the code, as displayed in the BIOFIRE® FILMARRAY® Software
- **Coding System:** The scheme used to define the codes used
- **Result Number:** An identifier assigned to a specific result type
- **Reporting Condition:** Rules describing when properties are applicable
- **Comment:** A note, warning, or action that may be associated with the test

Note that throughout this document, a grayed-out cell means that the particular property is not applicable/supported or will require further interpretation (as noted in the cell).

The first column of each table is color-coded based on the corresponding BIOFIRE Panel to improve readability, as follows:

Color	Panel Family
	Blood Culture Identification
	Gastrointestinal
	Meningitis/Encephalitis
	Pneumonia
	Respiratory
	Joint Infection
	Tropical Fever

2. BIOFIRE BCID2 Panel Pouch

The BIOFIRE® Blood Culture Identification 2 (BCID2) Panel, run using a BCID2 Panel v1.0 pouch, is used to detect and discriminate pathogens found in blood culture, as well as select antibiotic resistance genes, of samples from individuals with signs or symptoms of pathogenic organisms in the blood stream.

An electronic report for the BIOFIRE BCID2 Panel contains information from a single test run using the BCID2 Panel v1.0 pouch.

The key code to download the BIOFIRE BCID2 Panel ERM from the e-labeling website is: **ITILIS17**

Note that the mapping instructions below are compatible with the BCID2 Panel v1.0 ERM, v1.0.1 and Pouch Module, v2.0.5 (or later versions). If using previous versions, these instructions may not be correct. We recommend updating to the latest ERM and Pouch Module versions before continuing.

2.1. BIOFIRE BCID2 Panel Disposable (Pouch)

The BIOFIRE BCID2 Panel is run using a pouch as the disposable, whose properties are indicated in Table 2.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 2.1.1: Disposable (Pouch)

Code	Display Name	Coding System
BCID2 Panel v1.0		99BMX

2.2. BIOFIRE BCID2 Panel Universal Service ID (Panel)

The BCID2 Panel v1.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 2.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 2.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
BCID2	BioFire Blood Culture Identification 2 (BCID2) Panel - IVD	99BMX

2.3. BIOFIRE BCID2 Panel Associated Sample Type(s)

The BCID2 Panel v1.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 2.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 2.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
BC	Blood Culture	99BMX

2.4. BIOFIRE BCID2 Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE BCID2 Panel are indicated in Table 2.4.1. Note that not every result in Table 2.4.1 will be associated with all of the BIOFIRE BCID2 Panel observations. Refer to section 2.5 and 2.6 to see which of the possible results each observation on the panel may be associated with.

Table 2.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
NOT_APPLICABLE	N/A	**4**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

2.5. BIOFIRE BCID2 Panel Possible Panel Observations

The BIOFIRE BCID2 Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE BCID2 Panel and their properties are indicated in Table 2.5.1.

Table 2.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 2.4.1)*	**Possible Result Code(s)** *(from Table 2.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 2.4.1)*	**Possible Result Code(s)** *(from Table 2.4.1)*
BC2x08001	CTX-M	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08002	IMP	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08003	KPC	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08004	mcr-1	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08005	mecA/C	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE

BC2x08006	mecA/C and MREJ (MRSA)	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08007	NDM	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08008	OXA-48-like	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08009	vanA/B	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x08010	VIM	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BC2x05001	Enterococcus faecalis	**1**	DETECT
		2	NOT_DETECT
BC2x05002	Enterococcus faecium	**1**	DETECT
		2	NOT_DETECT
BC2x05003	Listeria monocytogenes	**1**	DETECT
		2	NOT_DETECT
BC2x05004	Staphylococcus spp.	**1**	DETECT
		2	NOT_DETECT
BC2x05005	Staphylococcus aureus	**1**	DETECT
		2	NOT_DETECT
BC2x05006	Staphylococcus epidermidis	**1**	DETECT
		2	NOT_DETECT
BC2x05007	Staphylococcus lugdunensis	**1**	DETECT
		2	NOT_DETECT
BC2x05008	Streptococcus spp.	**1**	DETECT
		2	NOT_DETECT
BC2x05009	Streptococcus agalactiae (Group B)	**1**	DETECT
		2	NOT_DETECT
BC2x05010	Streptococcus pneumoniae	**1**	DETECT
		2	NOT_DETECT

BC2x05011	Streptococcus pyogenes (Group A)	**1**	DETECT
		2	NOT_DETECT
BC2x06001	Acinetobacter calcoaceticus-baumannii complex	**1**	DETECT
		2	NOT_DETECT
BC2x06002	Bacteroides fragilis	**1**	DETECT
		2	NOT_DETECT
BC2x06003	Enterobacterales	**1**	DETECT
		2	NOT_DETECT
BC2x06004	Enterobacter cloacae complex	**1**	DETECT
		2	NOT_DETECT
BC2x06005	Escherichia coli	**1**	DETECT
		2	NOT_DETECT
BC2x06006	Klebsiella aerogenes	**1**	DETECT
		2	NOT_DETECT
BC2x06007	Klebsiella oxytoca	**1**	DETECT
		2	NOT_DETECT
BC2x06008	Klebsiella pneumoniae group	**1**	DETECT
		2	NOT_DETECT
BC2x06009	Proteus spp.	**1**	DETECT
		2	NOT_DETECT
BC2x06010	Salmonella spp.	**1**	DETECT
		2	NOT_DETECT
BC2x06011	Serratia marcescens	**1**	DETECT
		2	NOT_DETECT
BC2x06012	Haemophilus influenzae	**1**	DETECT
		2	NOT_DETECT
BC2x06013	Neisseria meningitidis	**1**	DETECT
		2	NOT_DETECT
BC2x06014	Pseudomonas aeruginosa	**1**	DETECT
		2	NOT_DETECT
BC2x06015	Stenotrophomonas maltophilia	**1**	DETECT
		2	NOT_DETECT
BC2x07001	Candida albicans	**1**	DETECT
		2	NOT_DETECT

	BC2x07002	Candida auris	**1**	DETECT
			2	NOT_DETECT
	BC2x07003	Candida glabrata	**1**	DETECT
			2	NOT_DETECT
	BC2x07004	Candida krusei	**1**	DETECT
			2	NOT_DETECT
	BC2x07005	Candida parapsilosis	**1**	DETECT
			2	NOT_DETECT
	BC2x07006	Candida tropicalis	**1**	DETECT
			2	NOT_DETECT
	BC2x07007	Cryptococcus neoformans/gattii	**1**	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

2.6. BIOFIRE BCID2 Panel Observation Conditional Reporting

There are no observations on the BIOFIRE BCID2 Panel that are conditionally reported on the electronic report, as indicated in section 2.5 and Table 2.6.1.

Table 2.6.1: Conditional Reporting

	Observation Display Name *(from Table 2.5.1)*	**Result Display Name** *(from Table 2.4.1)*	**Reporting Condition**

2.7. BIOFIRE BCID2 Panel Warnings and Notes

The BIOFIRE BCID2 Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE BCID2 Panel are indicated in Table 2.7.1.

Note, that for BCID2, each comment below will be concatenated together into a single string. Each comment will be prepended with "[Text]" to identify the start of a unique comment.

Table 2.7.1: Test Notes

	Comment	Reporting Condition
	[Text] 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.	This note is always included in the electronic report.
	[Text] Note: All BIOFIRE BCID2 Panel results are intended to be interpreted in conjunction with Gram stain results. In some cases, the Gram stain result and the BIOFIRE BCID2 Panel result may be discrepant. In these cases, the BIOFIRE BCID2 Panel results should be confirmed, e.g., by culture or other laboratory, epidemiological, or clinical findings. Blood culture media may contain non-viable organisms and/or nucleic acids that may lead to false positive BIOFIRE BCID2 Panel results. Typically, these false positives present with more than one positive result from the BIOFIRE BCID2 Panel.	This note is always included in the electronic report.

3. BIOFIRE GI Panel Pouch

The BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel, run using a GI Panel v2.1 pouch, is used to detect and discriminate pathogens found in stool samples from individuals with signs or symptoms of pathogenic organisms in the GI tract.

An electronic report for the BIOFIRE GI Panel contains information from a single test run using the GI Panel v2.1 pouch.

The key code to download the BIOFIRE GI Panel ERM from the e-labeling website is: **ITILIS29**

3.1. BIOFIRE GI Panel Disposable (Pouch)

The BIOFIRE GI Panel is run using a pouch as the disposable, whose properties are indicated in Table 3.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 3.1.1: Disposable (Pouch)

Code	Display Name	Coding System
GI Panel v2.1		99BMX

3.2. BIOFIRE GI Panel Universal Service ID (Panel)

The GI Panel v2.1 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 3.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 3.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
GI	GI Panel	99BMX

3.3. BIOFIRE GI Panel Associated Sample Type(s)

The GI Panel v2.1 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 3.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 3.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
STO	Stool	99BMX

3.4. BIOFIRE GI Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE GI Panel are indicated in Table 3.4.1. Note that not every result in Table 3.4.1 will be associated with all of the BIOFIRE GI Panel observations. Refer to section 3.5 and 3.6 to see which of the possible results each observation on the panel may be associated with.

