

VITEK® MS Selection of publications 2020 EDITION



PIONEERING DIAGNOSTICS

VITEK® MS MOVING MICROBIOLOGY FORWARD

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 year¹. 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.



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.

The VITEK[®] MS system offers several features, including:

EVOLVING DATABASE

- routine for rapid action, easier adoption and reduced errors
- 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 veasts for traceability and time savings
- 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
- deliver rapid 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
 - daily lab activities

RUO APPLICATIONS

VITEK MS Plus integrates both In Vitro Diagnostic (IVD) and Research Use Only (RUO) databases to allow users to expand their research capabilities by adding spectra or performing protocols such as strain typing or resistance detection. With only one sample preparation, users can simply switch between the VITEK® MS IVD and VITEK® MS RUO database for maximum data generation from each sample while meeting compliance and IVD regulations.

• Takes into account microbial and technical variability to ensure a single choice result in your daily

• Allows differentiation of closely related species with regular database updates covering emerging

• Ready-to-use kits for Mycobacterium, Nocardia and molds for simple, rapid and safe preparation System designed to fit into your laboratory workflow from sample preparation to results review to

• A complete and integrated microbiology solution from sample preparation to result interpretation to

Additional services and consultancy support to maximize instrument uptime and streamline

EVOLVING DATABASE

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Mycobacterium species

Luo L, Cao W, Chen WW, Zhang RR, Jing LJ, Chen HP, Yu FY, Yue J. EMERGING MICROBES AND INFECTIONS 2018;7(1):114

WORKFLOW EFFICIENCY

Comparison of the VITEK MS and Bruker Microflex LT MA identification of commonly isolated bacteria and yeast in

Deak E, Charlton CL, Bobenchik AM, Miller SA, Pollett S, McHardy IH DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE 2015;81(1):27-33

Evaluation of IVD 3.0 VITEK MS matrix-assisted laser desimass spectrometry for identification of *Mycobacterium tu* mycobacteria and its use in routine diagnostics

Cenci E, Luciano E, Bucaioni M, Rubeca M, Cesarini A, Bozza S, De So EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES 201

Performance of Microflex LT Biotyper and VITEK MS for R Byun J-H, Yu A-R, Kim MS, Lee K. ANNALS OF LABORATORY MEDICINE 2018;38:487-489

INTEGRATED ID AND AST SOLUT

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 $Cavalieri SJ, Kwon S, Vivekanandan R, Ased S, Carroll C, Anthone J, \\ \textit{DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE 2019;95(2):208-211}$

Effect of Matrix-Assisted Laser Desorption Ionization-Time (MALDI-TOF MS) Alone versus MALDI-TOF MS Combined w Interventions on Time to Optimal Antimicrobial Therapy in

Beganovic M, Costello M, Wieczorkiewicz SM. 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

RUO (RESEARCH USE ONLY) APP

RAPID IDENTIFICATION OF POSITIVE BLOOD

Rapid direct identification of positive paediatric blood cul technology and its clinical impact in the paediatric hospit

Samaranayake WAMP, Dempsey S, Howard-Jones AR, Outhred AC, BMC RESEARCH NOTES 2020;13(1):12

■ NEW APPLICATIONS

Rapid pathogen identification and antimicrobial susceptil with matrix assisted laser desorption-ionization Time-of-I and VITEK 2 without prior culture

Chun LY, Dolle-Molle L, Bethel C, Dimitroyannis RC, Williams BL, Schechet SA, Hariprasad SM, Missiakas D, Schneewind O, Beavis KG, Skondra D. *PLOS ONE*. 2019;14(12):e0227071

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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

6

- 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.

EVOLVING DATABASE BACTERIA

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

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
S. pneumoniae	98% (¹² =91,3,P(0,1)	100% (¹² =6,P>0,1)
S. agalactiae	100% (¹² =55,8,P<0,1)	100% (¹² =0,P>0,1)
S. pyogenes	100% (12 =52,3,P<0,1)	100% (¹² =0,P>0,1)
S. mitis/oralis	85% (¹² =95,8,P(0,1)	100% (¹² =23,3,P>0,1)
S. intermedius	33% (¹² =100,P(0,1)	100% (¹² =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."

