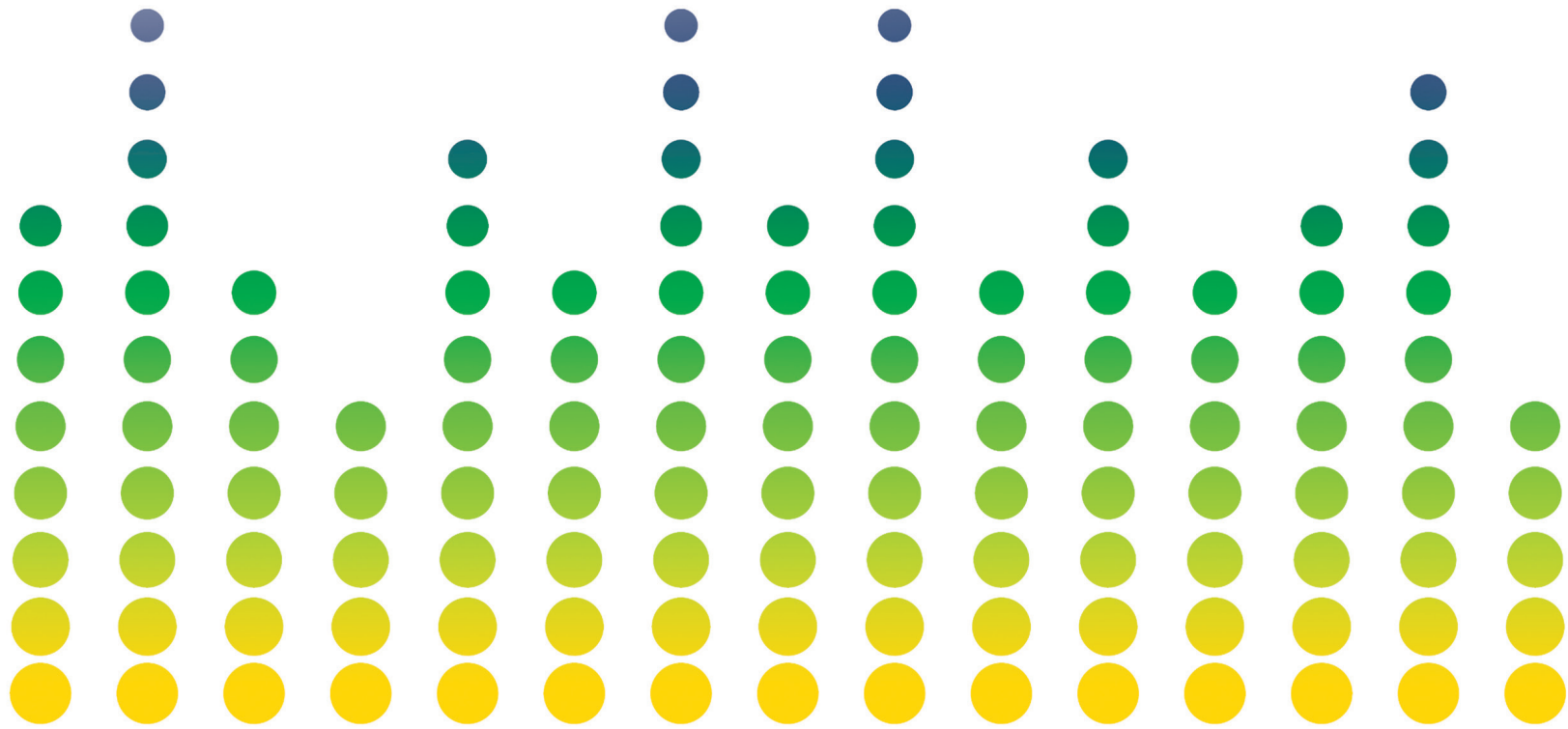




# VITEK<sup>®</sup> MS

Selection of publications  
**2020 EDITION**



PIONEERING DIAGNOSTICS

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# VITEK® MS

## MOVING MICROBIOLOGY FORWARD

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Antimicrobial resistance poses an increasingly urgent global challenge. If nothing changes, forecasts for 2050 estimate that antimicrobial resistance may be associated with as many as 10 million deaths every year<sup>1</sup>. Fortunately, the careful and responsible management of antimicrobials along with the **use of fast and actionable diagnostics** can significantly reduce antimicrobial resistance and save lives.

**Organism identification** is an important step in the microbiology workflow. Together with antimicrobial susceptibility testing (AST), fast identification (ID) provides critical information to the clinician to **tailor antimicrobial therapy**, particularly for initiation, monitoring, and discontinuation. **Fast, accurate ID results** are essential to support **optimal antimicrobial therapy decisions** ensuring improved patient outcomes and supporting antimicrobial stewardship programs.

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## VITEK® MS



By providing a **single technology for identification of bacteria and fungi**, mass spectrometry has disrupted the way ID testing is done in the microbiology laboratory in terms of **time to result, accuracy, ease of use, and cost per test**.

bioMérieux has embedded its microbiology expertise in the **VITEK MS MALDI-TOF** (Matrix Assisted Laser Desorption Ionization-Time of Flight) system to ensure the technology is fully adapted to laboratory practices. VITEK MS is a mass spectrometry system developed by microbiologists to provide **fast, accurate, and reliable identification results** to the microbiology laboratory.