Table 3.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**
Conditionality		
		Result Number
Observation is conditionally reported, and may therefore not be present in the electronic report (*see section 3.6 for conditional reporting conditions, if applicable*)		**150**

3.5. BIOFIRE GI Panel Possible Panel Observations

The BIOFIRE GI Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE GI Panel and their properties are indicated in Table 3.5.1.

Table 3.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 3.4.1)*	**Possible Result Code(s)** *(from Table 3.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE

		204	INV_RI

Target Observations
Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)

Code	Display Name	Possible Result Number(s) *(from Table 3.4.1)*	Possible Result Code(s) *(from Table 3.4.1)*
PCR_CAMPHY	Campylobacter	1	DETECT
		2	NOT_DETECT
PCR_CLODIF_TAB	Clostridium difficile toxin A/B	1	DETECT
		2	NOT_DETECT
		150	*see section 3.6 for conditional reporting of this observation
PCR_PLESHI	Plesiomonas shigelloides	1	DETECT
		2	NOT_DETECT
PCR_SALMON	Salmonella	1	DETECT
		2	NOT_DETECT
PCR_VIBRIO	Vibrio	1	DETECT
		2	NOT_DETECT
PCR_VIBCHO	Vibrio cholerae	1	DETECT
		2	NOT_DETECT
PCR_YERENT	Yersinia enterocolitica	1	DETECT
		2	NOT_DETECT
PCR_EAEC	Enteroaggregative E. coli (EAEC)	1	DETECT
		2	NOT_DETECT
PCR_EPEC	Enteropathogenic E. coli (EPEC)	1	DETECT
		2	NOT_DETECT
		150	*see section 3.6 for conditional reporting of this observation
PCR_ETEC_LTST	Enterotoxigenic E. coli (ETEC) lt/st	1	DETECT
		2	NOT_DETECT
PCR_STEC_STX12	Shiga-like toxin-producing E. coli (STEC) stx1/stx2	1	DETECT
		2	NOT_DETECT
PCR_ESCCOL_O157	E. coli O157	1	DETECT
		2	NOT_DETECT
		150	*see section 3.6 for conditional reporting of this observation

	PCR_EIEC	Shigella/Enteroinvasive E. coli (EIEC)	**1**	DETECT
			2	NOT_DETECT
	PCR_CRYPTO	Cryptosporidium	**1**	DETECT
			2	NOT_DETECT
	PCR_CYCCAY	Cyclospora cayetanensis	**1**	DETECT
			2	NOT_DETECT
	PCR_ENTHIS	Entamoeba histolytica	**1**	DETECT
			2	NOT_DETECT
	PCR_GIALAM	Giardia lamblia	**1**	DETECT
			2	NOT_DETECT
	PCR_ADENOV_F4041	Adenovirus F 40/41	**1**	DETECT
			2	NOT_DETECT
	PCR_ASTROV	Astrovirus	**1**	DETECT
			2	NOT_DETECT
	PCR_NOROV_GIGII	Norovirus GI/GII	**1**	DETECT
			2	NOT_DETECT
	PCR_ROTAV_A	Rotavirus A	**1**	DETECT
			2	NOT_DETECT
	PCR_SAPOV	Sapovirus	**1**	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

3.6. BIOFIRE GI Panel Observation Conditional Reporting

Some observations on the BIOFIRE GI Panel are conditionally reported on the electronic report, as indicated in section 3.5. The reporting conditions for conditionally reported observations on the BIOFIRE GI Panel are indicated in Table 3.6.1.

Table 3.6.1: Conditional Reporting

Observation Display Name *(from Table 3.5.1)*	Result Display Name *(from Table 3.4.1)*	Reporting Condition
Enteropathogenic E. coli (EPEC)	Detected	This observation is included in the electronic report if: • Enteropathogenic E. coli (EPEC) organism is Detected **AND** • Shiga-like toxin-producing E. coli (STEC) stx1/stx2 organism is Not Detected
	Not Detected	This observation is included in the electronic report if: • Enteropathogenic E. coli (EPEC) organism is Not Detected **AND** • Shiga-like toxin-producing E. coli (STEC) stx1/stx2 organism is Not Detected
		Otherwise, this observation is **not** included in the electronic report.
E. coli O157	Detected	This observation is included in the electronic report if: • E. coli O157 organism is Detected **AND** • Shiga-like toxin-producing E. coli (STEC) stx1/stx2 organism is Detected
	Not Detected	This observation is included in the electronic report if: • E. coli O157 organism is Not Detected **AND** • Shiga-like toxin-producing E. coli (STEC) stx1/stx2 organism is Detected
		Otherwise, this observation is **not** included in the electronic report.

	Clostridium difficile toxin A/B	Detected	This observation is included in the electronic report if: • Clostridium difficile toxin A/B organism is Detected **AND** • GI Panel v2.1 Pouch Module, v2.0.3 is used
			This observation is included in the electronic report if: • Clostridium difficile toxin A/B organism is Detected **AND** • FilmArray Software settings are toggled to report Clostridium difficile toxin A/B **AND** • GI Select Panel v2.1 Pouch Module, v2.1.0 is used
		Not Detected	This observation is included in the electronic report if: • Clostridium difficile toxin A/B organism is Not Detected **AND** • GI Panel v2.1 Pouch Module, v2.0.3 is used
			This observation is included in the electronic report if: • Clostridium difficile toxin A/B organism is Not Detected **AND** • FilmArray Software settings are toggled to report Clostridium difficile toxin A/B **AND** • GI Select Panel v2.1 Pouch Module, v2.1.0 is used
			This observation is **not** included in the electronic report if: • GI-NoCdiff Panel v2.1 Pouch Module, v2.0.200 is used
			This observation is included in the electronic report if: • FilmArray Software settings are toggled *not* to report Clostridium difficile toxin A/B **AND** • GI Select Panel v2.1 Pouch Module, v2.1.0 is used

3.7. BIOFIRE GI Panel Warnings and Notes

The BIOFIRE GI Panel is not associated with warnings and notes that give additional information to help with interpretation of the information on the report, as indicated in Table 3.7.1.

Table 3.7.1: Test Notes

	Comment	Reporting Condition

4. BIOFIRE GI Panel Mid Pouch

The BIOFIRE® FILMARRAY® Gastrointestinal Panel Mid (GI Mid), run using a GI Panel Mid v2.1 pouch, is used to detect and identify nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection.

An electronic report for the BIOFIRE GI Panel Mid contains information from a single test run using the GI Panel Mid v2.1 pouch.

The key code to download the BIOFIRE GI Panel ERM from the e-labeling website is: **ITILIS61**

4.1. BIOFIRE GI Panel Mid Panel Disposable (Pouch)

The BIOFIRE GI Panel Mid is run using a pouch as the disposable, whose properties are indicated in Table 4.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 4.1.1: Disposable (Pouch)

Code	Display Name	Coding System
GI Panel Mid v2.1		99BMX

4.2. BIOFIRE GI Panel Mid Universal Service ID (Panel)

The GI Panel Mid v2.1 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 4.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 4.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
GIMID	GI Panel Mid	99BMX

4.3. BIOFIRE GI Panel Mid Associated Sample Type(s)

The GI Panel Mid v2.1 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 4.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 4.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
STO	Stool	99BMX

4.4. BIOFIRE GI Panel Mid Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE GI Panel Mid are indicated in Table 4.4.1. Note that not every result in Table 4.4.1 will be associated with all of the BIOFIRE GI Panel Mid observations. Refer to section 4.5 and 4.6 to see which of the possible results each observation on the panel may be associated with.

Table 4.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**
Conditionality		
		Result Number
Observation is conditionally reported, and may therefore not be present in the electronic report (*see section 4.6 for conditional reporting conditions, if applicable*)		**150**

4.5. BIOFIRE GI Panel Mid Possible Panel Observations

The BIOFIRE GI Panel Mid tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE GI Panel Mid and their properties are indicated in Table 4.5.1.

Table 4.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 4.4.1)*	**Possible Result Code(s)** *(from Table 4.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE

		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 4.4.1)*	**Possible Result Code(s)** *(from Table 4.4.1)*
GIMx02001	Campylobacter (C. jejuni/C. coli/C. upsaliensis)	**1**	DETECT
		2	NOT_DETECT
GIMx02002	Clostridioides (Clostridium) difficile (toxin A/B)	**1**	DETECT
		2	NOT_DETECT
		150	*see section 4.6 for conditional reporting of this observation
GIMx02003	Salmonella	**1**	DETECT
		2	NOT_DETECT
GIMx02004	Shiga-like toxin-producing E. coli (STEC) stx1/stx2	**1**	DETECT
		2	NOT_DETECT
GIMx02005	Shigella/Enteroinvasive E. coli (EIEC)	**1**	DETECT
		2	NOT_DETECT
GIMx02006	Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)	**1**	DETECT
		2	NOT_DETECT
GIMx02007	Yersinia enterocolitica	**1**	DETECT
		2	NOT_DETECT
GIMx04001	Cryptosporidium	**1**	DETECT
		2	NOT_DETECT
GIMx04002	Cyclospora cayetanensis	**1**	DETECT
		2	NOT_DETECT
GIMx04003	Giardia lamblia	**1**	DETECT
		2	NOT_DETECT
GIMx01001	Norovirus GI/GII	**1**	DETECT
		2	NOT_DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

4.6. BIOFIRE GI Panel Mid Observation Conditional Reporting

Some observations on the BIOFIRE GI Panel Mid are conditionally reported on the electronic report, as indicated in section 4.5. The reporting conditions for conditionally reported observations on the BIOFIRE GI Panel Mid are indicated in Table 4.6.1.