- 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.







EVOLVING DATABASE YEASTS

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

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® MS V3.2 vs. MALDI Biotyper® 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.

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 rapid and reliable identification of Prevotella species.

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

- 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.





EVOLVING DATABASE MOLDS

MEDICAL MYCOLOGY 2020;58(3):322-327

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 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.

JOURNAL OF CLINICAL MICROBIOLOGY

2018;56(2):e01353-17

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.

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	Ν	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%)
Total molds	1,519	1,387 (91%)

 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.

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), ß-tubulin, calmodulin, and other housekeeping genes plus 59 non-replicate clinical isolates identified by morphology and sequencing of ITS and B-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

	ALL ISOLATES		DATABASE ISOLATES ONLY	
SYSTEM	% 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.
- are known to exhibit antifungal resistance.



VITEK MS IVD v3.0 can correctly identify the cryptic azole-resistant species contained in the database, which



EVOLVING DATABASE MOLDS

FOOD MICROBIOLOGY 2019;81:76-88

Development and application of MALDI-TOF MS for identification of food spoilage fungi

Quéro L, Girard V, Pawtowski A, Tréguer S, Weill A, Arend S, Celliere B, Polsinelli S. Monnin V, van Belkum A, Vasseur V, Nodet P, Mounier J.

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 B-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.

MYCOPATHOLOGIA

2019;184:645-651

VITEK® MS v3.0 System in the Identification

of Filamentous Fungi

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

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 rapid method for identification of the most common clinical mold species. Its ability to rapidly 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."

OBJECTIVE

This development study was performed to add spectra from 136 species to the VITEK® MS database to enable identification of the most common food spoilage molds. After database modification, a two-step approach was used for validation (cross-validation of internal data followed by testing independent external isolates) to evaluate performance of the new database.

STUDY DESIGN

Data from 618 isolates belonging to 136 mold species were collected using an experimental design that included various cultivation conditions resulting in collection of 6.477 new spectra for these food spoilage-relevant molds. The reference method included macroscopic and microscopic morphology in addition to DNA sequencing (internal transcribed spacer (ITS), ß-tubulin, elongation factor (EF), etc.) of at least one isolate of each species or having a type strain representative for spectral comparison.

Validation was performed on the new knowledge base (KB) using first a cross validation (leave in-leave out) method where 20% of the data are removed and challenged vs. the remaining 80% of KB data. This 5-fold process was used to evaluate the entire KB. The second step of validation was done using 73 well characterized and independent isolates belonging to 52 of the KB species and 15 non-KB species for a more objective approach to performance evaluation.

RESULTS

Cross validation of the new KB showed 94.1% of spectra were identified correctly at the species level, 4.5% were unidentified, and 1.4% were discordant at species level but correct at genus level and often in the same clade of highly related species.

The external isolate validation showed that for species in the new KB, 89.5% were identified correctly to species level, 4.1% were unidentified, and 6.4% were discordant for highly related species within the same genus.

For the isolates of species not contained in the database, 70.7% were unidentified and 29.3% were discordant with most of these being misidentified to species level within the correct genus.

SYSTEM	% CORRECT TO SPECIES IN CROSS-VALIDATION	% CORRECT TO SPECIES IN EXTERNAL ISOLATES VALIDATION
VITEK [®] MS NEW DATABASE	94.1	89.5

CONCLUSIONS

VITEK MS is a rapid and robust tool for mold identification and this modification of the database allows for reliable identification of food spoilage molds.

"This study demonstrates that MALDI-TOF MS could be an alternative to conventional techniques for the rapid and reliable identification of spoilage fungi in food and industrial environments."

KEY FINDINGS

- The experimental design used to build the VITEK MS database with multiple isolates and culture conditions per species allows for robust performance with little to no impact from diversity of isolates or cultivation parameters.
- VITEK MS is a rapid reliable method for the accurate identification of food spoilage molds.

KEY FINDINGS

VITEK MS v3.0 is very rapid and accurate for identification of common clinical mold species.

E Environmental mold species which are not present in the VITEK MS v3.0 database are mostly unidentified, which is the desired result.