### SUPPORTED BY SCIENCE

The VITEK MS approach to integrating MALDI-TOF technology into laboratory workflow offers enhanced capacity to deliver actionable results every day. The articles summarized in this Selection of Publications provide scientific support for the efficacy of this approach and the functionality of the VITEK MS MALDI-TOF mass spectrometry system.

1. **Tackling drug-resistant infections globally: Final report and recommendations.** Review of Antimicrobial Resistance. May 2016. Available at: [https://amr-review.org/sites/default/files/160518\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf). Accessed June 29, 2020.

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## The VITEK MS system offers several features, including:

### \* EVOLVING DATABASE

- Takes into account microbial and technical variability to ensure a single choice result in your daily routine for rapid action, easier adoption, and reduced errors
- Allows differentiation of closely related species with regular database updates covering emerging pathogens to respond to both clinician's and microbiologist's needs

### \* WORKFLOW EFFICIENCY

- One validated protocol per organism group for easy implementation and daily use
- On-slide sample preparation for bacteria and yeasts for traceability and time savings
- Ready-to-use kits for *Mycobacterium*, *Nocardia* and molds for simple, fast, and safe preparation
- System designed to fit into your laboratory workflow from sample preparation to results review to optimize efficiency

### \* INTEGRATED ID AND AST SOLUTION

- Seamless connectivity and integration between VITEK MS ID and VITEK 2 AST to provide fast and accurate identification and susceptibility results to impact patient care
- Data transformed into insights with MYLA® middleware to impact patient care and monitor antimicrobial resistance
- A complete and integrated microbiology solution from sample preparation to result interpretation to deliver fast results for better treatment decisions including:
  - Blood culture: BACT/ALERT® 3D and BACT/ALERT VIRTUO®
  - Screening: CHROMID® Culture Media
  - Lab Automation: WASPLab®
  - AST: VITEK 2 and ETEST®
  - Data consolidation and connectivity: MYLA middleware
  - Additional services and consultancy support to maximize instrument uptime and streamline daily lab activities

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*PLOS ONE* 2017;12(5):e0177929

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*EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES* 2017;36(6):1005-1012

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*JOURNAL OF CLINICAL MICROBIOLOGY* 2019;57(4):e01624-18

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*JOURNAL OF CLINICAL MICROBIOLOGY* 2018;56(2):e01353-17

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*MYCOPATHOLOGIA* 2019;184:645-651

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*JOURNAL OF CLINICAL MICROBIOLOGY* 2018;56(6):e00237-18

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*DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE* 2015;81(1):27-33

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*EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES* 2018;37(10):2027-2029

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*ANNALS OF LABORATORY MEDICINE* 2018;38:487-489

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*JOURNAL OF CLINICAL MICROBIOLOGY* 2017;55(5):1437-1445

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Tran A, Alby K, Kerr A, Jones M, Gilligan PH.

*JOURNAL OF CLINICAL MICROBIOLOGY* 2015;53(8):2473-2479

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# EVOLVING DATABASE

Bacteria • Yeasts • Molds  
*Mycobacterium and Nocardia*

PLOS ONE  
2017;12(5):e0177929

# Head-to-head comparison of Microflex LT and VITEK MS systems for routine identification of microorganisms by MALDI-TOF mass spectrometry in Chile

Porte L, García P, Braun S, Ulloa MT, Lafourcade M, Montaña A, Miranda C, Acosta-Jamett G, Weitzel T.

## OBJECTIVE

This study evaluated head-to-head performance and user-friendliness between VITEK® MS and MALDI Biotyper®\* in a non-industrialized region using local microbial samples in a routine laboratory in Chile.

## STUDY DESIGN

804 isolates consisting of bacteria, including anaerobes, and yeasts were collected and tested in parallel on both VITEK MS and MALDI Biotyper between August 2012 and January 2013.

## RESULTS

VITEK MS achieved higher rates of correct identification to species and species complex level than MALDI Biotyper (81% vs. 85% and 87% vs. 93% respectively).

VITEK MS achieved better performance for Gram-positive cocci (99% correct ID vs 88% for MALDI Biotyper) and yeasts (98% correct ID vs 79% for MALDI Biotyper). Streptococci isolates were all identified correctly by VITEK MS whereas the MALDI Biotyper was less accurate especially with viridans streptococci.

An additional 20-minute extraction step needed by the MALDI Biotyper caused delays that were not experienced when using VITEK MS.

## CONCLUSIONS

VITEK MS achieved a higher diagnostic accuracy and better performance for all groups of microorganisms.

VITEK MS was seen as less challenging in overall workflow integration as VITEK MS software easily connected to the existing laboratory information system without the need to develop a novel interface (needed for MALDI Biotyper).

Overall, VITEK MS was found to be slightly more user-friendly than MALDI Biotyper, mainly due to ready-to-use components, easier connectivity, and higher level of local technical support.

\* Microflex LT = MALDI Biotyper

***“...VITEK MS reached a higher diagnostic accuracy for species and species complex identification, which mainly affected coagulase negative staphylococci and Candida species.”***

## KEY FINDINGS

- \* Results revealed a higher diagnostic efficiency for VITEK MS with better performance among Gram-positive cocci, coagulase negative staphylococci, and yeasts.
- \* VITEK MS user-friendliness was seen as an advantage and slightly better than the MALDI Biotyper due to disposable targets, ready-to-use matrix solution, easy connectivity, integration into the workflow, and availability of local technical support.
- \* VITEK MS was able to identify more uncommon species than the MALDI Biotyper.