Table 4.6.1: Conditional Reporting

Observation Display Name *(from Table 4.5.1)*	Result Display Name *(from Table 4.4.1)*	Reporting Condition
Clostridioides (Clostridium) difficile (toxin A/B)	Detected	This observation is included in the electronic report if: • Clostridioides (Clostridium) difficile (toxin A/B) organism is Detected **AND** • FilmArray Software settings are toggled to report Clostridioides (Clostridium) difficile (toxin A/B)
	Not Detected	This observation is included in the electronic report if: • Clostridioides (Clostridium) difficile (toxin A/B) organism is Not Detected **AND** • FilmArray Software settings are toggled to report Clostridioides (Clostridium) difficile (toxin A/B)
		This observation is included in the electronic report if: • FilmArray Software settings are toggled *not* to report Clostridioides (Clostridium) difficile (toxin A/B)

4.7. BIOFIRE GI Panel Mid Warnings and Notes

The BIOFIRE GI Panel Mid is not associated with warnings and notes that give additional information to help with interpretation of the information on the report, as indicated in Table 4.7.1.

Table 4.7.1: Test Notes

Comment	Reporting Condition

5. BIOFIRE ME Panel Pouch

The BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel, run using an ME Panel v1.4 pouch, is used detect and discriminate pathogens found in cerebrospinal fluid (CSF) samples from individuals with signs or symptoms of pathogenic organisms in the brain and spine.

An electronic report for the BIOFIRE ME Panel contains information from a single test run using the ME Panel v1.4 pouch.

The key code to download the BIOFIRE ME Panel ERM from the e-labeling website is: **ITILIS14**

5.1. BIOFIRE ME Panel Disposable (Pouch)

The BIOFIRE ME Panel is run using a pouch as the disposable, whose properties are indicated in Table 5.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 5.1.1: Disposable (Pouch)

Code	Display Name	Coding System
ME Panel v1.4		99BMX

5.2. BIOFIRE ME Panel Universal Service ID (Panel)

The ME Panel v1.4 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 5.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 5.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
ME	Meningitis / Encephalitis (ME) Panel - IVD	99BMX

5.3. BIOFIRE ME Panel Associated Sample Type(s)

The ME Panel v1.4 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 5.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 5.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
CSF	Cerebral Spinal Fluid	99BMX

5.4. BIOFIRE ME Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE ME Panel are indicated in Table 5.4.1. Note that not every result in Table 5.4.1 will be associated with all of the BIOFIRE ME Panel observations. Refer to section 5.5 and 5.6 to see which of the possible results each observation on the panel may be associated with.

Table 5.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

5.5. BIOFIRE ME Panel Possible Panel Observations

The BIOFIRE ME Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE ME Panel and their properties are indicated in Table 5.5.1.

Table 5.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 5.4.1)*	**Possible Result Code(s)** *(from Table 5.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			

Code	Display Name	Possible Result Number(s) *(from Table 5.4.1)*	Possible Result Code(s) *(from Table 5.4.1)*
PCR_ESCCOL_K1	Escherichia coli K1	**1**	DETECT
		2	NOT_DETECT
PCR_HAEINF	Haemophilus influenzae	**1**	DETECT
		2	NOT_DETECT
PCR_LISMOC	Listeria monocytogenes	**1**	DETECT
		2	NOT_DETECT
PCR_NEIMEN	Neisseria meningitidis	**1**	DETECT
		2	NOT_DETECT
PCR_STRAGA	Streptococcus agalactiae	**1**	DETECT
		2	NOT_DETECT
PCR_STRPNE	Streptococcus pneumoniae	**1**	DETECT
		2	NOT_DETECT
PCR_CMV	Cytomegalovirus	**1**	DETECT
		2	NOT_DETECT
PCR_ENTEROV	Enterovirus	**1**	DETECT
		2	NOT_DETECT
PCR_HSV_1	Herpes simplex virus 1	**1**	DETECT
		2	NOT_DETECT
PCR_HSV_2	Herpes simplex virus 2	**1**	DETECT
		2	NOT_DETECT
PCR_H_HV_6	Human herpesvirus 6	**1**	DETECT
		2	NOT_DETECT
PCR_H_PEV	Human parechovirus	**1**	DETECT
		2	NOT_DETECT
PCR_VZV	Varicella zoster virus	**1**	DETECT
		2	NOT_DETECT
PCR_CRYPTO_NEO_GAT	Cryptococcus neoformans/gattii	**1**	DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

5.6. BIOFIRE ME Panel Observation Conditional Reporting

There are no observations on the BIOFIRE ME Panel that are conditionally reported on the electronic report, as indicated in section 5.5 and Table 5.6.1.

Table 5.6.1: Conditional Reporting

Observation Display Name *(from Table 5.5.1)*	Result Display Name *(from Table 5.4.1)*	Reporting Condition

5.7. BIOFIRE ME Panel Warnings and Notes

The BIOFIRE ME Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE ME Panel are indicated in Table 5.7.1.

Table 5.7.1: Test Notes

Comment	Reporting Condition
Warning: The FilmArray ME Panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory, and epidemiological information.	This note is included in the electronic report if either of the following organisms are Detected: • Cytomegalovirus • Human herpesvirus 6 Otherwise, this note is **not** included in the electronic report.

6. BIOFIRE Pneumonia Panel Pouch

The BIOFIRE® FILMARRAY® Pneumonia Panel, run using a Pneumo v2.0 pouch, is used to detect and discriminate pathogens found in sputum (SPU) and bronchoalveolar lavage (BAL) samples from individuals with signs or symptoms of lower respiratory tract infection.

An electronic report for the BIOFIRE Pneumonia Panel contains information from a single test run using the Pneumo v2.0 pouch.

The key code to download the BIOFIRE Pneumonia Panel ERM from the e-labeling website is: **ITILIS04**

6.1. BIOFIRE Pneumonia Panel Disposable (Pouch)

The BIOFIRE Pneumonia Panel is run using a pouch as the disposable, whose properties are indicated in Table 6.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 6.1.1: Disposable (Pouch)

Code	Display Name	Coding System
Pneumo v2.0		99BMX

6.2. BIOFIRE Pneumonia Panel Universal Service ID (Panel)

The Pneumo v2.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 6.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 6.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
Pneumo	Pneumonia Panel - IVD	99BMX

6.3. BIOFIRE Pneumonia Panel Associated Sample Type(s)

The Pneumo v2.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 6.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 6.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
BAL	Bronchoalveolar Lavage	99BMX
SPU	Sputum	99BMX

6.4. BIOFIRE Pneumonia Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE Pneumonia Panel are indicated in Table 6.4.1. Note that not every result in Table 6.4.1 will be associated with all of the BIOFIRE Pneumonia Panel observations. Refer to section 6.5 and 6.6 to see which of the possible results each observation on the panel may be associated with.

Table 6.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
NOT_APPLICABLE	N/A	**4**
DETECT_BIN_10^4	Detected Bin 10^4 copies/mL	**5**
DETECT_BIN_10^5	Detected Bin 10^5 copies/mL	**6**
DETECT_BIN_10^6	Detected Bin 10^6 copies/mL	**7**
DETECT_BIN_10^7	Detected Bin >= 10^7 copies/mL	**8**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

Note: In HL7, the ^ character used in Codes and Display Names is represented using an escape character of \S\ (e.g., DETECT_BIN_10^4 will come across as DETECT_BIN_10\S\4).

6.5. BIOFIRE Pneumonia Panel Possible Panel Observations

The BIOFIRE Pneumonia Panel tests for a set of observations based on a specific syndrome. The BIOFIRE Pneumonia Panel can be run using either a BAL or Sputum sample type, which is indicated in the run by selecting a protocol. The electronic report distinguishes the observation properties based on the protocol that was run for the test.

The observations on the BIOFIRE Pneumonia Panel, run using the BAL v3.3 protocol (for the BAL sample type), and their properties are indicated in Table 6.5.1.

The observations on the BIOFIRE Pneumonia Panel, run using the Sputum v3.3 protocol (for the Sputum sample type), and their properties are indicated in Table 6.5.2.

