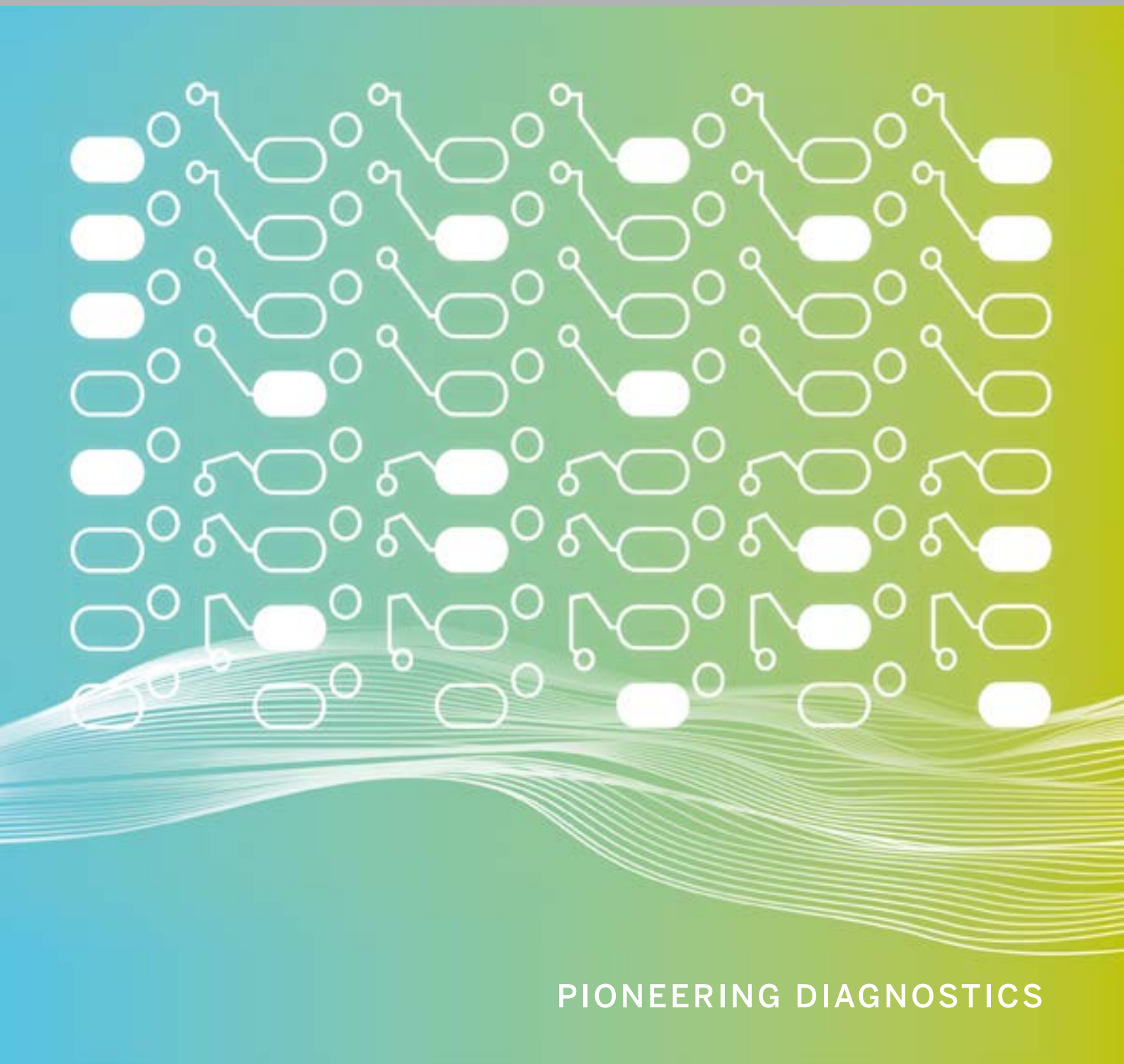
BIOMÉRIEUX

VITEK® 2

Selection of publications

2025 EDITION



PIONEERING DIAGNOSTICS

INNOVATING MICROBIOLOGY FOR BETTER PATIENT CARE

“We have definitely seen genuine advantages with using the bioMérieux system as an integrated workflow. We can connect the VITEK® MS with the VITEK® 2’s susceptibility testing through the MYLA® system, which integrates well with our laboratory information system and our own IT service.”*

IT: Information Technology

Dr Patrick Harris,
The University of Queensland,
Royal Brisbane & Women’s Hospital,
Brisbane, Queensland, Australia

“It is important that I, as the infectious disease specialist, or a doctor of any specialty that sees patient with infections, trust the results they receive. This is incredibly important. I define the bioMérieux diagnostic solution in one word as “reliability”.”

Dr Indira Berrio,
Internal Medicine, ID Physician,
Hospital General de Medellín,
Medellín, Colombia

As rates of antimicrobial resistance (AMR) and multidrug-resistant organisms (MDROs) rise, pathogen detection becomes increasingly complex. Microbiology labs play a pivotal role in this global challenge. Accurate microbial identification (ID) and antimicrobial susceptibility testing (AST) are essential for timely clinical interventions and improved patient outcomes.

THE FUTURE OF MICROBIOLOGY DIAGNOSTICS

Advancements in microbiology diagnostics are crucial in the fight against AMR. Automated ID and AST technologies, such as Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) for fast identification and novel fast AST methods from positive blood cultures, are revolutionizing clinical diagnostics. These technologies enable fast, accurate pathogen identification and resistance profiling, reducing diagnosis time. This timely information is vital for selecting appropriate therapies, reducing misuse of broad-spectrum antibiotics, and curbing AMR.

BIOMÉRIEUX AND VITEK® 2 ID/AST

As a global leader in microbiology diagnostics, bioMérieux is committed to advancing these technologies. Constant innovation ensures that bioMérieux remains at the forefront of addressing new antimicrobial challenges. The VITEK 2 ID/AST system exemplifies this commitment, providing fast, accurate results that support antimicrobial stewardship (AMS) initiatives. The phenotype-based VITEK 2 ADVANCED EXPERT SYSTEM™ (AES), with an evolving knowledge base of over 15,000 drug-microorganism combinations, makes VITEK 2 distinctive from other automated ID/AST systems.

INTEGRATING EMERGING TECHNOLOGIES

The integration of VITEK 2 with other key applications like MALDI-TOF and rapid AST methods, combined with the enhanced data insights provided by middleware solutions such as MAESTRIA™, significantly boosts overall workflow performance and diagnostic accuracy. This synergy enables comprehensive pathogen identification and susceptibility testing, empowering clinicians with valuable insights to make more informed and timely decisions.

2025 SELECTION OF PUBLICATIONS FOR MICROBIOLOGY DIAGNOSTICS

The following sections are covered in this Selection of Publications:

- **Identification / Antimicrobial Susceptibility Testing (ID/AST)**
- **Workflow Efficiency**
- **VITEK 2 ADVANCED EXPERT SYSTEM (AES)**
- **Clinical and Economic Impact**

We believe this 2025 Selection of Publications will be a valuable resource for healthcare professionals, empowering them to **optimize antimicrobial prescribing, enhance stewardship practices, and provide better patient care**.

CONTENTS

IDENTIFICATION / ANTIMICROBIAL SUSCEPTIBILITY TESTING (ID/AST)

WORKFLOW EFFICIENCY

VITEK® 2 ADVANCED EXPERT SYSTEM™ (AES)

CLINICAL AND ECONOMIC IMPACT

ABBREVIATIONS & ACRONYMS

The following abbreviations and acronyms are used throughout the Selection of Publications.

AST	antimicrobial susceptibility testing
BMD	broth microdilution
CA	categorical agreement
CLSI	Clinical Laboratory Standards Institute
CNE	carbapenemase non-producing *Enterobacteriacae*
CoNS	coagulase-negative *staphylococci*
CPE	carbapenemase producing *Enterobacteriacae*
C/T	ceftolozane-tazobactam
CZA	ceftazidime-avibactam
ESBL	extended-spectrum β-lactamase
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FDA	Food and Drug Administration
ID	identification
IPM	imipenem
ISO	International Standards Organization
mE	minor error
ME	major error
MHT	modified Hodge test
MIC	minimum inhibitory concentration
PCR	polymerase chain reaction
QC	quality control
rDNA	recombinant deoxyribonucleic acid
TZP	piperacillin-tazobactam
UCLA	University of California, Los Angeles
VME	very major error
WGS	whole genome sequencing

IDENTIFICATION / ANTIMICROBIAL SUSCEPTIBILITY TESTING (ID/AST)

MICROBIOLOGY SPECTRUM
2024;12(9):E0381523 DOI:10.1128/SPECTRUM.03815-23

Performance evaluation of cefoxitin screen test on two different automated antimicrobial susceptibility test systems: a comparative study.

Yuceel-Timur I, Garner C, Franklin S, Hardy DJ.

OBJECTIVE

Evaluate the performance of the new cefoxitin screen test with and without combination of the oxacillin test for the VITEK® 2 and BD Phoenix™ systems, for the detection of *mec*A and *mec*C-mediated β-lactam resistance in *Staphylococcus* spp.