## Performance of the matrix-assisted laser desorption ionization time-of-flight mass spectrometry system for rapid identification of streptococci: a review

Fan W-T, Qin T-T, Bi R-R, Kang H-Q, Ma P, Gu B.

### OBJECTIVE

The aim of this study was to assess the utility of MALDI-TOF MS to identify streptococci by performing a literature search followed by a meta-analysis on both, VITEK® MS and MALDI Biotyper® systems.

### STUDY DESIGN

27 publications were selected following an extensive search of the literature covering 3,540 strains of streptococci. Statistical calculations were performed to estimate the accuracy of identification by both systems for the most relevant streptococci species.

### RESULTS

SPECIES	ACCURACY WITH MALDI Biotyper	ACCURACY WITH VITEK MS
<i>S. pneumoniae</i>	98% ( <sup>12</sup> =91,3,P<0,1)	100% ( <sup>12</sup> =6,P>0,1)
<i>S. agalactiae</i>	100% ( <sup>12</sup> =55,8,P<0,1)	100% ( <sup>12</sup> =0,P>0,1)
<i>S. pyogenes</i>	100% ( <sup>12</sup> =52,3,P<0,1)	100% ( <sup>12</sup> =0,P>0,1)
<i>S. mitis/oralis</i>	85% ( <sup>12</sup> =95,8,P<0,1)	100% ( <sup>12</sup> =23,3,P>0,1)
<i>S. intermedius</i>	33% ( <sup>12</sup> =100,P<0,1)	100% ( <sup>12</sup> =14,6,P>0,1)

### CONCLUSIONS

VITEK MS correctly identified 98% of streptococci to the species level, compared to 94% using the MALDI Biotyper. Identification accuracy rates for VITEK MS were 100% for *S. pneumoniae*, *S. mitis/oralis*, and *S. intermedius*.

**“...MALDI TOF MS showed high accuracy for the identification of streptococci in the present meta-analysis.”**

### KEY FINDINGS

- \* The identification accuracy rate of streptococci was higher for VITEK MS (98%) compared to MALDI Biotyper (94%).
- \* The ID accuracy rate for *S. mitis/oralis* was 100% with VITEK MS vs 85% with MALDI Biotyper with 36 strains being misidentified as *S. pneumoniae*.



ANAEROBE  
2018;54:205-209

## Performance of mass spectrometric identification of clinical *Prevotella* species using the VITEK MS system: A prospective multi-center study

Ulger TN, Alida VCM, Urban E, Wybo I, Justesen US, Jean-Pierre H, Morris T, Akgul O, Kulekci G, Soyletir G, Nagy E; ESCMID Study Group for Anaerobic Infections (ESGAI).

### OBJECTIVE

The objective of this study was to evaluate the performance of the VITEK® MS system for the identification of clinically relevant *Prevotella* species.

### STUDY DESIGN

508 *Prevotella* strains collected from 13 countries between January 2014 and April 2016 were tested on VITEK MS v3.0. The species and genus level identifications obtained were compared with 16S rRNA gene sequencing identification.

### RESULTS

19 different *Prevotella* species were identified by using VITEK MS (v3.0).

	CORRECT IDENTIFICATION SPECIES LEVEL (%)	CORRECT IDENTIFICATION GENUS LEVEL (%)	MISIDENTIFIED MINOR ERROR*	MISIDENTIFIED MAJOR ERROR*	NO ID†
VITEK MS RESULTS	83.1%	90.4%	7.2%	0.9%	8.6%†

\*A minor error is an identification within the same genus. A major error is a misidentification to a different genus.

†NO ID occurred for species which are not claimed in the database in 63% of the cases.

### CONCLUSIONS

VITEK MS offers fast and reliable identification of *Prevotella* species.

**“...in general, the VITEK MS system performed well in the identification of clinically important, frequently found *Prevotella* strains.”**

### KEY FINDINGS

- \* This was the first study assessing the VITEK MS system for identification of clinical *Prevotella* using an extensive set of isolates covering 19 different species.
- \* Results showed that VITEK MS accurately identified frequently encountered *Prevotella* species during a prospective multi-center study with on-plate sample preparation.

## **Candida auris Clinical Isolates from South Korea: Identification, Antifungal Susceptibility, and Genotyping**

Kwon YJ, Shin JH, Byun SA, Choi MJ, Won EJ, Lee D, Lee SY, Chun S, Lee JH, Choi HJ, Kee SJ, Kim SH, Shin MG.

### OBJECTIVE

This study compared 61 isolates of *Candida auris* for identification (ID) on VITEK<sup>®</sup> MS V3.2 vs. MALDI Biotyper<sup>®</sup> and for Antimicrobial Susceptibility Testing (AST) on VITEK 2 vs the CLSI Broth Microdilution (BMD) reference method.

### STUDY DESIGN

61 isolates (4 blood and 57 ear) of *C. auris* were collected from 1996-2018 and tested on MALDI Biotyper and VITEK MS for ID, and VITEK 2 AST-YS07 and CLSI BMD for AST of 5 antifungals.

Multilocus sequence typing (MLST) and pulsed-field gel electrophoresis (PFGE) were done to compare the Korean isolates to one another and to the CDC reference isolates comprising the four different geographic clades of *C. auris*.