Table 6.5.1: Panel Observations (BAL Protocol)

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 6.4.1)*	**Possible Result Code(s)** *(from Table 6.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 6.4.1)*	**Possible Result Code(s)** *(from Table 6.4.1)*
BAL_ACIBAU	Acinetobacter calcoaceticus-baumannii complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_ENTCLOC	Enterobacter cloacae complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_ECOLI	Escherichia coli	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_HAEINF	Haemophilus influenzae	**2**	NOT_DETECT

		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_KLAERO	Klebsiella aerogenes	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_KLEOXY	Klebsiella oxytoca	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_KLEPNEG	Klebsiella pneumoniae group	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_MORCAT	Moraxella catarrhalis	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_PROTSP	Proteus spp.	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_PSEAER	Pseudomonas aeruginosa	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_SERMAR	Serratia marcescens	**2**	NOT_DETECT

			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STAAUR	Staphylococcus aureus	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRAGA	Streptococcus agalactiae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRPNE	Streptococcus pneumoniae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRPYO	Streptococcus pyogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_CTXM	CTX-M	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_IMP	IMP	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_KPC	KPC	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_MECA_MREJ	mecA/C and MREJ	**1**	DETECT
			2	NOT_DETECT

			4	NOT_APPLICABLE
	BAL_NDM	NDM	1	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_OXA48	OXA-48-like	1	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_VIM	VIM	1	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_CHLPNE	Chlamydia pneumoniae	1	DETECT
			2	NOT_DETECT
	BAL_LEGPNE	Legionella pneumophila	1	DETECT
			2	NOT_DETECT
	BAL_MYCPNE	Mycoplasma pneumoniae	1	DETECT
			2	NOT_DETECT
	BAL_ADENOV	Adenovirus	1	DETECT
			2	NOT_DETECT
	BAL_CORONAV	Coronavirus	1	DETECT
			2	NOT_DETECT
	BAL_H_METAPN	Human Metapneumovirus	1	DETECT
			2	NOT_DETECT
	BAL_H_RHI_ENT	Human Rhinovirus/Enterovirus	1	DETECT
			2	NOT_DETECT
	BAL_INFV_A	Influenza A	1	DETECT
			2	NOT_DETECT
	BAL_INFV_B	Influenza B	1	DETECT
			2	NOT_DETECT
	BAL_PARINFV	Parainfluenza Virus	1	DETECT
			2	NOT_DETECT
	BAL_RSV	Respiratory Syncytial Virus	1	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

Table 6.5.2: Panel Observations (Sputum Protocol)

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 6.4.1)*	**Possible Result Code(s)** *(from Table 6.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 6.4.1)*	**Possible Result Code(s)** *(from Table 6.4.1)*
SPU_ACIBAU	Acinetobacter calcoaceticus-baumannii complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
SPU_ENTCLOC	Enterobacter cloacae complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
SPU_ECOLI	Escherichia coli	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
SPU_HAEINF	Haemophilus influenzae	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5

			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLAERO	Klebsiella aerogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLEOXY	Klebsiella oxytoca	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLEPNEG	Klebsiella pneumoniae group	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_MORCAT	Moraxella catarrhalis	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_PROTSP	Proteus spp.	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_PSEAER	Pseudomonas aeruginosa	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_SERMAR	Serratia marcescens	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5

			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STAAUR	Staphylococcus aureus	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRAGA	Streptococcus agalactiae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRPNE	Streptococcus pneumoniae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRPYO	Streptococcus pyogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_CTXM	CTX-M	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	SPU_IMP	IMP	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	SPU_KPC	KPC	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	SPU_MECA_MREJ	mecA/C and MREJ	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	SPU_NDM	NDM	**1**	DETECT

		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_OXA48	OXA-48-like	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_VIM	VIM	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_CHLPNE	Chlamydia pneumoniae	**1**	DETECT
		2	NOT_DETECT
SPU_LEGPNE	Legionella pneumophila	**1**	DETECT
		2	NOT_DETECT
SPU_MYCPNE	Mycoplasma pneumoniae	**1**	DETECT
		2	NOT_DETECT
SPU_ADENOV	Adenovirus	**1**	DETECT
		2	NOT_DETECT
SPU_CORONAV	Coronavirus	**1**	DETECT
		2	NOT_DETECT
SPU_H_METAPN	Human Metapneumovirus	**1**	DETECT
		2	NOT_DETECT
SPU_H_RHI_ENT	Human Rhinovirus/Enterovirus	**1**	DETECT
		2	NOT_DETECT
SPU_INFV_A	Influenza A	**1**	DETECT
		2	NOT_DETECT
SPU_INFV_B	Influenza B	**1**	DETECT
		2	NOT_DETECT
SPU_PARINFV	Parainfluenza Virus	**1**	DETECT
		2	NOT_DETECT
SPU_RSV	Respiratory Syncytial Virus	**1**	DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

6.6. BIOFIRE Pneumonia Panel Observation Conditional Reporting

There are no observations on the BIOFIRE Pneumonia Panel that are conditionally reported on the electronic report, as indicated in section 6.5 and Table 6.6.1.

Table 6.6.1: Conditional Reporting

	Observation Display Name *(from Table 6.5.1)*	Result Display Name *(from Table 6.4.1)*	Reporting Condition

6.7. BIOFIRE Pneumonia Panel Warnings and Notes

The BIOFIRE Pneumonia Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE Pneumonia Panel are indicated in Table 6.7.1.

Table 6.7.1: Test Notes

Comment	Reporting Condition
Note: Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the FilmArray Pneumonia Panel are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.	This note is included in the electronic report if any of the following organisms are detected: • Acinetobacter calcoaceticus-baumannii complex • Enterobacter cloacae complex • Escherichia coli • Haemophilus influenza • Klebsiella aerogenes • Klebsiella oxytoca • Klebsiella pneumoniae group • Moraxella catarrhalis • Proteus spp. • Pseudomonas aeruginosa • Serratia marcescens • Staphylococcus aureus • Streptococcus agalactiae • Streptococcus pneumonia • Streptococcus pyogenes Otherwise, this note is **not** included in the electronic report.
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 FilmArray Pneumonia Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.	This note is always included in the electronic report.

7. BIOFIRE Pneumonia *plus* Panel Pouch

The BIOFIRE® FILMARRAY® Pneumonia *plus* Panel, run using a Pneumoplus v2.0 pouch, is used to detect and discriminate pathogens found in sputum (SPU) and bronchoalveolar lavage (BAL) samples from individuals with signs or symptoms of lower respiratory tract infection.

An electronic report for the BIOFIRE Pneumonia *plus* Panel contains information from a single test run using the Pneumoplus v2.0 pouch.

The key code to download the BIOFIRE Pneumonia *plus* Panel ERM from the e-labeling website is: **ITILIS15**

7.1. BIOFIRE Pneumonia *plus* Panel Disposable (Pouch)

The BIOFIRE Pneumonia *plus* Panel is run using a pouch as the disposable, whose properties are indicated in Table 7.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 7.1.1: Disposable (Pouch)

Code	Display Name	Coding System
Pneumoplus v2.0		99BMX

7.2. BIOFIRE Pneumonia *plus* Panel Universal Service ID (Panel)

The Pneumoplus v2.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 7.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 7.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
Pneumoplus	Pneumonia Panel plus - IVD	99BMX

7.3. BIOFIRE Pneumonia *plus* Panel Associated Sample Type(s)

The Pneumoplus v2.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 7.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 7.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
BAL	Bronchoalveolar Lavage	99BMX
SPU	Sputum	99BMX

7.4. BIOFIRE Pneumonia *plus* Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE Pneumonia *plus* Panel are indicated in Table 7.4.1. Note that not every result in Table 7.4.1 will be associated with all of the BIOFIRE Pneumonia *plus* Panel observations. Refer to section 7.5 and 7.6 to see which of the possible results each observation on the panel may be associated with.

Table 7.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
EQUIVOC	Equivocal	**3**
NOT_APPLICABLE	N/A	**4**
DETECT_BIN_10^4	Detected Bin 10^4 copies/mL	**5**
DETECT_BIN_10^5	Detected Bin 10^5 copies/mL	**6**
DETECT_BIN_10^6	Detected Bin 10^6 copies/mL	**7**
DETECT_BIN_10^7	Detected Bin >= 10^7 copies/mL	**8**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

Note: In HL7, the ^ character used in Codes and Display Names is represented using an escape character of \S\ (e.g., DETECT_BIN_10^4 will come across as DETECT_BIN_10\S\4).

7.5. BIOFIRE Pneumonia *plus* Panel Possible Panel Observations

The BIOFIRE Pneumonia *plus* Panel tests for a set of observations based on a specific syndrome. The BIOFIRE Pneumonia *plus* Panel can be run using either a BAL or Sputum sample type, which is indicated in the run by selecting a protocol. The electronic report distinguishes the observation properties based on the protocol that was run for the test.

The observations on the BIOFIRE Pneumonia *plus* Panel, run using the BAL v3.3 protocol (for the BAL sample type), and their properties are indicated in Table 7.5.1.

The observations on the BIOFIRE Pneumonia *plus* Panel, run using the Sputum v3.3 protocol (for the Sputum sample type), and their properties are indicated in Table 7.5.2.