JOURNAL OF CLINICAL MICROBIOLOGY

2018;56(6):e00237-18

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, lakhiaeva E, Vasireddy R, Vasireddy S, Smith T,

Wallace RJ Jr, Turner S, Curtis L, Butler-Wu S, Rychert J.

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

Tested samples comprised 651 Mycobacterium and 312 Nocardia clinical isolates. Mycobacteria from the Mycobacterium tuberculosis

Mycobacteria and Nocardia were cultured on solid media, and isolates were prepared for analysis using a Mycobacterium/Nocardia

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

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

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

Ν

45

402

202



NO. CORRECTLY IDENTIFIED TO SPECIES.

GROUP OR COMPLEX LEVEL

45 (100%)

371 (92%)

197 (98%)

EVOLVING DATABASE MYCOBACTERIUM AND NOCARDIA

EMERGING MICROBES AND INFECTIONS 2018;7(1):114

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.

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.

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.

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."

STUDY DESIGN

RESULTS

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

OBJECTIVE

RESULTS

level

STUDY DESIGN

reagent kit from bioMérieux.

identified at the complex level.

MYCOBACTERIA

NTM slow growers

NTM rapid growers

CONCLUSIONS

M. tuberculosis complex

Mycobacterium and Nocardia species.

complex as well as nontuberculous mycobacteria (NTM) were tested.

- 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.

- 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



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

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 a 10-minute tube extraction 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 Biotype

"...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

E 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.

WORKFLOW EFFICIENCY

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

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."

- 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.





ANNALS OF LABORATORY MEDICINE 2018;38:487-489

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 ≥ 2.0	% CORRECT SPECIES WITH LOG SCORES ≥ 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 ≥ 1.7).

INTEGRATED ID AND AST SOLUTION



DIAGNOSTIC MICROBIOLOGY AND INFECTIOUS DISEASE 2019,95(2):208-211

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.

INTEGRATED ID AND AST SOLUTION

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

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 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 consequence was a significant reduction in LOS and length of antimicrobial therapy.

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 then MALDI-TOF MS alone..."

- 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.



INTEGRATED ID AND AST SOLUTION



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

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 rapid, 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.

RUO APPLICATIONS

Rapid Identification of Positive Blood Cultures
New Applications • Resistance
Typing **BMC RESEARCH NOTES** 2020;13(1):12

Rapid direct identification of positive paediatric blood cultures by MALDI TOF MS technology and its clinical impact in the paediatric hospital setting

Samaranayake WAMP, Dempsey S, Howard-Jones AR, Outhred AC, Kesson AR.



RUO APPLICATIONS NEW APPLICATIONS

PLOS ONE 2019;14(12):e0227071

Rapid pathogen identification and antimicrobial susceptibility testing in in vitro endophthalmitis with matrix assisted laser desorption-ionization Time-of-Flight Mass spectrometry and VITEK 2 without prior culture

Chun L, Dolle-Molle L, Bethet C, Dimitroyannis RC, Williams BL, Schechet SA, Hariprasad SM, Missiakas D., Schneewind O, Beavis K, Skondra D.

OBJECTIVE

This study evaluated the performance of an in-house protocol for rapid identification of microorganisms isolated from blood cultures performed on pediatric patients using the VITEK® MS system. The clinical impact of such a method on the management of pediatric patients was also assessed on a smaller set of samples.

STUDY DESIGN

A total of 360 positive blood cultures were collected between November 2018 and November 2019 and were processed with both the routine method (overnight subculture followed by conventional phenotypic identification methods including VITEK MS v3.2) and the in-house identification protocol (several lysis and centrifugation steps followed by identification on VITEK MS v3.2). The identification obtained with the routine method was considered as the reference.

A prospective clinical impact analysis was conducted on 31 patient cases during a shorter time period and three possible benefits were monitored: change in antimicrobials, change in intervention and infection control.

RESULTS

The in-house method identified 99% of Gram-negative organisms and 81% of Gram-positive organisms to the species level, with accuracy of 100% for Staphylococcus aureus and Enterococcus. None of the yeasts were identified by this method. These results are consistent with other direct identification techniques from positive blood cultures using MALDI-TOF.