Sequencing of either internal transcribed spacer (ITS) or D1/D2 was performed as the ID reference method.

### RESULTS

SYSTEM	DATABASE	EXTRACTION	% CORRECT	% INCOMPLETE	% NO ID	% MISID
MALDI BIOTYPER	RUO v3.3.1.0	Initial tube	75.4	13.1	11.5	0.0
		+ tube retests	83.6	14.8	1.6	0.0
VITEK MS	RUO v4.14	On-target	93.4	6.6	0.0	0.0
	IVD v3.2	On-target	96.7	3.3	3.3	0.0

### CONCLUSIONS

VITEK MS is more accurate and has a simpler workflow than MALDI Biotyper for identification of *C. auris*.

VITEK 2 AST has excellent essential agreement (EA) and categorical agreement (CA) of 96.7% and 93.4%, respectively for fluconazole when compared to BMD.

**“...These data show for the first time that *C. auris* can be reliably identified by the VITEK MS system with the new IVD library (VITEK IVD 3.2).”**

### KEY FINDINGS

- \* VITEK MS showed much higher accuracy than MALDI Biotyper for *C.auris* identification on both RUO (93.4% vs. 83.6% respectively) and IVD (96.7% vs. N/A) databases, even when performing tube extractions, lowering the acceptable species level score to >1.7, and performing several retests (~25%) on isolates showing incomplete IDs or NO IDs with MALDI Biotyper.
- \* VITEK 2 AST-YS07 showed excellent correlation to the CLSI reference method with EA and CA of 96.7% and 93.4%, respectively, for fluconazole.

# Multicenter Evaluation of the VITEK MS v3.0 System for the Identification of Filamentous Fungi

Rychert J, Slechta ES, Barker AP, Miranda E, Babady NE, Tang YW, Gibas C, Wiederhold N, Sutton D, Hanson KE.

## OBJECTIVE

This study evaluated the accuracy of the VITEK® MS v3.0 system in identifying clinical mold isolates in comparison to identification by DNA sequence analysis supported by morphological and phenotypic testing.

## STUDY DESIGN

Each study site tested approximately 10 clinical isolates per species of a predefined list of organisms, for a total of 1,519 unique mold isolates tested representing organisms that are included in the VITEK MS v3.0 database. Isolates were prepared for analysis using a mold reagent kit from bioMérieux.

## RESULTS

ORGANISM GROUP	N	NO. CORRECTLY IDENTIFIED TO SPECIES LEVEL (%)
Mucorales	118	101 (86%)
Dimorphs	141	141 (100%)
Dermatophytes	291	246 (85%)
Dematiaceous	325	295 (91%)
Aspergillus species	328	305 (93%)
Other potential pathogens	316	299 (95%)
<b>Total molds</b>	<b>1,519</b>	<b>1,387 (91%)</b>

- A single identification to the species level was provided for 91% of the clinical isolates tested, with an additional 2% correctly identified at the genus level.
- Among isolates not represented in the database, the majority gave no identification.

## CONCLUSIONS

The VITEK MS v3.0 system has a simple and optimized extraction procedure specifically designed for molds and a well-developed database. Results obtained using this system are accurate and reproducible and it is now feasible for many clinical laboratories to easily identify clinical molds to the species level.

*“...the VITEK MS v3.0 system is highly accurate for the identification of commonly encountered molds in the clinical mycology laboratory. With this technology, it may now be feasible for more clinical laboratories to accurately identify a range of filamentous fungi to the species level.”*

## KEY FINDINGS

- \* This study demonstrates the excellent accuracy and reproducibility of the VITEK MS v3.0 system for the identification of common molds to the species level.
- \* The optimized extraction procedure specifically designed for molds provides increased ease of use.

## Evaluating VITEK MS for the identification of clinically relevant *Aspergillus* species

Américo FM, Machado Siqueira LP, Del Negro GMB, Favero Gimenes VM, Trindade MRS, Motta AL, Santos de Freitas R, Rossi F, Colombo AL, Benard G, de Almeida Júnior JN.

### OBJECTIVE

This study evaluated the performance of VITEK® MS IVD v3.0, VITEK MS RUO SARAMIS® v4.15, and a modified version of VITEK MS RUO SARAMIS v4.15 for the identification of clinically relevant *Aspergillus* spp. after authors' addition of reference spectra and SuperSpectra.

### STUDY DESIGN

A total of 106 isolates (47 reference strains identified by multilocus gene sequencing of internal transcribed spacer (ITS),  $\beta$ -tubulin, calmodulin, and other housekeeping genes plus 59 non-replicate clinical isolates identified by morphology and sequencing of ITS and  $\beta$ -tubulin) were used to evaluate the IVD and RUO databases. Then, data from 34 strains representing 24 species were collected in order to enhance the performance of the RUO database. The remaining 72 isolates were tested to evaluate the modified RUO database that included SuperSpectra built by the investigators.

### RESULTS

SYSTEM	ALL ISOLATES		DATABASE ISOLATES ONLY	
	% CORRECT TO SECTION	% CORRECT TO SPECIES	% CORRECT TO SECTION	% CORRECT TO SPECIES
IVD v3.0	91.6	84.7	100.0	98.3
RUO v4.15	84.7	79.1	89.7	83.8
RUO - USER MODIFIED	100.0	91.6	N/A	N/A

### CONCLUSIONS

VITEK MS v3.0 (IVD) shows good performance for identification of clinically relevant *Aspergillus* spp. and has the ability to correctly identify some of the cryptic azole-resistant species, i.e., *A. lentulus* and *A. calidoustus*, to species level. Additional spectra from cryptic species not included in the v3.0 database will improve performance and further aid the clinician in appropriate and timely therapy.