Table 7.5.1: Panel Observations (BAL Protocol)

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 7.4.1)*	**Possible Result Code(s)** *(from Table 7.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 7.4.1)*	**Possible Result Code(s)** *(from Table 7.4.1)*
BAL_ACIBAU	Acinetobacter calcoaceticus-baumannii complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
BAL_ENTCLOC	Enterobacter cloacae complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5

			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_ECOLI	Escherichia coli	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_HAEINF	Haemophilus influenzae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_KLAERO	Klebsiella aerogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_KLEOXY	Klebsiella oxytoca	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_KLEPNEG	Klebsiella pneumoniae group	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_MORCAT	Moraxella catarrhalis	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_PROTSP	Proteus spp.	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5

			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_PSEAER	Pseudomonas aeruginosa	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_SERMAR	Serratia marcescens	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STAAUR	Staphylococcus aureus	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRAGA	Streptococcus agalactiae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRPNE	Streptococcus pneumoniae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_STRPYO	Streptococcus pyogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	BAL_CTXM	CTX-M	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE

	BAL_IMP	IMP	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_KPC	KPC	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_MECA_MREJ	mecA/C and MREJ	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_NDM	NDM	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_OXA48	OXA-48-like	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_VIM	VIM	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	BAL_CHLPNE	Chlamydia pneumoniae	**1**	DETECT
			2	NOT_DETECT
	BAL_LEGPNE	Legionella pneumophila	**1**	DETECT
			2	NOT_DETECT
	BAL_MYCPNE	Mycoplasma pneumoniae	**1**	DETECT
			2	NOT_DETECT
	BAL_ADENOV	Adenovirus	**1**	DETECT
			2	NOT_DETECT
	BAL_CORONAV	Coronavirus	**1**	DETECT
			2	NOT_DETECT
	BAL_H_METAPN	Human Metapneumovirus	**1**	DETECT
			2	NOT_DETECT
	BAL_H_RHI_ENT	Human Rhinovirus/Enterovirus	**1**	DETECT
			2	NOT_DETECT
	BAL_INFV_A	Influenza A	**1**	DETECT
			2	NOT_DETECT
	BAL_INFV_B	Influenza B	**1**	DETECT

		2	NOT_DETECT
BAL_MERSC	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	**1**	DETECT
		2	NOT_DETECT
BAL_PARINFV	Parainfluenza Virus	**1**	DETECT
		2	NOT_DETECT
BAL_RSV	Respiratory Syncytial Virus	**1**	DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

Table 7.5.2: Panel Observations (Sputum Protocol)

Run Status Observation

Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)

Code	Display Name	Possible Result Number(s) *(from Table 7.4.1)*	Possible Result Code(s) *(from Table 7.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI

Target Observations

Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)

Code	Display Name	Possible Result Number(s) *(from Table 7.4.1)*	Possible Result Code(s) *(from Table 7.4.1)*
SPU_ACIBAU	Acinetobacter calcoaceticus-baumannii complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6
		8	DETECT_BIN_10^7
SPU_ENTCLOC	Enterobacter cloacae complex	**2**	NOT_DETECT
		5	DETECT_BIN_10^4
		6	DETECT_BIN_10^5
		7	DETECT_BIN_10^6

			8	DETECT_BIN_10^7
	SPU_ECOLI	Escherichia coli	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_HAEINF	Haemophilus influenzae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLAERO	Klebsiella aerogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLEOXY	Klebsiella oxytoca	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_KLEPNEG	Klebsiella pneumoniae group	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_MORCAT	Moraxella catarrhalis	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_PROTSP	Proteus spp.	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6

			8	DETECT_BIN_10^7
	SPU_PSEAER	Pseudomonas aeruginosa	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_SERMAR	Serratia marcescens	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STAAUR	Staphylococcus aureus	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRAGA	Streptococcus agalactiae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRPNE	Streptococcus pneumoniae	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_STRPYO	Streptococcus pyogenes	**2**	NOT_DETECT
			5	DETECT_BIN_10^4
			6	DETECT_BIN_10^5
			7	DETECT_BIN_10^6
			8	DETECT_BIN_10^7
	SPU_CTXM	CTX-M	**1**	DETECT
			2	NOT_DETECT
			4	NOT_APPLICABLE
	SPU_IMP	IMP	**1**	DETECT

		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_KPC	KPC	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_MECA_MREJ	mecA/C and MREJ	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_NDM	NDM	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_OXA48	OXA-48-like	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_VIM	VIM	**1**	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
SPU_CHLPNE	Chlamydia pneumoniae	**1**	DETECT
		2	NOT_DETECT
SPU_LEGPNE	Legionella pneumophila	**1**	DETECT
		2	NOT_DETECT
SPU_MYCPNE	Mycoplasma pneumoniae	**1**	DETECT
		2	NOT_DETECT
SPU_ADENOV	Adenovirus	**1**	DETECT
		2	NOT_DETECT
SPU_CORONAV	Coronavirus	**1**	DETECT
		2	NOT_DETECT
SPU_H_METAPN	Human Metapneumovirus	**1**	DETECT
		2	NOT_DETECT
SPU_H_RHI_ENT	Human Rhinovirus/Enterovirus	**1**	DETECT
		2	NOT_DETECT
SPU_INFV_A	Influenza A	**1**	DETECT
		2	NOT_DETECT
SPU_INFV_B	Influenza B	**1**	DETECT
		2	NOT_DETECT

	SPU_MERSC	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	**1**	DETECT
			2	NOT_DETECT
	SPU_PARINFV	Parainfluenza Virus	**1**	DETECT
			2	NOT_DETECT
	SPU_RSV	Respiratory Syncytial Virus	**1**	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

7.6. BIOFIRE Pneumonia *plus* Panel Observation Conditional Reporting

There are no observations on the BIOFIRE Pneumonia *plus* Panel that are conditionally reported on the electronic report, as indicated in section 7.5 and Table 7.6.1.

Table 7.6.1: Conditional Reporting

	Observation Display Name *(from Table 7.5.1)*	**Result Display Name** *(from Table 7.4.1)*	**Reporting Condition**

7.7. BIOFIRE Pneumonia *plus* Panel Warnings and Notes

The BIOFIRE Pneumonia *plus* Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE Pneumonia *plus* Panel are indicated in Table 7.7.1.

Table 7.7.1: Test Notes

Comment	Reporting Condition
Note: Detection of bacterial nucleic acid may be indicative of colonizing or normal respiratory flora and may not indicate the causative agent of pneumonia. Semi-quantitative Bin (copies/mL) results generated by the FilmArray Pneumonia Panel plus are not equivalent to CFU/mL and do not consistently correlate with the quantity of bacterial analytes compared to CFU/mL. For specimens with multiple bacteria detected, the relative abundance of nucleic acids (copies/mL) may not correlate with the relative abundance of bacteria as determined by culture (CFU/mL). Clinical correlation is advised to determine significance of semi-quantitative Bin (copies/mL) for clinical management.	This note is included in the electronic report if any of the following organisms are detected: • Acinetobacter calcoaceticus-baumannii complex • Enterobacter cloacae complex • Escherichia coli • Haemophilus influenza • Klebsiella aerogenes • Klebsiella oxytoca • Klebsiella pneumoniae group • Moraxella catarrhalis • Proteus spp. • Pseudomonas aeruginosa • Serratia marcescens • Staphylococcus aureus • Streptococcus agalactiae • Streptococcus pneumonia • Streptococcus pyogenes Otherwise, this note is **not** included in the electronic report.
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 FilmArray Pneumonia Panel plus results should be used in conjunction with culture results for the determination of susceptibility or resistance.	This note is always included in the electronic report.

8. BIOFIRE Respiratory 2.1 Panel Pouch

The BIOFIRE® Respiratory 2.1 Panel, run using a RP2.1 v1.0 pouch, is used to detect and discriminate upper respiratory pathogens in samples from individuals with signs or symptoms of upper respiratory tract infections.

An electronic report for the BIOFIRE Respiratory 2.1 Panel contains information from a single test run using a RP2.1 v1.0 pouch.

The key code to download the BIOFIRE Respiratory 2.1 Panel ERM from the e-labeling website is: **ITILIS89**

8.1. BIOFIRE Respiratory 2.1 Panel Disposable (Pouch)

The BIOFIRE Respiratory 2.1 Panel is run using a pouch as the disposable, whose properties are indicated in Table 8.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 8.1.1: Disposable (Pouch)

	Code	Display Name	Coding System
	RP2.1 v1.0		99BMX

8.2. BIOFIRE Respiratory 2.1 Panel Universal Service ID (Panel)

The RP2.1 v1.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 8.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 8.2.1: Universal Service ID (Panel)

	Code	Display Name	Coding System
	RP2.1	BioFire Respiratory Panel 2.1	99BMX

8.3. BIOFIRE Respiratory 2.1 Panel Associated Sample Type(s)

The RP2.1 v1.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 8.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 8.3.1: Associated Sample Type(s)

	Code	Display Name	Coding System
	NPS	Nasopharyngeal Swab	99BMX

8.4. BIOFIRE Respiratory 2.1 Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE Respiratory 2.1 Panel are indicated in Table 8.4.1. Note that not every result in Table 8.4.1 will be associated with all of the BIOFIRE Respiratory 2.1 Panel observations. Refer to section 8.5 and 8.6 to see which of the possible results each observation on the panel may be associated with.