STUDY DESIGN

- A total of 250 *Staphylococcus* spp. isolates were evaluated including 120 *mec*A-positive, 10 *mec*C-positive, 120-*mec*A and *mec*C-negative resistance profiles.
- VITEK 2 cards and the Phoenix Emerge™ PMIC-110 panel were evaluated with the cefoxitin screen test and oxacillin test.
- Positive *mec*A and/or *mec*C isolates were confirmed with PCR testing.
- Disk diffusion for cefoxitin screen test and broth microdilution for oxacillin susceptibility were performed as reference tests.
- Sensitivity and specificity rates for *mec*A and *mec*C-mediated β-lactam resistance were evaluated for VITEK 2 and Phoenix.

RESULTS

VITEK 2 demonstrated a higher sensitivity for the cefoxitin screen test alone when compared to Phoenix **(Table 1)**.

Table 1. VITEK 2 and Phoenix sensitivity and specificity rates for *Staphylococcus* spp.
Source: bioMérieux based on Yuceel-Timur I, *et al. Microbiol Spectrum* 2024;12(9):e0381523

Test	VITEK 2		Phoenix	
	Sensitivity	Specificity	Sensitivity	Specificity
Cefoxitin screen test	100%	98%	84%	100%
Oxacillin test	98%	99%	99%	100%
Combined	100%	98%	100%	100%

CONCLUSIONS

The redeveloped VITEK 2 cefoxitin test is robust in detecting *mec*A and *mec*C-mediated β-lactam resistance in *Staphylococcus* spp. isolates. VITEK 2 demonstrated a higher sensitivity for the cefoxitin screen alone compared to the Phoenix system.

"When considering cefoxitin alone, the Vitek 2 screen test showed a higher sensitivity than the Phoenix for the detection of mecA and mecC-mediated beta-lactam resistance."

KEY FINDINGS

- The newly redeveloped VITEK 2 cefoxitin screen test exhibited 100% sensitivity and 98% specificity, making it a robust test for the detection of β-lactam resistant isolates.
- Both VITEK 2 and Phoenix performed acceptably when combining the cefoxitin screen with the oxacillin result. However, VITEK 2 demonstrated a higher sensitivity for the cefoxitin screen test alone compared to Phoenix.

JOURNAL OF CLINICAL MICROBIOLOGY
2023;61(6):E0017423 DOI:10.1128/JCM.00174-23

Multicenter Clinical Performance Evaluation of Omadacycline Susceptibility Testing of *Enterobacterales* on VITEK 2 Systems.

Csiki-Fejer E, Traczewski M, Procop GW, Davis TE, Hackel M, Dwivedi HP, Pincus DH.

OBJECTIVE

Multisite study to evaluate performance of omadacycline AST on VITEK® 2 compared to the broth microdilution (BMD) reference method for *Enterobacterales* to support FDA 510(k) submission.

Omadacycline is a new broad-spectrum oral and intravenous antibiotic (FDA-approved in 2018) for the treatment of adult patients suffering from acute bacterial skin and skin-structure infections (ABSSSI) and community-acquired bacterial-pneumonia (CABP) infections caused by Gram-negative (GN), Gram-positive (GP) and atypical organisms.

Omadacycline is part of the third-generation tetracycline antibiotic class.

STUDY DESIGN

Multicenter study conducted at 4 external sites and 1 internal site (all in the US).

The different strains tested were:

- 300 clinical strains and 49 challenge strains of *K. pneumoniae*
- 30 clinical strains of *E.cloacae* (*E. cloacae* (27), *E. cloacae* complex (3) and 40 challenge strains (*E. cloacae* (35), *E. cloacae* complex (5)
- Additional *Enterobacterales* (no FDA BP) - *Citrobacter freundii* (15), *Citrobacter koseri* (34), *Klebsiella aerogenes* (30), *E. coli* (300), *Klebsiella oxytoca* (30), and *Serratia marcescens* (30)

A total of 769 clinical and 89 challenge isolates were tested.

RESULTS

Omadacycline has only FDA breakpoints (for GN- *K. pneumoniae* for CABP, and *K. pneumoniae* and *E. cloacae* for ABSSSI). The performance following FDA criteria using intended for use (IFU) species was the following:

- Including *K. pneumoniae* and *E. cloacae* for ABSSSI: essential agreement (EA) = 97.9% (410/419) and categorical agreement (CA) = 94.3% (395/419). There was 1 very major error (VME), rate 2.0% (1/51) and no major errors (ME).
- Including only *K.pneumoniae* isolates for CABP: EA = 98.0% (342/349) and CA 93.7% (327/349). VME rate was 2.7% (1/37), and no MEs were registered.
- For all *Enterobacterales* clinical isolates, after error resolution, EA = 97.9% (753/769) and CA = 97.1% (747/769) with no VME or ME.
- The mean incubation time for clinical isolates was 7.34 h, with a maximum standard deviation of 1.24.

CONCLUSIONS

The results obtained by the VITEK 2 AST-GN omadacycline test correlated to the BMD reference method results, making it a dependable alternative to the BMD reference method for determining omadacycline MICs in *Enterobacterales*.

"The new Vitek 2 AST-GN omadacycline test provides an alternative to the BMD reference method testing and increases the range of automated diagnostic tools available for determining omadacycline MICs in Enterobacterales."

KEY FINDINGS

- The VITEK 2 AST GN omadacycline test has been 510(k) cleared in 2022 and is only available for the US market (only FDA breakpoints).
- Good correlation was observed between VITEK 2 AST-GN omadacycline and the BMD reference method for *Enterobacterales*.
- This study demonstrated that the mean card incubation time for clinical isolates was 7.34 h, shorter than typical BMD overnight results.

ANTIBIOTICS
2022;11(8):1023 DOI:10.3390/ANTIBIOTICS11081023

Susceptibility of Meropenem-Resistant and/or Carbapenemase-Producing Clinical Isolates of *Enterobacterales* (*Enterobacteriaceae*) and *Pseudomonas aeruginosa* to Ceftazidime-Avibactam and Ceftolozane-Tazobactam as Assessed by *In Vitro* Testing Methods.

Cortazzo V, Posteraro B, Menchinelli G, Liotti FM, D'Inzeo T, Fiori B, Luzzaro F, Sanguinetti M, Spanu T.

OBJECTIVE

Comparative assessment of *in vitro* susceptibility testing methods to ceftazidime-avibactam (CZA) and ceftolozane-tazobactam (C/T) combinations, using ETEST® and VITEK® 2 AST-N397 card versus the MICRONAUT® AST-system broth microdilution (BMD) method against meropenem-resistant and/or carbapenemase-producing clinical isolates of *Enterobacterales* and *Pseudomonas aeruginosa*.

STUDY DESIGN

- 205 non-duplicate Gram-negative (153 *Enterobacteriaceae* - mostly *K. pneumoniae* and *E. coli* - and 52 *P. aeruginosa*) clinical isolates were tested from two Italian hospital clinical microbiology laboratories' collections, of which 53.7%, 31.2%, and 15.1% were recovered from bloodstream, respiratory tract, or urinary tract infections, respectively.
- 168 isolates were characterized as meropenem-resistant phenotypes and/or carbapenemase genes (165 isolates of which 37 were meropenem susceptible).
- EUCAST (version 11.0, 2021) clinical breakpoints were used to interpret MICs to CZA and C/T.

RESULTS

- For CZA testing, essential agreement (EA) and categorical agreement (CA) between VITEK 2 and BMD were 96.1% and 98%, respectively.
  For ETEST vs. BMD, EA and CA were 95.6% and 100%, respectively.
- For C/T testing, EA and CA between VITEK 2 and BMD were 98% and 100%, respectively.
  For ETEST vs. BMD, EA and CA were 96.6% and 100%, respectively.
- Four categorical errors were observed, 1 very major error (VME) and 3 major errors (ME) for CZA against *K. pneumoniae* with VITEK 2.
- For *P. aeruginosa*, CA were 100% for both CZA and C/T with 0 VME and 0 ME for VITEK 2 and ETEST.

CONCLUSIONS

CZA and C/T MIC results of clinically relevant *Enterobacterales* or *P. aeruginosa* organisms indicate excellent CA of 98% and 100% with the VITEK 2 AST-N397 card, respectively, and complete (100%) for CZA and C/T with the ETEST method. Both methods allow testing the susceptibility to CZA and C/T with less hands-on time compared to reference method. ETEST remains a reliable option when drugs are not present on VITEK 2 cards.

"While both ETEST and VITEK 2 allow testing the susceptibility to CZA and C/T with less hands-on time compared to reference method, the automation brought by VITEK 2 also allows its use in a routine workflow."

KEY FINDINGS

- Of the 153 *Enterobacterales* isolates, 55.6% and 0.0% (VITEK 2) and 56.9% and 0.0% (ETEST and BMD) were susceptible to CZA and C/T, respectively. Of 52 *P. aeruginosa* isolates, 50.0% and 40.4% (VITEK 2, ETEST, and BMD) were susceptible to CZA and C/T, respectively.
- VITEK 2 and ETEST yielded equivalent CZA and C/T susceptibility testing results, compared to the BMD method.