**“...VITEK MS and its IVD library correctly identified *A. lentulus* and *A. calidoustus*, two azole-resistant species that have been related to severe infections in immunocompromised patients.”**

### KEY FINDINGS

- \* VITEK MS IVD v3.0 shows good performance for identification of clinically relevant *Aspergillus* spp.
- \* VITEK MS IVD v3.0 can correctly identify the cryptic azole-resistant species contained in the database, which are known to exhibit antifungal resistance.

## VITEK® MS v3.0 System in the Identification of Filamentous Fungi

Pinheiro D, Monteiro C, Faria MA, Pinto E.

### OBJECTIVE

This study compared results of 90 mold isolates tested on VITEK MS v3.0 to a DNA sequencing reference method.

### STUDY DESIGN

A total of 90 mold isolates (70 clinical and 20 environmental) were tested on the VITEK MS v3.0 system and compared to a molecular reference method: sequencing of the  $\beta$ -tubulin and calmodulin genes for *Aspergillus* spp. and internal transcribed spacer (ITS) sequencing for the remaining genera. Thirteen out of 90 environmental isolates were not present in the database.

### RESULTS

SYSTEM	% CORRECT TO SPECIES COMPLEX	% CORRECT TO SPECIES	% UNIDENTIFIED	% MISIDENTIFIED
VITEK MS v3.0	81.1	52.2	17.8	1.1
With the 13 non-DB isolates counted as correct when unidentified*	95.6	52.2	3.3	1.1

\*non-DB isolates : isolates not present in the database (DB).

### CONCLUSIONS

VITEK MS v3.0 is a very accurate and fast method for identification of the most common clinical mold species. Its ability to quickly identify resistant species like *Aspergillus lentulus* helps the clinician in proper patient management.

**“Results [...] favor VITEK MS v3.0 as a very useful system for identification of most common clinical isolates of filamentous fungi.”**

### KEY FINDINGS

- \* VITEK MS v3.0 is very fast and accurate for identification of common clinical mold species.
- \* Environmental mold species which are not present in the VITEK MS v3.0 database are mostly unidentified, which is the desired result.

# Multicenter evaluation of three different MALDI-TOF MS systems for identification of clinically relevant filamentous fungi

Sun Y, Guo J, Chen R, Hu L, Xia Q, Wu W, Wang J, Hu F.

## OBJECTIVE

The aim of this study was to compare the performance of three commercial MALDI TOF systems (VITEK® MS KB 3.2, MALDI Biotyper mould 1.0, and AUTOF 1.0.137) for the identification of filamentous fungi.

## STUDY DESIGN

126 strains of well-characterized filamentous fungi representing 28 species were collected from five hospitals in Shanghai and tested at three different sites equipped with the different MALDI TOF systems. Only the commercially available databases were evaluated.

The mould extracts were prepared according to the respective manufacturer recommendations.

## RESULTS

	VITEK MS	MALDI BIOTYPER	AUTOF
Number of correct ID to species level	121/126 (96%)	53/126 (42.1%)	74/126 (58.7%)

## CONCLUSIONS

Performance is highly dependent on the database and the sample preparation protocol. VITEK MS performance for the identification of filamentous fungi is significantly higher than the other two commercial systems available in the market.

***“VITEK MS identified 121 (96.0%) to species-level and 124 (98.4%) to genus-level...”***

## KEY FINDINGS

- \* This study compares the performance of three commercially available MALDI TOF databases on 126 strains of filamentous fungi.
- \* VITEK MS demonstrated a much higher accuracy than the other two systems.
- \* VITEK MS identified 96% of the strains to the species level versus 42.1% for MALDI Biotyper and 58.7% for Autof.

# Evaluation of the VITEK MS v3.0 Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry System for Identification of *Mycobacterium* and *Nocardia* species

Body BA, Beard MA, Slechta ES, Hanson KE, Barker AP, Babady NE, McMillen T, Tang YW, Brown-Elliott BA, Iakhaeva E, Vasireddy R, Vasireddy S, Smith T, Wallace RJ Jr, Turner S, Curtis L, Butler-Wu S, Rychert J.

## OBJECTIVE

This study assessed the accuracy and reproducibility of the VITEK® MS v3.0 MALDI-TOF system for the identification of common *Mycobacterium* and *Nocardia* species.

## STUDY DESIGN

Tested samples comprised 651 *Mycobacterium* and 312 *Nocardia* clinical isolates. *Mycobacteria* from the *Mycobacterium tuberculosis* complex as well as nontuberculous mycobacteria (NTM) were tested.

*Mycobacteria* and *Nocardia* were cultured on solid media, and isolates were prepared for analysis using a *Mycobacterium/Nocardia* reagent kit from bioMérieux.

## RESULTS

Among the clinical *Mycobacterium* isolates, 94% were identified with a single correct identification to the species, group, or complex level.

Among the clinical *Nocardia* isolates (312), 76% (236) were correctly identified to the species level, with an additional 14% (44) identified at the complex level.

Seven common *Nocardia* species were correctly identified to the species level for every isolate tested, using four different media.