Table 8.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
EQUIVOC	Equivocal	**3**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**
Conditionality		
		Result Number
Observation is conditionally reported, and may therefore not be present in the electronic report (*see section 8.6 for conditional reporting conditions, if applicable*)		**150**

8.5. BIOFIRE Respiratory 2.1 Panel Possible Panel Observations

The BIOFIRE Respiratory 2.1 Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE Respiratory 2.1 Panel and their properties are indicated in Table 8.5.1.

Table 8.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 8.4.1)*	**Possible Result Code(s)** *(from Table 8.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE

		203	INV_IE
		204	INV_RI
Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 8.4.1)*	**Possible Result Code(s)** *(from Table 8.4.1)*
PCR_ADENOV	Adenovirus	**1**	DETECT
		2	NOT_DETECT
PCR_CORONAV_229E	Coronavirus 229E	**1**	DETECT
		2	NOT_DETECT
PCR_CORONAV_HKU1	Coronavirus HKU1	**1**	DETECT
		2	NOT_DETECT
PCR_CORONAV_NL63	Coronavirus NL63	**1**	DETECT
		2	NOT_DETECT
PCR_CORONAV_OC43	Coronavirus OC43	**1**	DETECT
		2	NOT_DETECT
PCR_COV2	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	**1**	DETECT
		2	NOT_DETECT
PCR_H_METAPNEUMOV	Human Metapneumovirus	**1**	DETECT
		2	NOT_DETECT
PCR_H_RHINO_ENTEROV	Human Rhinovirus/Enterovirus	**1**	DETECT
		2	NOT_DETECT
PCR_INFV_A	Influenza A	**2**	NOT_DETECT
		3	EQUIVOC
		150	*see section 8.6 for conditional reporting of this observation
PCR_INFV_A_NS	Influenza A (no subtype detected)	**1**	DETECT
		150	*see section 8.6 for conditional reporting of this observation
PCR_INFV_A_H1	Influenza A H1	**1**	DETECT
		3	EQUIVOC
		150	*see section 8.6 for conditional reporting of this observation
PCR_INFV_A_H1_2009	Influenza A H1-2009	**1**	DETECT
		3	EQUIVOC

			150	*see section 8.6 for conditional reporting of this observation
	PCR_INFA_V_H3	Influenza A H3	**1**	DETECT
			3	EQUIVOC
			150	*see section 8.6 for conditional reporting of this observation
	PCR_INFV_B	Influenza B	**1**	DETECT
			2	NOT_DETECT
	PCR_PARAINFV_1	Parainfluenza Virus 1	**1**	DETECT
			2	NOT_DETECT
	PCR_PARAINFV_2	Parainfluenza Virus 2	**1**	DETECT
			2	NOT_DETECT
	PCR_PARAINFV_3	Parainfluenza Virus 3	**1**	DETECT
			2	NOT_DETECT
	PCR_PARAINFV_4	Parainfluenza Virus 4	**1**	DETECT
			2	NOT_DETECT
	PCR_SYNCYTV	Respiratory Syncytial Virus	**1**	DETECT
			2	NOT_DETECT
	PCR_BORPARAP	Bordetella parapertussis (IS1001)	**1**	DETECT
			2	NOT_DETECT
	PCR_BORPET	Bordetella pertussis (ptxP)	**1**	DETECT
			2	NOT_DETECT
	PCR_CHLPNE	Chlamydia pneumoniae	**1**	DETECT
			2	NOT_DETECT
	PCR_MYCPNE	Mycoplasma pneumoniae	**1**	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

8.6. BIOFIRE Respiratory 2.1 Panel Observation Conditional Reporting

Some observations on the BIOFIRE Respiratory 2.1 Panel are conditionally reported on the electronic report, as indicated in section 8.5. The reporting conditions for conditionally reported observations on the BIOFIRE Respiratory 2.1 Panel are indicated in Table 8.6.1.

Additionally, Table 8.6.2 summarizes the 13 different scenarios that the conditional reporting of Influenza A may cause. Note that only one of the possible scenarios outlined can apply for any one given BIOFIRE Respiratory 2.1 Panel test.

Table 8.6.1: Conditional Reporting

Observation Display Name *(from Table 8.5.1)*	Result Display Name *(from Table 8.4.1)*	Reporting Condition
Influenza A	Not Detected	This observation is included in the electronic report if: • Both FluA-pan Assays are Negative • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
	Equivocal	This observation is included in the electronic report if: • Only one of the FluA-pan Assays is Positive • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
		Otherwise, this observation is **not** included in the electronic report.
Influenza A (no subtype detected)	Detected	This observation is included in the electronic report if: • Both FluA-pan Assays are Positive • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
		Otherwise, this observation is **not** included in the electronic report.
Influenza A H1	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H1-pan Assay is Positive
	Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H1-pan Assay is Positive
		Otherwise, this observation is **not** included in the electronic report.
Influenza A H1-2009	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H1-2009 Assay is Positive
	Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H1-2009 Assay is Positive
		Otherwise, this observation is **not** included in the electronic report.
Influenza A H3	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H3 Assay is Positive
	Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H3 Assay is Positive
		Otherwise, this observation is **not** included in the electronic report.

Table 8.6.2: Influenza A Conditional Reporting Scenarios

Scenario Number	Observation Display Name *(from Table 8.5.1)*	Result Number *(from Table 8.4.1)*	Result Code *(from Table 8.4.1)*
1	Influenza A	**2**	NOT_DETECT
2	Influenza A	**3**	EQUIVOC
3	Influenza A (no subtype detected)	**1**	DETECT
4	Influenza A H1	**1**	DETECT
5	Influenza A H1	**3**	EQUIVOC
6	Influenza A H1-2009	**1**	DETECT
7	Influenza A H1-2009	**3**	EQUIVOC
8	Influenza A H3	**1**	DETECT
9	Influenza A H3	**3**	EQUIVOC
10	Influenza A H1	**1**	DETECT
	Influenza A H3	**1**	DETECT
11	Influenza A H1	**3**	EQUIVOC
	Influenza A H3	**3**	EQUIVOC
12	Influenza A H1-2009	**1**	DETECT
	Influenza A H3	**1**	DETECT
13	Influenza A H1-2009	**3**	EQUIVOC
	Influenza A H3	**3**	EQUIVOC

8.7. BIOFIRE Respiratory 2.1 Panel Warnings and Notes

The BIOFIRE Respiratory 2.1 Panel is not associated with any warnings or notes that give additional information to help with interpretation of the information on the report, as indicated in Table 8.7.1.

Table 8.7.1: Test Notes

Comment	Reporting Condition

9. BIOFIRE Respiratory 2.1 plus Panel Pouch

The BIOFIRE® Respiratory 2.1 *plus* Panel, run using an RP2.1plus v1.0 pouch, is used to detect and discriminate upper respiratory pathogens in samples from individuals with signs or symptoms of upper respiratory tract infections.

An electronic report for the BIOFIRE Respiratory 2.1 *plus* Panel contains information from a single test run using the RP2.1plus v1.0 pouch.

The key code to download the BIOFIRE Respiratory 2.1 *plus* Panel ERM from the e-labeling website is: **ITILIS92**

9.1. BIOFIRE Respiratory 2.1 *plus* Panel Disposable (Pouch)

The BIOFIRE Respiratory 2.1 *plus* Panel is run using a pouch as the disposable, whose properties are indicated in Table 9.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 9.1.1: Disposable (Pouch)

Code	Display Name	Coding System
RP2.1plus v1.0		99BMX

9.2. BIOFIRE Respiratory 2.1 *plus* Panel Universal Service ID (Panel)

The RP2.1plus v1.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 9.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 9.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
RP2.1plus	BioFire Respiratory Panel 2.1 plus	99BMX

9.3. BIOFIRE Respiratory 2.1 *plus* Panel Associated Sample Type(s)

The RP2.1plus v1.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 9.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 9.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
NPS	Nasopharyngeal Swab	99BMX

9.4. BIOFIRE Respiratory 2.1 *plus* Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE Respiratory 2.1 *plus* Panel are indicated in Table 9.4.1. Note that not every result in Table 9.4.1 will be associated with all of the BIOFIRE Respiratory 2.1 *plus* Panel observations. Refer to section 9.5 and 9.6 to see which of the possible results each observation on the panel may be associated with.

Table 9.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
EQUIVOC	Equivocal	**3**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**
Conditionality		
		Result Number
Observation is conditionally reported, and may therefore not be present in the electronic report (*see section 9.6 for conditional reporting conditions, if applicable*)		**150**

9.5. BIOFIRE Respiratory 2.1 *plus* Panel Possible Panel Observations

The BIOFIRE Respiratory 2.1 *plus* Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE Respiratory 2.1 *plus* Panel and their properties are indicated in Table 9.5.1.