ANTIBIOTICS
2022;11(7):865 DOI:10.3390/ANTIBIOTICS11070865

Comparative Evaluation of Vitek 2 and Etest versus Broth Microdilution for Ceftazidime/Avibactam and Ceftolozane/Tazobactam Susceptibility Testing of *Enterobacterales* and *Pseudomonas aeruginosa*.

Papadomanolaki A, Siopi M, Karakosta P, Vourli S, Pournaras S.

OBJECTIVE

Evaluate and compare the performance of VITEK® 2 and ETEST® methods against the broth microdilution (BMD) reference method for testing the susceptibility of *Enterobacterales* and *Pseudomonas aeruginosa* to two novel antibiotics: ceftazidime-avibactam (CZA) and ceftolozane-tazobactam (C/T).

STUDY DESIGN

- A total of 100 non-repetitive Gram-negative isolates, consisting of 83 *Enterobacterales* and 17 *P. aeruginosa* were evaluated.
- Susceptibility testing was performed with the VITEK 2 AST-XN10 card (primary card used not identified), and gradient diffusion method using ETEST strips on Mueller-Hinton agar plates.
- BMD was used as the reference method with frozen customized antibiotic panels.
- The categorical agreement (CA), essential agreement (EA), and error rates including major errors (MEs) and very major errors (VMEs), were calculated per ISO standard 20776-2.

RESULTS

Table 1. CZA and C/T testing results

Source: bioMérieux adapted from Papadomanolaki A, *et al. Antibiotics* 2022;11(7):865

Performance metric	VITEK 2 (CZA)	VITEK 2 (C/T)	ETEST (CZA)	ETEST (C/T)
Enterobacterales				
CA	99%	98%	100%	99%
EA	100%	91%	97%	88%
VME	1%	1%	-	1%
ME	-	1%	-	-
P. aeruginosa				
CA	100%	100%	94%	100%
EA	100%	100%	85%	100%
VME	-	-	6%	-

CONCLUSIONS

This study demonstrated a good performance for CZA and C/T when testing *Enterobacterales* and *Pseudomonas aeruginosa*. VITEK 2 is a suitable alternative to the BMD reference method for susceptibility testing of *Enterobacterales* and *Pseudomonas aeruginosa*. ETEST is reliable for *Enterobacterales* but caution is advised when testing *Pseudomonas aeruginosa* due to higher VME rates.

"Overall, Vitek 2 measurements of CZA and C/T susceptibility correlated closely with the reference BMD, indicating that it can represent a suitable alternative to BMD for susceptibility testing of Enterobacterales and P. aeruginosa."

KEY FINDINGS

- VITEK 2 performed well for susceptibility testing of *Enterobacterales* and *Pseudomonas aeruginosa* to CZA and C/T.
- VITEK 2 is an accurate alternative to BMD for susceptibility testing of CZA and C/T in *Enterobacterales* and *Pseudomonas aeruginosa*.

JOURNAL OF CLINICAL MICROBIOLOGY
2022;60(1):E0161021 DOI:10.1128/JCM.01610-21

Multicenter Clinical Evaluation of Vitek 2 Meropenem-Vaborbactam for Susceptibility Testing of *Enterobacterales* and *Pseudomonas aeruginosa*.

Dwivedi HP, Franklin S, Chandrasekaran S, Garner O, Traczewski MM, Beasley D, Procop G, Tuohy M, Wilson D, Bala Y, Pincus DH.

OBJECTIVE

Evaluate the performance of the VITEK® 2 AST of meropenem-vaborbactam (MEV) compared to the reference broth microdilution (BMD) method in a multicenter clinical study on *Enterobacterales* and *P. aeruginosa* isolates.

STUDY DESIGN

- Clinical isolates were provided by three study sites in the US (Cleveland Clinic, Clinical Microbiology Institute and UCLA).
- For the comparative study, a total of 526 *Enterobacterales* and *P. aeruginosa* isolates including 408 clinical isolates and 118 challenge isolates were evaluated against EUCAST criteria.
- 449 *Enterobacterales* isolates including 331 clinical isolates and 118 challenge isolates were evaluated using the FDA/CLSI interpretive criteria. A separate performance analysis on FDA intended use was also performed on 438/449 of the isolates.
- A set of 10 gram-negative organisms was used for reproducibility of VITEK 2 MEV at the test sites and QC was performed for the VITEK 2 and BMD at each site using the CLSI QC strains set.
- Comparative performance analysis of clinical and challenge isolates testing was performed using the VITEK 2 automatic dilution method and BMD according to FDA/CLSI, ISO standard 20776-2 interpretive criteria and EUCAST breakpoints for essential agreement (EA), evaluable EA, and categorical agreement (CA).

RESULTS

Clinical performance of VITEK 2 MEV:

- Out of 331 *Enterobacterales* isolates analyzed per FDA/CLSI breakpoints, EA was 99.1% and CA was 99.4% with 0% very major errors (VME) and 0% major errors (ME).
- A total of 408 *Enterobacterales* and *Pseudomonas* isolates were analyzed using EUCAST breakpoints. EA and CA were 97.8% and 99.3%, respectively with 6.3% VME and 0.5% ME.

Overall performance combining clinical and challenge isolates:

- Out of 449 *Enterobacterales* isolates interpreted according to FDA/CLSI or EUCAST criteria, EA and CA were 98.2% and 98.7%, respectively, with 0% VME and 0% ME. For FDA intended for use, 438 *Enterobacterales* isolates analyzed per FDA/CLSI breakpoints, performance was 98.2% EA and 98.6% CA with 0% VME and 0% ME.
- A total of 526 *Enterobacterales* and *P. aeruginosa* isolates were analyzed using EUCAST breakpoints. After error resolution, performance was 97.3% EA and 99.4% CA with 2.2% VME and 0.4% ME.

CONCLUSIONS

Meropenem-vaborbactam susceptibility testing using VITEK 2 automated AST platform for *Enterobacterales* and *P. aeruginosa* could be an alternate solution to the manual labor-intensive reference BMD method.

"These findings support Vitek 2 MEV as an accurate automated system for MEV susceptibility testing of Enterobacterales and P. aeruginosa and could be an alternate solution to the manual-labor-intensive reference BMD method."

KEY FINDINGS

- MIC values from VITEK 2 and reference BMD methods demonstrated a very high agreement for *Enterobacterales* with essential agreement (EA) and categorical agreement (CA) of 98.2% and 98.7%, respectively, according to FDA/CLSI or EUCAST criteria.
- For *Enterobacterales* and *P. aeruginosa*, the performance after error resolution was 97.3% EA and 99.4% CA using EUCAST breakpoints for sets of clinical and challenge isolates.

JOURNAL OF CLINICAL MICROBIOLOGY
2021;59(3):E01870-20 DOI:10.1128/JCM.01870-20

Multicenter Evaluation of Ceftazidime-Avibactam Susceptibility Testing of *Enterobacterales* and *Pseudomonas aeruginosa* on the Vitek 2 System.

Humphries R, Campeau S, Davis TE, Nagaro KJ, LaBombardi VJ, Franklin S, Heimbach L, Dwivedi HP.

OBJECTIVE

Evaluate the AST performance of the VITEK® 2 AST-GN Ceftazidime/Avibactam (CZA) card vs. the CLSI broth microdilution (BMD) reference method in a multicenter study on *Enterobacterales* and *P. aeruginosa* isolates.

STUDY DESIGN

- Four testing sites were selected to test 1,073 isolates (*Enterobacterales*, n=866 and *P. aeruginosa*, n=207) of which 980 (105 stock and 875 fresh) were clinical and 93 were challenge isolates; 2% (20/980) of the clinical isolates were CZA-resistant and 7% (75/10730) of the total isolates were CZA-resistant.
- 10 isolates were used for QC and reproducibility testing.
- VITEK 2 test results were compared to the CLSI BMD reference method to evaluate performance according to FDA and ISO criteria for essential agreement (EA) and categorical agreement (CA).

RESULTS

- EA and CA were 94.5% and 98.7% respectively according to FDA criteria and 94.5% and 98.9% respectively according to ISO criteria.
- No very major errors (VME) were observed.
- Reproducibility and QC test results were >95.0% within acceptable ranges.

CONCLUSIONS

VITEK 2 is a reproducible and accurate method for CZA susceptibility testing of *Enterobacterales* spp. and *P. aeruginosa*.

"Vitek 2 overall performance for Enterobacterales and P. aeruginosa met or exceeded the FDA and ISO performance criteria; thus, it is a reliable alternative to the BMD reference method for routine CZA susceptibility testing."

KEY FINDINGS

- Essential agreement (EA) and categorical agreement (CA) between the VITEK 2 AST-GN Ceftazidime/Avibactam card and BMD method were 94.5% and 98.7%, respectively, according to FDA criteria.
- There is no intermediate category for ceftazidime-avibactam (CZA) so the major error (ME) rate was adjusted from 1.3% to 0.5% and no very major error (VME) was reported.

CLICK TO ACCESS ARTICLE

INFECTION & CHEMOTHERAPY
2015;47(3):167-174. DOI.ORG/10.3947/IC.2015.47.3.167

Detection of Carbapenemases in Clinical *Enterobacteriaceae* Isolates Using the VITEK AST-N202 Card.