MYCOBACTERIA	N	NO. CORRECTLY IDENTIFIED TO SPECIES, GROUP OR COMPLEX LEVEL
<i>M. tuberculosis</i> complex	45	45 (100%)
NTM slow growers	402	371 (92%)
NTM rapid growers	202	197 (98%)

## CONCLUSIONS

The VITEK MS v3.0 system has a simple and optimized extraction procedure specifically designed for *Mycobacterium* and *Nocardia* and a well-developed database.

Results obtained using this system are accurate and reproducible and it is now feasible for many clinical laboratories to easily identify commonly encountered *Mycobacterium* and *Nocardia*.

**“...using standardized methods for growth, sample preparation, and analysis, the VITEK MS v3.0 system was 93% accurate for the identification of *Mycobacterium* and *Nocardia* isolates to the species, group, or complex level.”**

## KEY FINDINGS

- \* This study demonstrates that VITEK MS v3.0 is a robust and reliable system for the routine identification of *Mycobacterium* and *Nocardia* in clinical practice.
- \* The optimized extraction procedure specifically designed for *Mycobacterium* and *Nocardia* provides increased ease of use.

## Evaluation of the VITEK® MS knowledge base version 3.0 for the identification of clinically relevant *Mycobacterium* species

Luo L, Cao W, Chen WW, Zhang RR, Jing LJ, Chen HP, Yu FY, Yue J.

### OBJECTIVE

The introduction of MALDI-TOF MS has been revolutionary for the identification of microorganisms especially for *Mycobacterium*. However, identification results can vary depending on the publications. This study evaluated the identification performance of VITEK MS v3.0 for clinical *Mycobacterium* in combination with the VITEK MS *Mycobacterium/Nocardia* sample preparation kit.

### STUDY DESIGN

Five hundred and seven *Mycobacterium* isolates [46 *Mycobacterium tuberculosis* and 461 non tuberculosis mycobacteria (NTM)] recovered between June 2015 and March 2017 were tested on VITEK MS v3.0. The VITEK MS *Mycobacterium/Nocardia* kit was used for inactivation and protein extraction. The NTM isolates included both slow growing mycobacteria (SGM) and rapid growing mycobacteria (RGM).

All analyzed isolates were sequenced across the full 16 S rRNA gene. If the VITEK MS result was consistent with the gene sequence, then the result was considered correct.

### RESULTS

VITEK MS correctly identified 476/507 (93.9%) isolates. 23/507 (4.5%) isolates were unidentified and 8/507 (1.6%) isolates were misidentified. There were no misidentifications at the genus level.

### CONCLUSIONS

This study not only evaluated a large number of clinical *Mycobacterium* isolates, but was also able to demonstrate a high level of identification performance of these species using VITEK MS v3.0 and the VITEK MS *Mycobacterium/Nocardia* kit for sample preparation.

**“This study further confirmed that the implementation of MALDI-TOF MS in the clinical laboratory enables the highly accurate identification of *Mycobacterium* species.”**

### KEY FINDINGS

- \* This is the most comprehensive study to date of CE/IVD/FDA-cleared VITEK MS v3.0 for the identification of clinically relevant mycobacteria.
- \* The identification rate for *M. tuberculosis* was 97.8%.
- \* Complete and reliable inactivation and reproducible sample extraction were achieved thanks to the *Mycobacterium/Nocardia* kit.



# **WORKFLOW EFFICIENCY**

# Comparison of the VITEK MS and Bruker Microflex LT MALDI-TOF MS platforms for routine identification of commonly isolated bacteria and yeast in the clinical microbiology laboratory

Deak E, Charlton CL, Bobenchik AM, Miller SA, Pollett S, McHardy IH, Wu MT, Garner OB.

## OBJECTIVE

This study was designed to perform a comprehensive analysis of clinically relevant bacteria and yeasts by comparing the most recent database versions of the VITEK® MS and MALDI Biotyper® systems. Furthermore, a user assessment was carried out to determine the preference of use of both devices for routine identification of bacteria and yeasts.

## STUDY DESIGN

This study compared the identification performance for 477 isolates on both MALDI Biotyper and VITEK MS. Bacteria and yeast isolates from frozen stocks of clinical specimens were chosen to represent commonly encountered isolates in a clinical laboratory including 161 Gram-positive, 213 Gram-negative aerobic bacteria, 34 anaerobic bacteria, and 69 yeasts. All isolates were tested concurrently in duplicate on each platform. The study also included an evaluation of user preference for each MALDI-TOF platform.

## RESULTS

Both systems performed equivalently in terms of species identification.

SYSTEM	DATABASE	% CORRECT ID (GENUS)	% CORRECT ID (SPECIES)	% NO ID	% MISID
MALDI BIOTYPER	Flex Control 3.0 + RUO Database	98.1%	93.9%	1.9%	4.2%
VITEK MS	IVD v2.0	99%	93.7%	0.6%	5.9%

Eighteen of 24 technologists preferred VITEK MS due to three factors: ease of spotting the colony on the slide, confidence in being able to walk away during a run, and the fit into laboratory workflow.

The MALDI Biotyper recommends a 10-minute tube extraction for analysis of yeast, and this was performed on 30% of yeast isolates and 5% of bacterial isolates due to low confidence level identifications.