Table 9.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 9.4.1)*	**Possible Result Code(s)** *(from Table 9.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF

		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI

Target Observations

Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)

Code	Display Name	Possible Result Number(s) *(from Table 9.4.1)*	Possible Result Code(s) *(from Table 9.4.1)*
PCR_ADENOV	Adenovirus	1	DETECT
		2	NOT_DETECT
PCR_CORONAV_229E	Coronavirus 229E	1	DETECT
		2	NOT_DETECT
PCR_CORONAV_HKU1	Coronavirus HKU1	1	DETECT
		2	NOT_DETECT
PCR_CORONAV_NL63	Coronavirus NL63	1	DETECT
		2	NOT_DETECT
PCR_CORONAV_OC43	Coronavirus OC43	1	DETECT
		2	NOT_DETECT
PCR_CORONAV_MERS	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	1	DETECT
		2	NOT_DETECT
		3	EQUIVOC
PCR_COV2	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	1	DETECT
		2	NOT_DETECT
PCR_H_METAPNEUMOV	Human Metapneumovirus	1	DETECT
		2	NOT_DETECT
PCR_H_RHINO_ENTEROV	Human Rhinovirus/Enterovirus	1	DETECT
		2	NOT_DETECT
PCR_INFV_A	Influenza A	2	NOT_DETECT
		3	EQUIVOC
		150	*see section 9.6 for conditional reporting of this observation
PCR_INFV_A_NS	Influenza A (no subtype detected)	1	DETECT
		150	*see section 9.6 for conditional reporting of this observation

PCR_INFV_A_H1	Influenza A H1	**1**	DETECT
		3	EQUIVOC
		150	*see section 9.6 for conditional reporting of this observation
PCR_INFV_A_H1_2009	Influenza A H1-2009	**1**	DETECT
		3	EQUIVOC
		150	*see section 9.6 for conditional reporting of this observation
PCR_INFA_V_H3	Influenza A H3	**1**	DETECT
		3	EQUIVOC
		150	*see section 9.6 for conditional reporting of this observation
PCR_INFV_B	Influenza B	**1**	DETECT
		2	NOT_DETECT
PCR_PARAINFV_1	Parainfluenza Virus 1	**1**	DETECT
		2	NOT_DETECT
PCR_PARAINFV_2	Parainfluenza Virus 2	**1**	DETECT
		2	NOT_DETECT
PCR_PARAINFV_3	Parainfluenza Virus 3	**1**	DETECT
		2	NOT_DETECT
PCR_PARAINFV_4	Parainfluenza Virus 4	**1**	DETECT
		2	NOT_DETECT
PCR_SYNCYTV	Respiratory Syncytial Virus	**1**	DETECT
		2	NOT_DETECT
PCR_BORPARAP	Bordetella parapertussis (IS1001)	**1**	DETECT
		2	NOT_DETECT
PCR_BORPET	Bordetella pertussis (ptxP)	**1**	DETECT
		2	NOT_DETECT
PCR_CHLPNE	Chlamydia pneumoniae	**1**	DETECT
		2	NOT_DETECT
PCR_MYCPNE	Mycoplasma pneumoniae	**1**	DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

9.6. BIOFIRE Respiratory 2.1 *plus* Panel Observation Conditional Reporting

Some observations on the BIOFIRE Respiratory 2.1 *plus* Panel are conditionally reported on the electronic report, as indicated in section 9.5. The reporting conditions for conditionally reported observations on the BIOFIRE Respiratory 2.1 *plus* Panel are indicated in Table 9.6.1.

Additionally, Table 9.6.2 summarizes the 13 different scenarios that the conditional reporting of Influenza A may cause. Note that only one of the possible scenarios outlined can apply for any one given BIOFIRE Respiratory 2.1 *plus* Panel test.

Table 9.6.1: Conditional Reporting

Observation Display Name *(from Table 9.5.1)*	Result Display Name *(from Table 9.4.1)*	Reporting Condition
Influenza A	Not Detected	This observation is included in the electronic report if: • Both FluA-pan Assays are Negative • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
	Equivocal	This observation is included in the electronic report if: • Only one of the FluA-pan Assays is Positive • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
		Otherwise, this observation is **not** included in the electronic report.
Influenza A (no subtype detected)	Detected	This observation is included in the electronic report if: • Both FluA-pan Assays are Positive • FluA-H1-pan Assay is Negative • FluA-H1-2009-pan Assay is Negative • FluA-H3 Assay is Negative
		Otherwise, this observation is **not** included in the electronic report.
Influenza A H1	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H1-pan Assay is Positive
	Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H1-pan Assay is Positive
		Otherwise, this observation is **not** included in the electronic report.
Influenza A H1-2009	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H1-2009 Assay is Positive

		Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H1-2009 Assay is Positive
			Otherwise, this observation is **not** included in the electronic report.
	Influenza A H3	Detected	This observation is included in the electronic report if: • At least one of the FluA-pan Assays are Positive • FluA-H3 Assay is Positive
		Equivocal	This observation is included in the electronic report if: • Both of the FluA-pan Assays are Negative • FluA-H3 Assay is Positive
			Otherwise, this observation is **not** included in the electronic report.

Table 9.6.2: Influenza A Conditional Reporting Scenarios

Scenario Number	Observation Display Name *(from Table 9.5.1)*	Result Number *(from Table 9.4.1)*	Result Code *(from Table 9.4.1)*
1	Influenza A	**2**	NOT_DETECT
2	Influenza A	**3**	EQUIVOC
3	Influenza A (no subtype detected)	**1**	DETECT
4	Influenza A H1	**1**	DETECT
5	Influenza A H1	**3**	EQUIVOC
6	Influenza A H1-2009	**1**	DETECT
7	Influenza A H1-2009	**3**	EQUIVOC
8	Influenza A H3	**1**	DETECT
9	Influenza A H3	**3**	EQUIVOC
10	Influenza A H1	**1**	DETECT
	Influenza A H3	**1**	DETECT
11	Influenza A H1	**3**	EQUIVOC
	Influenza A H3	**3**	EQUIVOC
12	Influenza A H1-2009	**1**	DETECT
	Influenza A H3	**1**	DETECT
13	Influenza A H1-2009	**3**	EQUIVOC
	Influenza A H3	**3**	EQUIVOC

9.7. BIOFIRE Respiratory 2.1 *plus* Panel Warnings and Notes

The BIOFIRE Respiratory 2.1 *plus* Panel is not associated with any warnings or notes that give additional information to help with interpretation of the information on the report, as indicated in Table 9.7.1.

Table 9.7.1: Test Notes

	Comment	Reporting Condition

10. BIOFIRE JI Panel Pouch

The BIOFIRE® Joint Infection (JI) Panel, run using a JI Panel v1.1 pouch, is used to detect and discriminate pathogens and associated antimicrobial resistances found in synovial fluid (SF) samples from individuals with signs or symptoms of joint infection.

An electronic report for the BIOFIRE JI Panel contains information from a single test run using the JI Panel v1.1 pouch.

The key code to download the BIOFIRE JI Panel ERM from the e-labeling website is: **ITILIS36**

10.1. BIOFIRE JI Panel Disposable (Pouch)

The BIOFIRE JI Panel is run using a pouch as the disposable, whose properties are indicated in Table 10.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 10.1.1: Disposable (Pouch)

Code	Display Name	Coding System
JI Panel v1.1		99BMX

10.2. BIOFIRE JI Panel Universal Service ID (Panel)

The JI Panel v1.1 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 10.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 10.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
JI	BioFire Joint Infection (JI) Panel	99BMX

10.3. BIOFIRE JI Panel Associated Sample Type(s)

The JI Panel v1.1 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 10.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 10.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
SF	Synovial Fluid	99BMX

10.4. BIOFIRE JI Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE JI Panel are indicated in Table 10.4.1. Note that not every result in Table 10.4.1 will be associated with all of the BIOFIRE JI Panel observations. Refer to section 10.5 and 10.6 to see which of the possible results each observation on the panel may be associated with.

Table 10.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
NOT_APPLICABLE	N/A	**4**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

10.5. BIOFIRE JI Panel Possible Panel Observations

The BIOFIRE JI Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE JI Panel and their properties are indicated in Table 10.5.1.