Concerning the clinical impact observed in 31 patient cases, in eleven cases (35.5%), early identification with MALDI-TOF would have had clinical benefit. In ten cases (32.3%), a change of antimicrobials would have been facilitated and in six cases (19.4%), medical and surgical interventions could have happened earlier.

CONCLUSIONS

This study demonstrates the utility of MALDI-TOF for the rapid identification of organisms isolated from positive blood cultures in pediatric patients and the potential impact of this diagnostic approach on clinical decision-making. The in-house protocol is simple, rapid and highly accurate for Gram-negative organisms and Staphylococcus aureus, with a potential impact on length of stay, antibiotic rationalization and early confirmation of contamination

> "...results from our study demonstrate that direct identification of organisms in positive blood culture bottles using MALDI TOF MS could have important clinical impacts."

KEY FINDINGS

- First study assessing the VITEK MS system for early identification of organisms isolated from positive blood cultures in pediatric patients and potential impact on clinical management of patients.
- Results showed that the RUO in-house method developed by the authors could accurately identify 99% of Gram-negative and 81% of Gram-positive organisms.
- Early identification of organisms from positive blood cultures could lead to potential impacts on de-escalation of antibiotics, shortening of hospital stay, and infection control decision-making.

OBJECTIVE

This study investigated the ability of VITEK® MS and VITEK® 2 to identify and establish the antimicrobial susceptibility profile (AST) of the microorganisms involved in endophtalmitis using an in vitro model.

STUDY DESIGN

Vitreous humor (VH) aspirated from enucleated porcine eyes and inoculated with an isolated colony of Staphylococcus aureus was used as an in vitro model. After incubation at 37°C for seven hours to obtain bacterial stock, the samples were centrifuged and the bacterial pellets were either applied on a VITEK MS spot for identification or resuspended in sterile saline solution for VITEK 2 AST analysis.

RESULTS

All VH samples that produced visible pellets were correctly identified as S. aureus using VITEK MS v3.2 with a limit of detection of 7,889x10³ cfu/µl of VH. The time to obtain identification was less than 30 minutes per sample. The samples that reached the adequate McFarland units were analyzed by VITEK 2 and the result showed 94.44% accuracy compared to the positive control (S. aureus strain grown on plate).

CONCLUSIONS

This study demonstrates that direct analysis of vitreous samples using MALDI-TOF and VITEK 2 is possible and, according to the authors, could serve as a new and innovative method for rapid identification and targeted treatment of endophthalmitis. Further studies are needed to validate this potential clinical application.

"Directly applying endophthalmitis vitreous samples onto MALDI-TOF MS and VITEK 2 presents a promising new technique for the rapid identification of pathogens ..."

KEY FINDINGS

- First study assessing the VITEK MS system capability of directly analyzing intraocular samples using an in vitro model.
- identification and targeted treatment of endophthalmitis.



The authors observe that using MALDI-TOF MS (VITEK MS) and VITEK 2 could be a promising technique for rapid



JOURNAL OF MEDICAL MICROBIOLOGY 2018;67:1474-1479

Evaluation of rapid KPC carbapenemase detection method based on MALDI TOF VITEK MS spectra analysis

Centonze AR Bertoncelli A Savio C Orza P Benedic B Mazzariol A

RUO APPLICATIONS RESISTANCE

EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES 2018:37:57-68

Development of a rapid MALDI-TOF MS based epidemiological screening method using MRSA as a model organism

Lindgren Å, Karami N, Karlsson R, Åhrén C, Welker M, Moore ERB, Svensson Stadler L

OBJECTIVE

This study was conducted to evaluate the utility of the VITEK® MS RUO system to identify Klebsiella pneumoniae carbapenemase (KPC) producing strains through the presence of a characteristic peak in the MALDI-TOF spectra.