## CONCLUSIONS

Both systems performed equivalently in terms of species identification, but 75% of the technologists preferred working with VITEK MS due to ease of use including sample preparation and fit into laboratory workflow.

\* Microflex LT = MALDI Biotyper

***“...75% of the users preferred the VITEK MS over the Microflex LT. There was a higher median rating for ease of spotting on the target plate. (...) Technologists also saw the VITEK MS fitting more easily into their workflow.”***

## KEY FINDINGS

\* Even though the VITEK MS and MALDI Biotyper systems performed equivalently in terms of proportion of isolates correctly identified, technologists preferred working with VITEK MS due to ease of use and workflow efficiency.

# Evaluation of IVD 3.0 VITEK MS matrix-assisted laser desorption ionization-time of flight mass spectrometry for identification of *Mycobacterium tuberculosis* and nontuberculous mycobacteria and its use in routine diagnostics

Cenci E, Luciano E, Bucaioni M, Rubeca M, Cesarini A, Bozza S, De Socio GV, Mencacci A.

## OBJECTIVE

This study evaluated the performance of VITEK® MS v3.0 for the identification of *Mycobacterium tuberculosis* (MT) and nontuberculous mycobacteria (NTM) as well as the impact of the introduction of this new workflow on the Time to Report (TTR).

## STUDY DESIGN

Eighty-two well-characterized isolates of MT and NTM collected during a 24-month period were tested on VITEK MS for identification (ID).

Time-to-result obtained with VITEK MS, defined as the time between mycobacteria growth incubator tube (MGIT) positivity and the report of the ID in the patient electronic medical record, was also recorded for 15 NTM isolates collected in 2018. This TTR was compared to those obtained on the same number of isolates identified by a conventional molecular method in a similar period in 2017.

## RESULTS

Correct identification was obtained for 95.2% of the isolates.

The introduction of VITEK MS resulted in a significant reduction of TTR, with median values of 37h 33min for VITEK MS vs 87h 22min for conventional methods.

## CONCLUSIONS

VITEK MS can be routinely used for both MT and NTM identification and can have a significant impact on TTR.

***“...IVD V3.0 VITEK MS can represent a valuable tool for MT and importantly NTM identification. It can be performed immediately on positive liquid cultures resulting in a significant reduction in TTR.”***

## KEY FINDINGS

- \* VITEK MS gave 95.2% correct identification of the MT and NTM isolates.
- \* The VITEK MS workflow for mycobacteria showed a reduction in TTR of almost 50 hours.

## Performance of Microflex LT Biotyper and VITEK MS for Routine Identification of Yeasts

Byun J-H, Yu A-R, Kim MS, Lee K.

### OBJECTIVE

This study compared two commercially available MALDI-TOF MS platforms and VITEK® 2 YST using different approaches with respect to sample preparation methods.

### STUDY DESIGN

This study compared the performance of the MALDI Biotyper®, bioMérieux VITEK MS, and VITEK 2 YST on 208 yeast isolates. Yeasts were first identified by conventional phenotypic methods including the VITEK 2 YST card. If results of the VITEK 2 YST card agreed with the two MALDI-TOF MS systems, the result was considered the reference. When either the VITEK 2 YST card result was unidentified, or if a discrepancy was observed between any of the three methods, internal transcribed spacer (ITS) sequencing was used as the arbitrator. In order to increase the performance of the MALDI Biotyper, two approaches were evaluated: various lower log scores and in-tube vs. on-plate extractions.

### RESULTS

VITEK MS showed 99.5% correct IDs at the species level with the routine on-plate extraction method. Only one isolate that was unclaimed by the database was not identified at species level.

The MALDI Biotyper showed only 48.1% correct identification to species level when using the manufacturer’s recommended cutoff log score of  $\geq 2.0$  in combination with an on-plate extraction. Lowering the cutoff to  $\geq 1.7$  allowed for an increased performance level of 95.2% correct identification to the species level. In order to be equivalent to VITEK MS, full tube extractions were required in addition to the lowered cutoff value of  $\geq 1.7$ .

SYSTEM	EXTRACTION	% CORRECT SPECIES WITH LOG SCORES $\geq 2.0$	% CORRECT SPECIES WITH LOG SCORES $\geq 1.7$
MALDI Biotyper	On-plate	48.1	95.2
	In-tube	89.4	100.0
VITEK MS	On-plate extraction ONLY with 99.5% correct species		

### CONCLUSIONS

VITEK MS showed excellent performance with on-plate extraction as recommended by the manufacturer. Manipulation of score interpretation and tube extractions were both needed with the MALDI Biotyper in order to achieve the same level of performance as VITEK MS.

\* Microflex LT = MALDI Biotyper

***“VITEK MS yields accurate results using the simple on-plate method. The Biotyper requires the in-tube extraction method to reach a score  $\geq 2.0$ ; however, with the application of a flexible cut-off value ( $\geq 1.7$ ), the on-plate method is sufficient to achieve a correct identification rate of  $>95\%$ .”***

### KEY FINDINGS

\* To achieve yeast identification performance equivalent to VITEK MS, the MALDI Biotyper required a more laborious workflow (in-tube extraction) and user-modified interpretation (log scores  $\geq 1.7$ ).

# **INTEGRATED ID AND AST SOLUTION**

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

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

### OBJECTIVE

The aim of this study was to 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 antimicrobial stewardship (ASP) team.