Table 10.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 10.4.1)*	**Possible Result Code(s)** *(from Table 10.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI

Target Observations

Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)

Code	Display Name	Possible Result Number(s) *(from Table 10.4.1)*	Possible Result Code(s) *(from Table 10.4.1)*
BJIx08001	CTX-M	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08002	IMP	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08003	KPC	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08004	mecA/C and MREJ (MRSA)	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08005	NDM	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08006	OXA-48-like	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08007	vanA/B	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx08008	VIM	1	DETECT
		2	NOT_DETECT
		4	NOT_APPLICABLE
BJIx05001	Anaerococcus prevotii/vaginalis	1	DETECT
		2	NOT_DETECT
BJIx05002	Clostridium perfringens	1	DETECT
		2	NOT_DETECT
BJIx05003	Cutibacterium avidum/granulosum	1	DETECT
		2	NOT_DETECT

BJIx05004	Enterococcus faecalis	**1**	DETECT
		2	NOT_DETECT
BJIx05005	Enterococcus faecium	**1**	DETECT
		2	NOT_DETECT
BJIx05006	Finegoldia magna	**1**	DETECT
		2	NOT_DETECT
BJIx05007	Parvimonas micra	**1**	DETECT
		2	NOT_DETECT
BJIx05008	Peptoniphilus	**1**	DETECT
		2	NOT_DETECT
BJIx05009	Peptostreptococcus anaerobius	**1**	DETECT
		2	NOT_DETECT
BJIx05010	Staphylococcus aureus	**1**	DETECT
		2	NOT_DETECT
BJIx05011	Staphylococcus lugdunensis	**1**	DETECT
		2	NOT_DETECT
BJIx05012	Streptococcus spp.	**1**	DETECT
		2	NOT_DETECT
BJIx05013	Streptococcus agalactiae	**1**	DETECT
		2	NOT_DETECT
BJIx05014	Streptococcus pneumoniae	**1**	DETECT
		2	NOT_DETECT
BJIx05015	Streptococcus pyogenes	**1**	DETECT
		2	NOT_DETECT
BJIx06001	Bacteroides fragilis	**1**	DETECT
		2	NOT_DETECT
BJIx06002	Citrobacter	**1**	DETECT
		2	NOT_DETECT
BJIx06003	Enterobacter cloacae complex	**1**	DETECT
		2	NOT_DETECT
BJIx06004	Escherichia coli	**1**	DETECT
		2	NOT_DETECT
BJIx06005	Haemophilus influenzae	**1**	DETECT
		2	NOT_DETECT

	BJIx06006	Kingella kingae	**1**	DETECT
			2	NOT_DETECT
	BJIx06007	Klebsiella aerogenes	**1**	DETECT
			2	NOT_DETECT
	BJIx06008	Klebsiella pneumoniae group	**1**	DETECT
			2	NOT_DETECT
	BJIx06009	Morganella morganii	**1**	DETECT
			2	NOT_DETECT
	BJIx06010	Neisseria gonorrhoeae	**1**	DETECT
			2	NOT_DETECT
	BJIx06011	Proteus spp.	**1**	DETECT
			2	NOT_DETECT
	BJIx06012	Pseudomonas aeruginosa	**1**	DETECT
			2	NOT_DETECT
	BJIx06013	Salmonella spp.	**1**	DETECT
			2	NOT_DETECT
	BJIx06014	Serratia marcescens	**1**	DETECT
			2	NOT_DETECT
	BJIx07001	Candida	**1**	DETECT
			2	NOT_DETECT
	BJIx07002	Candida albicans	**1**	DETECT
			2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

10.6. BIOFIRE JI Panel Observation Conditional Reporting

There are no observations on the BIOFIRE JI Panel that are conditionally reported on the electronic report, as indicated in section 10.5 and Table 10.6.1.

Table 10.6.1: Conditional Reporting

	Observation Display Name *(from Table 10.5.1)*	**Result Display Name** *(from Table 10.4.1)*	**Reporting Condition**

10.7. BIOFIRE JI Panel Warnings and Notes

The BIOFIRE JI Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE JI Panel are indicated in Table 10.7.1.

Table 10.7.1: Test Notes

Comment	Reporting Condition
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 Joint Infection Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.	This note is always included in the electronic report.

11. BIOFIRE TF Panel Pouch

The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel, run using a TF Panel v1.0 pouch, is used to detect and identify selected bacterial, viral, and parasitic nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), Leptospira spp., and Plasmodium spp. (including species differentiation of Plasmodium falciparum and Plasmodium vivax/ovale).

An electronic report for the BIOFIRE TF Panel contains information from a single test run using the TF Panel v1.0 pouch.

The key code to download the BIOFIRE TF Panel ERM from the e-labeling website is: **ITILIS10**

11.1. BIOFIRE TF Panel Disposable (Pouch)

The BIOFIRE TF Panel is run using a pouch as the disposable, whose properties are indicated in Table 11.1.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 11.1.1: Disposable (Pouch)

Code	Display Name	Coding System
TF Panel v1.0		99BMX

11.2. BIOFIRE TF Panel Universal Service ID (Panel)

The TF Panel v1.0 pouch is used to test for a panel, which is a syndromic test comprised of multiple pathogens. The panel (or test) properties are indicated in Table 11.2.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 11.2.1: Universal Service ID (Panel)

Code	Display Name	Coding System
TF	Tropical Fever Panel	99BMX

11.3. BIOFIRE TF Panel Associated Sample Type(s)

The TF Panel v1.0 pouch may be used with a subset of cleared sample type(s), whose properties are indicated in Table 11.3.1.

Note that this codification is only applicable for the HL7 interface, but some properties may apply to the electronic report created by the XML interface.

Table 11.3.1: Associated Sample Type(s)

Code	Display Name	Coding System
WB	EDTA Whole Blood	99BMX

11.4. BIOFIRE TF Panel Possible Panel Results

The possible results (derived from Table 1.3.1) for the BIOFIRE TF Panel are indicated in Table 11.4.1. Note that not every result in Table 11.4.1 will be associated with all of the BIOFIRE TF Panel observations. Refer to section 11.5 and 11.6 to see which of the possible results each observation on the panel may be associated with.

Table 11.4.1: Possible Panel Results

Qualitative Results *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*		
Code	**Display Name**	**Result Number**
DETECT	Detected	**1**
NOT_DETECT	Not Detected	**2**
PASS	Pass	**100**
INV_CF	Invalid Internal Process Control Failure	**200**
INV_AB	Invalid Aborted Run	**201**
INV_SE	Invalid Software Error	**202**
INV_IE	Invalid Instrument Error	**203**
INV_RI	Invalid Run Incomplete	**204**

11.5. BIOFIRE TF Panel Possible Panel Observations

The BIOFIRE TF Panel tests for a set of observations based on a specific syndrome. The observations on the BIOFIRE TF Panel and their properties are indicated in Table 11.5.1.

Table 11.5.1: Panel Observations

Run Status Observation *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 11.4.1)*	**Possible Result Code(s)** *(from Table 11.4.1)*
RUN_STAT	Run Status	**100**	PASS
		200	INV_CF
		201	INV_AB
		202	INV_SE
		203	INV_IE
		204	INV_RI

Target Observations *Coding System: 99BMX (for HL7 interface) or BMX (for XML interface)*			
Code	**Display Name**	**Possible Result Number(s)** *(from Table 11.4.1)*	**Possible Result Code(s)** *(from Table 11.4.1)*
TFx01001	Chikungunya virus	**1**	DETECT
		2	NOT_DETECT
TFx01002	Dengue virus	**1**	DETECT
		2	NOT_DETECT
TFx04001	Plasmodium spp.	**1**	DETECT
		2	NOT_DETECT
TFx04002	Plasmodium falciparum	**1**	DETECT
		2	NOT_DETECT
TFx04003	Plasmodium vivax/ovale	**1**	DETECT
		2	NOT_DETECT
TFx02001	Leptospira spp.	**1**	DETECT
		2	NOT_DETECT

Note: Possible result values shown in blue will only be sent when the FilmArray System is set to transmit failed run data. This feature may be toggled on/off in the FilmArray settings menu.

11.6. BIOFIRE TF Panel Observation Conditional Reporting

There are no observations on the BIOFIRE TF Panel that are conditionally reported on the electronic report, as indicated in section 11.5 and Table 11.6.1.

Table 11.6.1: Conditional Reporting

Observation Display Name (from Table 11.5.1)	**Result Display Name** *(from Table 11.4.1)*	**Reporting Condition**

11.7. BIOFIRE TF Panel Warnings and Notes

The BIOFIRE TF Panel is associated with warnings and notes that give additional information to help with interpretation of the information on the report. The notes on the BIOFIRE TF Panel are indicated in Table 11.7.1.

Notes:

- ***Each comment will be prepended with "[Text]" to identify the start of a unique comment.***
- ***The TF Panel PDF report will display a comment for failed runs due to control failures. However, at this time, this comment will not be transmitted in XML or HL7 reports.***

Table 11.7.1: Test Notes

Comment	Reporting Condition
[Text] Action: This result may be uncommon for travelers, but not in endemic areas. Consult the Instructions for Use for additional information on uncommon results.	This note is included when an uncommon number of organisms are Detected (i.e., 2 or more interpretations are detected), excluding Plasmodium.
[Text] Action: This result may be uncommon for travelers, but not in endemic areas. Consult the Instructions for Use for additional information on uncommon results and Plasmodium results.	This note is included when an uncommon number of organisms are Detected (i.e., 2 or more interpretations are detected), including one or more Plasmodium interpretations (i.e., Plasmodium spp., Plasmodium falciparum, Plasmodium vivax/ovale) and at least one non-Plasmodium interpretation.
[Text] Action: Consult the Instructions for Use for additional information on Plasmodium results.	This note is included when any of the following organism combinations are Detected, and where all other organisms on the panel are Not Detected: • Plasmodium spp. • Plasmodium spp. AND Plasmodium falciparum • Plasmodium spp. AND Plasmodium vivax/ovale

12. Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact your local bioMérieux representative or your authorized distributor.

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