Bae IK, Kang HK, Jang IH, Lee W, Kim K, Kim JO, Jeong SH, Lee K.

OBJECTIVE

Evaluate the VITEK® 2 AST-N202 card's ability to detect carbapenemase-producing *Enterobacteriaceae* (CPE) in clinical settings.

STUDY DESIGN

- A total of 122 *Enterobacteriaceae* clinical isolates including 43 CPE isolates (*Klebsiella pneumoniae*, *Escherichia coli*, *Enterobacter cloacae*), and 79 carbapenemase-non-producing *Enterobacteriaceae* (CNE) isolates were tested.
- Bacterial species were identified using matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS) and by analysis of partial 16S rDNA sequences.
- Carbapenemases were screened using VITEK® 2 AST-N202 cards and modified Hodge tests (MHTs).
- PCR and sequencing were used to identify β-lactamase genes.
- The sensitivity and specificity of MHT and VITEK® 2 AST-N202 card were assessed for detecting CPE, i.e., intermediate or resistant results to more than one carbapenem (ertapenem, meropenem, or imipenem).

RESULTS

Table 1. VITEK 2 and Modified Hodge Test sensitivity and specificity for the detection of CPE strains
Reproduced with permission from Infection & Chemotherapy. Bae IK, *et al*. *Infect & Chemother*. 2015;47(3):167-174

Method	Antimicrobial agent	Sensitivity	Specificity
Modified Hodge test	Ertapenem	81.4% (35/43)	100% (79/79)
	Meropenem	81.4% (35/43)	
	Ertapenem+Meropenem	88.4% (38/43)	
VITEK® 2	Ertapenem	100.0% (43/43)	89.8% (71/79)*
	Meropenem	95.3% (41/43)	
	Imipenem	93.0% (40/43)	

* Specificity improved to 100% when excluding eight carbapenem-resistant CNE isolates.

CONCLUSIONS

The VITEK 2 AST-N202 card demonstrated high sensitivity for detecting carbapenemase-producing *Enterobacteriaceae* (CPE), particularly with ertapenem, imipenem, and meropenem. Resistance to carbapenems such as ertapenem, imipenem and meropenem can help predict the presence of carbapenemases.

Fast and accurate detection of CPE is crucial for effective treatment and infection control, highlighting the importance of reliable diagnostic tools like the VITEK 2 AST-N202 card.

"The VITEK 2 AST-N202 card showed high sensitivity for the detection of carbapenemases in Enterobacteriaceae strains."

KEY FINDINGS

- The fast and accurate detection of carbapenemase-producing *Enterobacteriaceae* (CPE) in clinical laboratories is crucial for the treatment of infections and infection control.
- The identification of CPE can be difficult due to some CPE isolates exhibiting low-level resistance or susceptibility to carbapenems.
- The VITEK 2 AST-N202 card shows high sensitivity for detecting carbapenemases in *Enterobacteriaceae*.

CLICK TO ACCESS ARTICLE

DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE
2013;77(1):37-40. DOI: 10.1016/J.DIAGMICROBIO.2013.05.019

Comparison of the Vitek 2 yeast susceptibility system with CLSI microdilution for antifungal susceptibility testing of fluconazole and voriconazole against *Candida* spp., using new clinical breakpoints and epidemiological cutoff values.

Pfaller MA, Diekema DJ, Procop GW, Rinaldi MG.

OBJECTIVE

Compare MIC results for fluconazole and voriconazole with *Candida* spp. obtained with the VITEK® 2 system, to those obtained by the CLSI reference broth microdilution (BMD) method in three laboratories.

STUDY DESIGN

- **Test organisms**: Included 2 ATCC strains and a challenge set of 80 isolates of *Candida* spp. representing both clinically important species and resistance mechanisms.
- **Clinical isolates**: An additional 346 recent clinical isolates of *Candida* spp. were tested.
- **Reproducibility**: Assessed within and among laboratories using a panel of 10 *Candida* spp. isolates tested in triplicate on 3 different days in each of the 3 laboratories.
- The epidemiological cutoff value (ECV) of 0.5 µg/mL was used for voriconazole and *C. glabrata* to differentiate wild-type (WT; MIC ≤ ECV) from non-WT (MIC > ECV). The ECVs for fluconazole and voriconazole, respectively, were used for *Candida lusitaniae* (2 µg/mL and 0.03 µg/mL), *Candida dubliniensis* (0.5 µg/mL and 0.03 µg/mL), *Candida guilliermondii* (8 µg/mL and 0.25 µg/mL), and *Candida pelliculosa* (4 µg/mL and 0.25 µg/mL).

RESULTS

- Essential Agreement (EA) between VITEK 2 and 24-hour CLSI BMD MICs was 97.9% for fluconazole and 96.7% for voriconazole.
- Categorical Agreement (CA) between the two methods was 96.8% for fluconazole and 96.5% for voriconazole.
- Very Major Errors (VME): Less than 1% for both fluconazole and voriconazole.
- Major Errors (ME): Fluconazole: 1.3%; Voriconazole: 3.0%.
- Species-specific results:
  - *C. albicans*: High CA for both fluconazole (96.5%) and voriconazole (98.5%).
  - *C. glabrata*: Lower CA for voriconazole (85.6%) with 2.5% VMEs.
  - Other *Candida* spp.: Generally high CA and low error rates.

CONCLUSIONS

The VITEK 2 yeast susceptibility system is highly comparable to the CLSI BMD method for testing fluconazole and voriconazole against *Candida* species, with excellent agreement and low error rates.

"The Vitek 2 system using the new CBPs reliably identifies fluconazole resistance among Candida spp. and demonstrates excellent quantitative and qualitative agreement with the reference BMD method when testing either fluconazole or voriconazole."

KEY FINDINGS

- **Standardization**: The Clinical and Laboratory Standards Institute (CLSI) has standardized the broth microdilution (BMD) reference method for testing triazoles against *Candida* spp.
- **Quality Control**: CLSI has published quality control (QC) limits and validated 24-hour MIC readings.
- **Breakpoints**: New species-specific clinical breakpoints and epidemiological cutoff values (ECVs) have been developed for these agents and several species of *Candida*.

CLICK TO ACCESS ARTICLE

JOURNAL OF CLINICAL MICROBIOLOGY
2017;55(2):450-456. DOI:10.1128/JCM.01859-16

Performance of Vitek 2 for Antimicrobial Susceptibility Testing of *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Stenotrophomonas maltophilia* with Vitek 2 (2009 FDA) and CLSI M100S 26th Edition Breakpoints.

Bobenchik AM, Deak E, Hindler JA, Charlton CL, Humphries RM.

OBJECTIVE

This study evaluated the performance of VITEK® 2 for antimicrobial susceptibility testing (AST) of *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Stenotrophomonas maltophilia*, comparing the results obtained from VITEK 2 with those from the CLSI reference broth microdilution (BMD) method.

STUDY DESIGN

- Ninety-nine *P. aeruginosa* isolates, 26 *A. baumannii* isolates, and 11 *S. maltophilia* isolates were evaluated in this study.
- Fifteen antimicrobials were evaluated, with 11 for *P. aeruginosa*, 14 for *A. baumannii*, and 2 for *S. maltophilia*.
- BMD MIC testing was performed according to CLSI standards and VITEK 2 testing used AST-GN69 and AST-XN06 cards.
- The categorical agreement (CA), essential agreement (EA), and error rates including major errors (MEs), minor errors (mEs) and very major errors (VMEs) were calculated using VITEK 2 and 2016 CLSI M100S 26th edition breakpoints.

RESULTS

- **EA results**: high agreement between VITEK 2 and BMD **(Table 1)**
  - *P. aeruginosa*: 99.5%;
  - *A. baumannii*: 99.2%;
  - *S. maltophilia*: 100%.
- **CA results**: good overall agreement **(Table 1)**
  - *P. aeruginosa*: 94.1% (VITEK 2 breakpoints), 93.4% (CLSI breakpoints);
  - *A. baumannii*: 92.7% (VITEK 2 breakpoints), 92.3% (CLSI breakpoints);
  - *S. maltophilia*: 95.5% (both breakpoints).
- **Piperacillin-tazobactam (TZP) results with *P. aeruginosa* and *A. baumannii* respectively were**: 98.9% and 100% EA; 96.7% and 88.5% CA; and 3 ME with *P. aeruginosa* 3 mEs with *A. baumannii*.
- **Imipenem (IPM) results with *P. aeruginosa* and *A. baumannii* respectively were**: 100% and 100% EA; 92.3% and 100% CA; and 7 mEs with *P. aeruginosa*.
- **Study limitations**: a small number of *S. maltophilia* and a small number of resistant *A. baumannii* were included in the study, leading to a higher mE rate and a lower CA rate.

CONCLUSIONS

This study concludes that the VITEK 2 system performs well for antimicrobial susceptibility testing of *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia*, with high EA and CA rates as compared to the BMD method. The reformulated piperacillin-tazobactam (TZP) and imipenem (IPM) demonstrate an improved performance with low error rates.