### STUDY DESIGN

For the 2017 time period, organism ID and AST were performed on 77 patients using the Microscan microdilution system and limited 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 ASP 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

TIME VARIABLE	MICROSCAN AND NO DEDICATED ASP TEAM	ASP + VITEK® MS / VITEK® 2	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 ASP team leads to significant reduction in antibiotic therapy duration (or antibiotic exposure) and hospital LOS.

*“...use of ASP and MALDI-TOF/VITEK2 rapid identification and AST demonstrated... 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 in 2018 (21.5 hours less on average) using VITEK MS / VITEK 2, in conjunction with workflow optimization, which allowed the ASP team to recommend significantly more adjustments to antimicrobial therapy.
- \* The result was a significant reduction in LOS and length of antimicrobial therapy.

# Effect of Matrix-Assisted Laser Desorption Ionization–Time of Flight Mass Spectrometry (MALDI-TOF MS) Alone versus MALDI-TOF MS Combined with Real Time Antimicrobial Stewardship Interventions on Time to Optimal Antimicrobial Therapy in Patients with Positive Blood Cultures

Beganovic M, Costello M, Wieczorkiewicz SM.

## OBJECTIVE

The purpose of this study was to evaluate the impact of MALDI-TOF MS alone versus MALDI-TOF MS combined with real-time, pharmacist-driven, antimicrobial stewardship (AMS) intervention on patient outcomes.

## STUDY DESIGN

This study analyzed blood culture results and outcomes of 126 patients from a 645 bed hospital with bloodstream infections over a 3-month period (Nov 2014-Jan 2015). Results were analyzed by VITEK® MS after a short incubation and posted to the laboratory information system but were not otherwise communicated to health care providers.

After the implementation of a guideline including 24/7 antimicrobial stewardship monitoring and intervention by pharmacists, blood cultures and outcomes of 126 other patients from the same facility from Nov 2015-January 2016 were analyzed using the same microbiological procedures.

Mean time to effective therapy as well as LOS and length of antimicrobial therapy and overall costs were compared between the two periods.

## RESULTS

CATEGORY	MEAN TIME TO EFFECTIVE THERAPY (HRS)	MEAN HOSPITAL LOS (DAYS)	MEAN ICU LOS (DAYS)	MEAN LENGTH OF ANTIMICROBIAL THERAPY	AVG. DIRECT COSTS
Pre-Intervention	16.8	15	4.3	18.6	\$28,677
Post -Intervention	12.5	9	1.2	15.9	\$15,784
Difference	4.3	6	3.1	2.6	\$12,893
p-value	.082	.021	.053	.117	.010

## CONCLUSIONS

MALDI-TOF MS is most impactful when implemented in conjunction with an antimicrobial stewardship program.

*“This study demonstrated that combining rapid culture techniques and MALDI-TOF MS with real-time AMS intervention consistently provided more favorable outcomes than MALDI-TOF MS alone...”*

## KEY FINDINGS

- \* Combining MALDI-TOF MS with real-time AMS interventions provided more favorable patient outcomes than MALDI-TOF MS alone.
- \* Laboratories should take the impact of AMS and workflow optimization into account when budgeting for any technology that significantly improves time to result.

# Cost Savings Realized by Implementation of Routine Microbiological Identification by Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry

Tran A, Alby K, Kerr A, Jones M, Gilligan PH.

## OBJECTIVE

MALDI-TOF technology can provide accurate and reliable results in minutes from a single isolated colony, and has the potential to improve laboratory efficiency, reduce turnaround times, and lower costs in comparison to conventional methods. Therefore, the cost of performing bioMérieux VITEK® MS was compared to conventional microbiological methods to determine the amount saved by a laboratory converting to this new technology.

## STUDY DESIGN

Between April 2013 and March 2014, identification costs were collected and compared between MALDI-TOF MS (VITEK MS) and conventional methodologies for 21,930 isolates. Reagent cost and a total cost analysis were analyzed.

## RESULTS

Reagent costs for traditional methods are \$3.59/isolate and \$0.43 for MALDI-TOF MS. Using MALDI-TOF MS, there was a net savings of \$69,108.61 (88% reduction) in reagent costs annually compared to traditional methods.

Total costs (including technologist time and maintenance costs) resulted in a laboratory savings of \$73,646.18 (51.7%) annually with the use of the MALDI-TOF MS technology.

## CONCLUSIONS

In conclusion, MALDI-TOF MS provides significant cost savings for the laboratory compared to traditional methods. As the capital cost of the instrument is high, each lab may differ on how long it will take to offset that cost. However, the net savings continue to increase as more organisms are run on the MALDI-TOF MS system due to less need for molecular sequencing and labor-intensive technologist time.

***“MALDI-TOF MS not only represents an innovative technology for the rapid and accurate identification of bacterial and fungal isolates, it also provides significant cost savings for the laboratory. Despite the high capital cost of the instrument, the ease of performance, the rapid turnaround time to results, and the modest cost of testing for each sample make this new methodology a paradigm shift in the field of clinical microbiology.”***

## KEY FINDINGS

- \* In addition to being an innovative technology offering fast, accurate identification of bacterial and fungal isolates, MALDI-TOF MS also provides significant cost savings for the microbiology laboratory.
- \* Annual net savings of \$69,108.61 (88% reduction) in reagent costs were observed using MALDI-TOF MS, with the greatest reduction (92.9%) obtained for the identification of Gram-negative organisms.





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