"Overall, the Vitek 2 performance was comparable to that of BMD using both Vitek 2 breakpoints and 2016 CLSI M100S 26th edition breakpoints."

KEY FINDINGS

- VITEK 2 system is a reliable method for antimicrobial susceptibility testing of *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Stenotrophomonas maltophilia*.
- The performance of VITEK 2 was comparable to the reference BMD, with high essential and categorical agreement rates and low error rates.
- VITEK 2 can be effectively used in clinical laboratories for testing these bacteria.

Table 1. Overall performance of VITEK® 2 AST-GN69 and AST-XN06 cards compared to BMD
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Organism group	BP[a]	Total[b]	EA (%)	CA (%)	VMEs (no. [%])	MEs (no. [%])	mEs (no. [%])
P. aeruginosa	V2	1,001	99.5	94.1	0 (0)	12 (1.9)	51 (4.6)
A. baumannii	V2	364	99.2	92.7	1 (7.1)	0 (0)	31 (5.2)
S. maltophilia	V2	22	100	95.5	0 (0)	0 (0)	1 (4.6)
P. aeruginosa	CLSI	1,001	99.5	93.4	0 (0)	1 (0.12)	67 (6.5)
A. baumannii	CLSI	364	99.2	92.7	1 (7.1)	0 (0)	33 (5.3)
S. maltophilia	CLSI	22	100	95.5	0 (0)	0 (0)	1 (4.6)

a BP, breakpoint used to interpret MIC results; V2, VITEK 2 breakpoints; CLSI, M100S 26th edition breakpoints.
b Total represents the number of isolates tested multiplied by the number of antimicrobials tested.
EA, essential agreement (MIC ±1 doubling dilution); CA, categorical agreement; VMEs, very major errors; MEs, major errors; mEs, minor errors.

WORKFLOW EFFICIENCY

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JOURNAL OF CLINICAL MICROBIOLOGY
2025:E0004825 DOI:10.1128/JCM.00048-25

Evaluation of MicroScan and VITEK 2 systems for susceptibility testing of *Enterobacterales* with updated breakpoints.

Richter SS, Dominguez EL, Hupp AA, Griffis M, MacVane S.

OBJECTIVE

Compare the performance and workflow of two commercial antimicrobial susceptibility testing (AST) systems, VITEK® 2 and MicroScan® using broth microdilution (BMD) as the reference standard.

STUDY DESIGN

- 200 *Enterobacterales* clinical isolates, including various species such as *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* complex, were tested.
- Included 25% extended-spectrum β-lactamase (ESBL), 23% carbapenem-resistant *Enterobacterales* (CRE), and 4.5% AmpC resistance genotypes.
- Testing was performed using VITEK 2 AST test cards (AST-N802 and AST-XN15) and MicroScan NM56 AST panels.
- Essential Agreement (EA), Categorical Agreement (CA), and error rates were calculated for each system using BMD as the reference standard, and CLSI 2022 breakpoints.
- Time to results (TTR) was assessed for each instrument with 200 isolates, and hands-on time was assessed by timing two different technologists setting up 12 batches of five isolates on each system (six batches per technologist).

RESULTS

- Accuracy: VITEK 2 and MicroScan showed high accuracy with overall CA rates of >94% and EA rates of ≥96%.
- Categorical Agreement: CA was ≥90% for most antimicrobial agents tested, except for ampicillin-sulbactam (MicroScan), cefoxitin (both systems), minocycline (MicroScan), and nitrofurantoin (both systems).
- Time to Results (TTR): VITEK 2 had a faster median TTR of 11.7 hours, compared to MicroScan's 18 hours.
- Hands-on Time: MicroScan required less hands-on setup time (1.29 min/isolate) compared to VITEK® 2 (1.83 min/isolate).

Table 1. Summary of study results for VITEK 2 and Microscan.
Source: bioMérieux adapted from Richter SS, *et al*. *J Clin Microbiol*. 2025:e0004825

Parameter	VITEK 2	MicroScan
Essential Agreement (EA)	96%	98%
Categorical Agreement (CA)	94.5% overall, 90% for most agents	94.7% overall, 90% for most agents
Hands-on Time	1.83 min/isolate	1.29 min/isolate
Median time to results (TTR)	11.7 hours	18 hours

CONCLUSIONS

The findings of this study support the reliability and efficiency of VITEK 2 and MicroScan, with each having distinct advantages in terms of speed and ease of use. VITEK 2 offers a faster turnaround time with a median TTR of 11.7 hours, while MicroScan requires less hands-on setup time (1.29 min/isolate).

"The shorter run time is an advantage of VITEK 2, assuming the AST results are released and acted upon when they become available."

KEY FINDINGS

- VITEK 2 demonstrated high accuracy in determining minimum inhibitory concentrations (MICs) for various antimicrobials with high categorical agreement (CA) and essential agreement (EA) rates.
- VITEK 2 reported a faster median Time to Results (TTR) which is crucial for effective patient care, particularly in the management of infectious diseases.

CLICK TO ACCESS ARTICLE

DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE
2023;107(2):116032 DOI:10.1016/J.DIAGMICROBIO.2023.116032

Evaluation of VITEK® 2 AST cards (AST-N376 and AST-N397) for susceptibility testing of challenging Gram negatives.

Riccobono E, Aiezza N, Niccolai C, Giani T, Rossolini GM.

OBJECTIVE

Evaluate the performance of the VITEK® 2 AST-N376 and AST-N397 cards for antibiotic susceptibility testing (AST) of challenging Gram-negative bacteria.

STUDY DESIGN

- Performance and workflow comparison between updated VITEK 2 cards (AST-N376 and AST-N397) and MICRONAUT®-S MDR MRGN-Screening (MERLIN Diagnostika GmbH) at Florence Careggi University Hospital. Of note, MICRONAUT-S is a commercial broth microdilution (BMD) method.
- Results were read with the VITEK 2 ADVANCED EXPERT SYSTEM™ (AES v9.02) for VITEK 2 and manually for the MICRONAUT-S panel. EUCAST v9.0 was used as reference for interpretative criteria.
- Performance evaluation was conducted according to ISO 20776-1:2019 criteria: essential agreement (EA), categorical agreement (CA), major discrepancies/error (ME), very major discrepancies/error (VME), minor discrepancies/error (mE) and bias (according to ISO 20776-2:2021 criteria).
- AST results were analyzed to assess VITEK 2 cards performance compared to MICRONAUT-S. BMD reference method was performed for tobramycin (not included in MICRONAUT-S panel) and in case of discordance results.
- Workflow analysis considered preparing suspension, setting up VITEK 2/ MICRONAUT-S, and reading MICRONAUT-S times.

RESULTS

Performance: A collection of 180 non-duplicated gram-negatives isolates corresponding to a total of 1571 organism-antimicrobial agent combinations were analyzed. Among them, 68% (n=123) were *Enterobacterales* isolates [incl. 83% (n=102) of strains with challenging phenotypes: MDR/XDR, ESBL, class A and/or class B-carbapenemase]; 25% (n=45) were *Pseudomonas aeruginosa* isolates [with 27% (n=12) of carbapenemase producers]; 7% (n=12) were *Acinetobacter baumannii* isolates [with 83% (n=10) of carbapenemase producers]. All quality controls were in range in each testing session.

- *Enterobacterales*: Overall, CA and EA reached ISO acceptance criteria (≥ 90%) for all molecules tested except for EA of cefepime, ceftolozane/tazobactam, tobramycin with a percentage of 80.5%, 87.8% and 83.7%, respectively. After the BMD adjudication, all discrepancies were within the limits allowed.
- *P. aeruginosa*: Overall, CA and EA were within ISO acceptance criteria for all antibiotics except for EA of ceftazidime/avibactam (84.4%). For VITEK 2, rates of ME for ceftolozane/tazobactam (4.0%, n=1) and VME for cefepime (3.7%, n=1) and ceftazidime (3.3%, n=1) were higher than the limits allowed by ISO criteria.
- *A. baumannii*: All isolates showed EA and CA values in accordance with ISO acceptance criteria for all antibiotics. One VME was reported for gentamicin corresponding to 9.1%.
- Overall: The study collection showed EA ≥90% and −30%≤ bias ≤+30% for all antibiotics tested except for EA of cefepime (85.1%) and bias of tobramycin (-33.8%), pointing out a tendency to underestimate MICs for this antibiotic.

Workflow: Among 73 isolates, the mean time to perform antibiotic susceptibility testing for a single isolate by VITEK 2 was 181.7 seconds (SD ±43.0 seconds), while the mean time required by MICRONAUT-S was 1.6-fold higher with 291.2 seconds (SD ±36.5 seconds) (p<0.0001).

CONCLUSIONS

The VITEK 2 AST-N376 and AST-N397 cards provide reliable susceptibility results for the combinations of antibiotic-microorganism evaluated. These cards require a short hands-on time to prepare panels, enhancing the efficiency of VITEK 2.

"VITEK® 2 is a valid system that ensures accurate results for AST of the molecules evaluated in this study and speeds up the workflow in the laboratory of diagnostic microbiology."

KEY FINDINGS

- The VITEK 2 cards (AST-N376 and AST-N397) proved to be reliable in determining the antibiotic susceptibility against a challenging collection of isolates with contemporary resistance mechanisms.
- VITEK 2 showed a shorter hands-on time to prepare panels compared to MICRONAUT-S.

CLICK TO ACCESS ARTICLE

ANNALS OF CLINICAL MICROBIOLOGY AND ANTIMICROBIALS
2016;15(1):45. DOI 10.1186/S12941-016-0158

Comparison of methods for the identification of microorganisms isolated from blood cultures.

Monteiro AC, Fortaleza CM, Ferreira AM, Cavalcante Rde S, Mondelli AL, Bagagli E, da Cunha Mde L.

OBJECTIVE

Evaluate the accuracy of the VITEK® 2 system in the identification of microorganisms isolated from blood cultures and compare the results to those obtained with conventional phenotypic and genotypic methods.

STUDY DESIGN

- Isolates studied: 400 microorganisms isolated from positive blood cultures of patients hospitalized in intensive care units.
- Phenotypic identification consisted of Gram staining for the observation of morphology and specific staining, followed by a series of biochemical tests specific for each group of microorganisms.
- Automated phenotypic identification was performed using specific identification cards of the VITEK 2 system.
- The DNA of these microorganisms was extracted directly from the blood culture bottles for genotypic identification by the polymerase chain reaction (PCR) and DNA sequencing.
- Agreement between the results obtained with the different identification methods was analyzed by the Kappa test, and the accuracy of the conventional phenotypic identification methods and identification by the VITEK 2 system were compared to results from genotypic methods.

RESULTS

- VITEK 2 correctly identified 94.7% (379/400) of the isolates.
- The yeast (YST) and Gram-negative bacilli (GN) cards resulted in 100% correct identification of yeasts (15/15) and Gram-negative bacilli (165/165) respectively.
- The Gram-positive cocci (GP) card correctly identified 92.6% (199/215) of Gram-positive cocci.
- The Anaerobic and Corynebacteria (ANC) card was unable to correctly identify any Gram-positive bacilli (0/5), which can be explained by the variability of the genera and species of the microorganisms.
- The Kappa values showed reliability of the results obtained by the VITEK system **(Table 1)**.

Table 1. Kappa values of agreement between the identification methods

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Group	Number of isolates	Kappa	
		(Conventional method × Genotypic method)	(Automated method × Genotypic method)
Gram-positive cocci	255	0.969	0.904
CoNS*	186	0.969	0.886
Gram-negative bacilli	165	0.993	1.000
Gram-positive bacilli	5	NP	0
Yeasts	15	1.000	1.000
Total	400	0.958	0.945

* CoNS: Coagulase-negative staphylococci

CONCLUSIONS

This study concludes that the VITEK 2 system is suitable for rapid and efficient identification of most microorganisms isolated from blood cultures in clinical microbiology laboratories.

VITEK 2 demonstrated high accuracy, particularly with yeasts and Gram-negative bacilli, with rates of 100%. A good identification rate was also noted with Gram-positive cocci, but not with Gram-positive bacilli.

"The performance of the VITEK® 2 system was considered acceptable and statistical analysis showed that the system is a suitable option for routine clinical microbiology laboratories to identify different microorganisms."

KEY FINDINGS

- **The VITEK 2 system correctly identified 94.7% of the 400 isolates collected from blood cultures.**
- **Greater than 90% correct identifications were obtained for yeasts, Gram-negative bacilli and Gram-positive cocci. VITEK 2 delivers reliable and timely results for isolates subcultured from positive blood cultures.**

VITEK® 2 ADVANCED EXPERT SYSTEM™ (AES)

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MICROBIOLOGY SPECTRUM
2023;11(1):E0467322 DOI:10.1128/SPECTRUM.04673-22

Performance of the Vitek 2 Advanced Expert System (AES) as a Rapid Tool for Reporting Antimicrobial Susceptibility Testing (AST) in *Enterobacterales* from North and Latin America.

Carvalhaes CG, Shortridge D, Woosley LN, Gurung N, Castanheira M.

OBJECTIVE

Evaluate the performance of the VITEK 2 ADVANCED EXPERT SYSTEM (AES) confidence level report as a rapid tool for reporting antimicrobial susceptibility testing (AST) results for a challenging set of *Enterobacterales* isolates from North and Latin America.

STUDY DESIGN

- The study evaluated 513 clinical isolates of *Enterobacterales* from North and Latin America (6 countries, 123 isolates [24.0% overall]). The isolates were assessed by VITEK 2 (N802 and XN15 AST cards) and CLSI broth microdilution (BMD). Included isolates were wild-type and those having acquired β-lactamases, as characterized by whole genome sequencing.
- The AES identified a phenotype to three confidence levels:
  (i) green, for consistent or typical (all minimum inhibitory concentrations [MICs] match with the phenotype);
  (ii) yellow, for consistent with correction or atypical (one MIC does not match with closest phenotype(s));
  (iii) red, for inconsistent (at least two MICs do not match with any phenotype or a phenotype cannot be identified with sufficient confidence).
- Comparison of AES assessment of confidence level was performed with BMD results and known genotypes. Review by an experienced microbiologist was conducted for accuracy.

RESULTS

Overall performance of VITEK 2 AES assessment:

- 148 (28.8%) isolates were wild-type, and 365 (71.2%) harbored carbapenemase (211 [41.1%]), extended-spectrum β-lactamase (122 [23.8%]), and/or transferable AmpC (32 [6.2%]) genes.
- VITEK 2 displayed essential agreement (EA) of >83% and categorical agreement (CA) rate of >81% in the more than 14,058 pathogen/antimicrobial combinations that were tested.
- For each β-lactam, CA rates were <90% for cefepime (87.4%) and cefoxitin (86.9%), primarily due to minor errors.
- Cefepime very major errors (VMEs) were observed mainly in isolates with carbapenemase genes (14/16).
- Improving AES corrections based on organism phenotype can reduce cefepime VME from 5.8% to 1.8%.

VITEK 2 AES assessment for rapid AST report:

- AES confidence level was evaluated for 488 isolates, and phenotype was identified for 447 (91.6%).
- AES reports were green, yellow, and red for 382 (78.3%), 65 (13.3%), and 41 (8.4%) isolates, respectively.
- As compared to BMD, 96.3% of green AES reports could be confidently and quickly auto-released, which enables rapid adjustments to antimicrobial therapy.
- 69.2% of yellow reports were acceptable; 16 (24.6%) isolates in yellow-labeled reports were consistent with BMD results.
- A red report was issued for 8.4% of evaluated isolates, and 80.5% displayed consistent results with BMD method.

CONCLUSIONS

VITEK 2 AES continues to provide accurate susceptibility testing for contemporaneous *Enterobacterales* harboring diverse mechanisms of resistance to β-lactams.

"Compared to BMD, 96.3% of green AES reports could be confidently and rapidly auto-released, enabling rapid adjustments to antimicrobial therapy."

KEY FINDINGS

- The AES confidence level report is a valuable tool for clinical laboratories, 96.3% of consistent (i.e., green) AES reports could be confidently and quickly auto-released.
- For contemporaneous *Enterobacterales* isolates with diverse β-lactam resistance mechanisms, VITEK 2 AES provides accurate susceptibility testing analysis.

CLICK TO ACCESS ARTICLE

DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE
2024;110(1):116358 DOI:10.1016/J.DIAGMICROBIO.2024.116358

β-Lactam resistant Phenotypes Reported by VITEK® 2 Advanced Expert System™ (AES) Compared to Whole Genome Sequencing in *Enterobacterales* from North and Latin America.

Carvalhaes CG, Shortridge D, Rhomberg P, Castanheira M.

OBJECTIVE

Evaluate the performance of the VITEK 2 ADVANCED EXPERT SYSTEM (AES) in identifying β-lactam resistant phenotypes in *Enterobacterales* compared to resistance genotypes provided by whole genome sequencing (WGS) for a challenge collection of *Enterobacterales* isolates from North and Latin America. Accuracy, sensitivity, and specificity were determined for the following phenotypes: carbapenemases, extended spectrum β-lactamase (ESBL), and transferable AmpC (tAmpC).

STUDY DESIGN

- A total of 488 *Enterobacterales* clinical isolates were collected from 72 medical centers across North and Latin America.
- Isolates were tested using the VITEK 2 system (N802 and XN15 cards), and the VITEK 2 MIC results were generated using AES with the 9.02 software version.
- The VITEK 2 MIC results were compared to the BMD MIC values in the SENTRY database. Discordant results (major error (ME) and very major error (VME)) were repeated in parallel by both methods using the same inoculum.
- Isolates displaying specific MIC values for key β-lactam antibiotics were subjected to whole genome sequencing (WGS) to identify β-lactamase–encoding genes.
- Isolates were classified into carbapenemase, ESBL and tAmpC genotypes based on WGS results.
- The AES β-lactam phenotype dispositions were compared to WGS genotypes to evaluate accuracy, sensitivity and specificity.

RESULTS

- The overall accuracy rate of the AES was 96.9% (433/447 isolates).
- Phenotype detection: carbapenamase detected in 188/195 isolates with a sensitivity of 96.4% and specificity of 91.7%; extended spectrum β-lactamase (ESBL) detected in 101/103 isolates with a sensitivity of 98.1% and specificity of 92.4%; transferable AmpC (tAmpC) detected in 23/28 isolates with a sensitivity of 82.1% and specificity of 99.5%; and wildtype correctly identified in 121 isolates with a sensitivity of 100% and specificity of 98.8% **(Table 1** page 34**)**.
- Among the 447 isolates, 382 had consistent AES reports. The accuracy of consistent reports was 95.8% for carbapenemase, 98.7% for ESBL, 99.2% for tAmpC and 99.5% for wildtype **(Table 2** page 34**)**.
- 14 isolates carrying carbapenemase, ESBL and tAmpC-encoding genes were not correctly identified by the AES.

CONCLUSIONS

The study supports the use of the AES as a reliable tool in clinical microbiology laboratories for managing β-lactam resistance in *Enterobacterales*. The AES system's fast and accurate detection capabilities can significantly aid in antimicrobial stewardship initiatives and improve patient care by enabling timely and appropriate antibiotic treatment.

"The AES phenotypic report detected resistance mechanisms among Enterobacterales rapidly and could significantly aid future antimicrobial stewardship initiatives and patient care."

KEY FINDINGS

- The VITEK 2 AES is highly effective in accurately detecting β-lactam resistance phenotypes in Enterobacterales isolates from North and Latin America.
- The system demonstrated a sensitivity of 96.4% and specificity of 91.7% in the detection of carbapenemases.

CONTINUED FROM PAGE 25

Table 1. The overall accuracy, sensitivity and specificity rates for VITEK 2 AES phenotypes
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β-lactam resistance genotype (No. of isolates)	AES phenotypic report		
	Accuracy	Sensitivity	Specificity
Carbapenemase (195)	93.7%	96.4%	91.7%
ESBL (103)	93.7%	98.1%	92.4%
tAmpC (28)	98.4%	82.1%	99.5%
WT (121)	99.1%	100.0%	98.8%

Table 2. The accuracy, sensitivity and specificity rates for VITEK 2 AES phenotypes considering only the results reported with high confidence (Green Reports)
Reproduced with permission from Carvalhaes CG, *et al. Diag Microbiol Inf Dis*. 2024;110(1):116358

β-lactam resistance genotype (No. of isolates)	AES phenotypic report		
	Accuracy	Sensitivity	Specificity
Carbapenemase (170)	95.8%	98.2%	93.9%
ESBL (83)	98.7%	97.6%	99.0%
tAmpC (16)	99.2%	93.8%	99.5%
WT (113)	99.5%	100.0%	99.3%

VITEK® 2 ADVANCED EXPERT SYSTEM™ (AES)

CLICK TO ACCESS ARTICLE

EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
2021;40(6):1333-5 DOI:10.1007/S10096-021-04162-0

Performance of the VITEK®2 advanced expert system™ for the validation of antimicrobial susceptibility testing results.

Pages Monteiro L, Von Allmen N, Friesen I, Huth K, Zambardi G.

OBJECTIVE

Assess the reliability of the VITEK 2 ADVANCED EXPERT SYSTEM (AES) software to effectively alert the microbiologist in the detection of atypical and inconsistent antimicrobial susceptibility test (AST) results in a clinical laboratory setting.

STUDY DESIGN

- 3-month prospective study at the Labor Berlin – Charités Vivantes services.
- VITEK 2 routine reports were expertized with the AES software version 8.01 and reviewed by a team of four trained and experienced microbiologists.
- N223, N228 and P616, P586, P654, P632, ST03 VITEK 2 AST cards were used for Gram-negative and Gram-positive isolates, respectively.
- MICs not matching with an established phenotype were verified by ETEST® and disk diffusion methods.

RESULTS

- 433 reports were reviewed according to the following pre-determined proportions:
  - 300 (70%) were typical: 168 gram-negative bacteria (GNB), 29 *Enterococcus* spp., 65 *Staphylococcus* spp., and 38 *Streptococcus* spp.
  - 124 (28%) were atypical, i.e., one MIC does not match with the closest phenotype: 94 GNB, 8 *Enterococcus* spp., 15 *Staphylococcus* spp., and 7 *Streptococcus* spp.
  - 9 (2%) were « inconsistent », i.e., when at least 2 MICs do not match with any phenotypes or no phenotype can be identified with enough confidence: 9 GNB.
- The 433 reports came from 256 *Enterobacterales*, 15 non-fermenters, 37 *Enterococcus*, 80 *Staphylococcus* spp., and 45 *Streptococcus* spp.
- Among the 300 typical reports, 99.3% were confirmed as typical after review, and 2 reports were corrected by the microbiologist team.
- Among the 133 atypical or inconsistent reports:
  - 68% (91/133) showed 1 MIC that was not confirmed by ETEST or disk diffusion and coherently needed to be halted for microbiologist's review and decision.
  - 32% (42/133) had MIC confirmed by ETEST or disk diffusion and therefore inappropriately warned the microbiologists (18/42 were β-lactam efflux phenotypes in *P. aeruginosa*, a phenotype not included in the AES Knowledge Base).

CONCLUSIONS

The AES is a reliable tool in the clinical setting: the high sensitivity (99.3%) observed for typical reports supports the feasibility of direct release of AST results to clinicians without additional review.
Atypical and inconsistent reports need to be reviewed for possible additional tests prior to the release of AST results.

"The high sensitivity of 99.3% found in this study at Labor Berlin may support the release of AST results to the physician, as soon as they are complete, prior to the final sign out."

KEY FINDINGS

- **99.3% (298/300) of « typical » reports were in agreement with the microbiologists' review.**
- **68% (91/133) of « atypical » or « inconsistent » results were confirmed by an alternate method as needing a review.**

CLINICAL AND ECONOMIC IMPACT

DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE
2019;95(2):208-11 DOI:10.1016/J.DIAGMICROBIO.2019.05.020

Effect of antimicrobial stewardship with rapid MALDI-TOF identification and Vitek 2 antimicrobial susceptibility testing on hospitalization outcome.

Cavalieri SJ, Kwon S, Vivekanandan R, Ased S, Carroll C, Anthone J, Schmidt D, Baysden M, Destache CJ.

OBJECTIVE

Assess the time needed to obtain identification (ID) and antimicrobial susceptibility testing (AST) results and to initiate appropriate therapy before and after the implementation of VITEK® MS, VITEK® 2 and a dedicated AMS team in patients with bloodstream, respiratory and urinary infections.

STUDY DESIGN

A decision analytic model was developed, from a French payer perspective, to compare the health outcomes and direct healthcare costs for a hypothetical cohort of 20,000 hospitalized patients diagnosed with BSI.

The cohort was divided into two groups:

- For the 2017 time period, organism ID and AST were performed on 77 patients using the MicroScan microdilution system and a limited antimicrobial stewardship program (ASP) was available.
- For the 2018 time period, organism ID and AST were performed on 77 patients using VITEK MS / VITEK 2 and a dedicated AMS team was hired.
- Time to obtain ID and AST results as well as length of stay (LOS) and length of antimicrobial therapy were compared between the two periods.

RESULTS

Table 1. Study results comparing time variables before and after implementation of the VITEK MS, VITEK 2 and AMS team intervention
Source: bioMérieux adapted from Cavalieri SJ, *et al*. *Diag Microbiol Infect Dis*. 2019;95(2):208-11

Time variable	MicroScan and no dedicated AMS team	VITEK® MS / VITEK® 2 + AMS	Statistical significance
Identify and report organism (hours)	33.8 +/- 17	24.9 +/- 14.4	*p*=0.001
Perform and report AST (hours)	28.5 +/- 14.9	18.2 +/- 14	*p*<0.001
Length of hospitalization (days)	15.5 +/- 18.1	10.7 +/- 11.1	*p*=0.05
Length of in-patient antimicrobial therapy (days)	8.8 +/- 7.8	6.7 +/- 3.8	*p*=0.036

CONCLUSIONS

Use of VITEK MS / VITEK 2 leads to an average 21.5 hours faster ID and AST results and, in conjunction with a dedicated AMS team, leads to significant reduction in antimicrobial therapy duration (or antimicrobial exposure) and hospital LOS.

"Use of ASP and MALDI-TOF/Vitek 2 rapid identification and AST demonstrated for urine, blood, and sputum cultures a significant reduction in time to isolate identification and AST results, which translated to significant reduction in antibiotic length of therapy and hospital LOS..."

KEY FINDINGS

- The time to obtain both ID and AST results was significantly faster when using VITEK MS/VITEK 2 (21.5 h less on average) which, in conjunction with workflow optimization, allowed the AMS team to recommend significantly more adjustments for appropriate antimicrobial therapy.
- The consequence was a significant reduction in LOS (length of stay; 4 days for general ward and 7 days in ICU) and length of antimicrobial therapy (2 days).

EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
2012;31(9):2445-2452 DOI: 10.1007/S10096-012-1588-8

Clinical and economic impact of rapid reporting of bacterial identification and antimicrobial susceptibility results of the most frequently processed specimen types

Galar A, Yuste JR, Espinosa M, Guillén-Grima F, Hernáez-Crespo S, Leiva J.

OBJECTIVE

Measure the clinical and economic impact of fast microbiological reporting on the most frequently processed specimen types in the laboratory.

STUDY DESIGN

- **Population**: Hospitalized patients treated by the Infectious Diseases Division and who had a significant bacterial isolate from one of the included specimens.
- **Groups**: Historical control group (consisting of specimens where the microbiological results were made available the day following the analysis) vs. intervention group (consisting of specimens where the microbiological results were made available on the same day as the analysis).
- **Specimens**: wound and abscess, blood, and urine.
- **Outcome parameters**: impact on hospital stay, hospital costs and mortality rates.

RESULTS

- **Time reduction**: significant reduction in the median length of time from the introduction of the microorganism in the VITEK® 2 system until microbiological reporting for wound and abscess, blood, and urine specimens.
- **Hospital stay reduction**: faster reporting was associated with a significant reduction in hospital stay for patients with wound, abscess, and urine specimens.
- **Cost reduction**: overall hospital costs were reduced for patients with wound, abscess, and urine specimens.

Table 1. Median times to report according to specimen type
Source: bioMérieux adapted from Galar A, *et al*. *Eur J Clin Microbiol Infect Dis*. 2012;31(9):2445-2452

Specimen type	Median time to report	Median time to report (after receipt)	*p*-value
Wound and Abscess	23.5 hours	9.5 hours	<0.001
Blood	23.5 hours	9.2 hours	<0.001
Urine	23.4 hours	9.3 hours	<0.001

CONCLUSIONS

Fast (same day) reporting of bacterial identification and antimicrobial susceptibility results using the VITEK 2 system significantly reduces hospital stay and overall costs for patients with wound, abscess, and urine specimens. No significant difference was observed between control and intervention group for blood culture isolates.

"Faster reporting of identification and antimicrobial susceptibility results was associated with a significant reduction in hospital stay and in overall costs for those patients from whom wound, abscess, and urine specimens were analyzed."

KEY FINDINGS

- Fast reporting of results significantly reduced the median time to results for wound, abscess, blood, and urine specimens.
- Faster (same day) VITEK 2 reporting was associated with reduction in hospital stay for patients and a significant reduction in overall hospital costs for such patients.

CLINICAL AND ECONOMIC IMPACT

ECCMID 2013 POSTER P-1536

Comparison of bioMerieux Vitek 2 XL, BD Phoenix, and Siemens MicroScan Walkaway 96 plus: Choosing an Identification and Antimicrobial Susceptibility Testing System for a Medium Sized Microbiology Laboratory.

Hooper M, Hill C, Hadwell V, Blondel-Hill E.

OBJECTIVE

Performance of an automated identification (ID) and antimicrobial susceptibility testing (AST) instrument is not limited to accuracy of ID and AST results. Other parameters must also be taken into consideration. This study evaluated three automated systems (bioMérieux VITEK® 2 XL [VTK], BD Phoenix™ [PHX] and Siemens MicroScan Walkaway96 plus® [MS]) based on inoculum preparation, test menu, requirement for manual testing, time to reporting, biohazardous waste, space requirements and environmental footprint.

STUDY DESIGN

All three instruments were evaluated simultaneously over a 2 month period at the Larissa Yarr Microbiology Laboratory at Kelowna General Hospital, British Columbia, Canada. Set up time and biohazardous waste results were determined using groups of 10 isolates to simulate a typical workflow situation.

RESULTS

Inoculum preparation time (in minutes for 10 samples) was 18.5 for VTK, 19.3 for MS and 21.5 for PHX **(Table 1)**. For the MS, its most rapid sample preparation method was used (PROMPT™) and for the PHX extra time required for the AP system to prepare dilutions and add AST indicator was not included (as more samples or other work could be done during this time). No manual testing was required for VTK or PHX, for MS oxidase or β-lactamase tests were routinely required. Time to result of final ID/AST was 4-18h for VTK, 4-16h for PHX and 16 or 24h for MS (preliminary ID resulted earlier for both VTK and PHX).

The VTK produced the least biohazardous waste in kg per samples (0.048) with an estimated annual cost in CAD of $2628.00, the PHX was 0.109 ($5967.50) and the MS 0.122 ($6679.50) **(Table 2)**. The PHX instrument with the AP system required the most bench space. The PHX and the MS required more storage space for their ID/AST panels and reagents/supplies than the VTK. The VTK has a more extensive ID test menu including aerobic Gram-positive (GP) and Gram-Negative (GN) organisms along with fastidious GNs, anaerobes and yeast while the PHX does not include fastidious GN, anaerobes or yeast and the MS test menu includes aerobic GP cocci, and aerobic GN and fastidious GN **(Table 3)**.

CONCLUSIONS

Accuracy of ID/AST was similar for all three systems. The VTK was deemed the best fit for a medium sized clinical microbiology laboratory given its larger ID test menu, rapid inoculum preparation, minimal manual testing, ability to use inoculum for offline testing, time to results, ability to test ID and AST separately, reduced biohazard waste cost and favorable environmental footprint.

"Vitek 2 was deemed the best fit for a medium sized clinical microbiology laboratory given its larger ID test menu, rapid inoculum preparation, ability to use inoculum for offline testing, time to results, ability to test ID and AST panels separately, reduced biohazard waste cost and favourable environmental footprint"

KEY FINDINGS

- **VITEK 2 demonstrated the fastest set-up time per test (1.845 minutes), the least biohazard waste produced per sample (0.048 kg) and the most extensive test menu.**
- **The availability of separate ID and AST panels make VITEK 2 advantageous over other instruments.**

Table 1. Comparison of Annual Cost in Technologist Time for Inoculum Preparation
Adapted from Hooper M, *et al*. ECCMID 2013 POSTER P-1536

Instrument	Weight/10 tests (MIN)	Annual time (120 tests/day)	Cost ($) technologist salary
VITEK® 2	1.845	1346.85	40,405.50
Phoenix™	2.153	1571.93	47,157.90
MicroScan	1.928	1407.68	42,230.40

Table 2. Comparison of Annual Cost of Biohazardous Waste
Adapted from Hooper M, *et al*. ECCMID 2013 POSTER P-1536

Instrument	Waste (kg)/Sample	Annual mass (kg) (120 tests/day)	Annual cost ($)
VITEK 2	0.048	2102.4	2628.00
Phoenix	0.109	4774.2	5967.50
MicroScan	0.122	5343.6	6679.50

Table 3. Comparison of Major Differences Between VTK, PHX and MS Systems
Adapted from Hooper M, *et al*. ECCMID 2013 POSTER P-1536

	Instrument		
	VITEK 2	Phoenix	MicroScan
Test Menu	Gram positive cocci Gram negative bacilli Fastidious Gram negative bacilli Gram positive bacilli Anaerobes Yeast	Gram positive cocci Gram negative bacilli	Gram positive cocci Gram negative bacilli Fastidious Gram negative bacilli Anaerobes Yeast
Set up Time/ Sample	1.845 min	2.153 min	1.928 min
Biohazard Waste /Sample	0.048 kg	0.109 kg	0.122 kg
Required Reagents	None	AST indicator	Kovacs Reagent, a-Napthol, KOH, Sulfanic acid, N-N-dimethyl-a-Naphthylamine, Ferric Chloride, NaOH, Peptidase Reagent, Xylene, Ehrlichs Reagent, Iodine Reagent, Rapid indole reagent, HNID indole reagent

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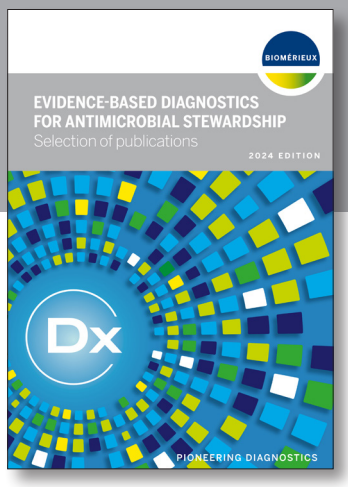

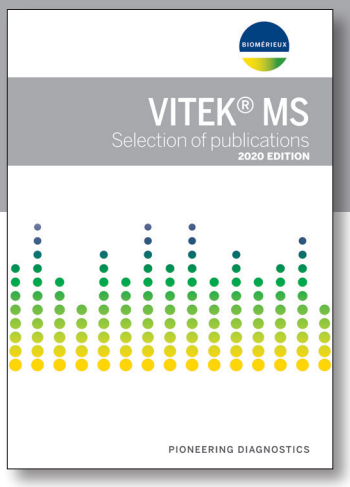

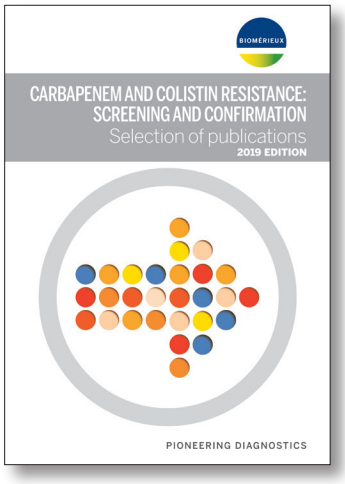

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