STUDY DESIGN

Four hundred and thirty-six Enterobacteriaceae strains were isolated following a screening at one hospital between April 2013 and January 2014, and from clinical samples from a second hospital from August 2014 to March 2015 in Italy. KPC-producers were distinguished from non-KPC-producers by antimicrobial susceptibility testing (AST), phenotypic carbapenemase resistance assays and molecular testing. One hundred and seventy-six strains were found to produce KPC. The remaining strains were used as a control group. Spectra were acquired on a VITEK® MS RUO system in a positive linear mode in the mass range of 2000–20000 m/z, without changing the instrument parameters and were visually inspected for the presence of the peak at 11109 Daltons (Da), which is specific for KPC- producing organisms.

RESULTS

The first analysis showed that 98.7% of the KPC-producing K.pneumoniae (KPN) strains and 92.3% of the KPC-producing E.coli strains (ECO) were found positive for the 11109 Da peak. After retesting the discrepant strains, 99.4% of KPN and 100% of ECO were positive. All the strains from the control group were found to be negative for this specific peak.

CONCLUSIONS

This study confirmed the strong correlation between KPC production and the presence of the 11109 Da peak in VITEK MS spectra in a large collection of isolates.

"... The correlation between the presence of the 11109 da peak and positive results for the carba NP test confirmed the reliability of MALDI TOF MS analysis as a rapid screening method for KPC-producing bacterial strains in endemic areas."

OBJECTIVE

This study used MRSA as a model organism and MALDI-TOF MS spectra to perform rapid epidemiological screening and recognition of the 19 most common PFGE-types of MRSA found clinically in Sweden.

STUDY DESIGN

The bioMérieux VITEK® MS RUO database (SARAMIS®) and Applied Maths BIONUMERICS® software were used to analyze molecular sequencing data to determine PFGE-types and VITEK MS spectral data to select the most relevant peaks for creation of 19 PFGE-type specific SuperSpectra (SSp).

A set of 111 strains were tested in quadruplicate and the three most similar spectra with >100 peaks and >85% similarity were retained for construction of SSp in SARAMIS. The most relevant peaks selected with BIONUMERICS were used to construct SSp for the 19 PFGE-types and were further characterized into 10 MALDI-types, five of which were comprised of single PFGE-types while the remainder comprised multiple related PFGE-types.

A test set of 255 strains were evaluated against the SARAMIS database to confirm species identification and then against the 19 PFGE-type SSp and further classified using the 10 MALDI-types (MTs).

RESULTS

SYSTEM	% CORRECT	% NO MATCH	% MISMATCH
SARAMIS® MTs	67.4	24.7*	5.5

*15.3% close to matching but below the 65% threshold.

CONCLUSIONS

The VITEK MS RUO database (SARAMIS) in combination with BIONUMERICS are useful tools to create a fast, cost-effective screening method to rule out epidemiological relatedness of isolates or identify the need for further typing by more complex molecular typing methods.

"...MALDI-TOF MS is a rapid and inexpensive method that may prove to serve an important role as a screening tool for rapid epidemiological typing and tracking of outbreaks, especially in a local setting."

KEY FINDINGS

- VITEK MS RUO, in conjunction with data analytics, could be used to create a rapid, screening method for epidemiological typing and outbreak tracking.
- MALDI-TOF MS could provide rapid epidemiological screening of MRSA, reducing time and costs associated with molecular typing methods.

KEY FINDINGS

This study confirms the correlation between KPC production and a characteristic MALDI TOF peak at 11109 Da on a wide range of isolates and when using a VITEK MS RUO system.





JOURNAL OF CLINICAL MICROBIOLOGY 2016;54(12):2982-2989

Evaluation of Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry for Identification of *Mycobacterium abscessus* Subspecies According to Whole-Genome Sequencing

Luo L, Liu W, Li B, Li M, Huang D, Jing L, Chen H, Yang J, Yue J, Wang F, Chu H, Zhang Z.

OBJECTIVE

This study was conducted to evaluate the utility of the VITEK[®] MS PLUS system to differentiate subspecies of *Mycobacterium abscessus*. Differentiation of subspecies is important to help improve therapy of cystic fibrosis patients as the subspecies can have different antimicrobial resistance patterns.

STUDY DESIGN

One hundred and seventy-five strains of *M. abcessus* were first characterized by whole genome sequencing and then used to expand and validate the RUO database SARAMIS® v4.12. SuperSpectra specific to each subspecies were created with 40 strains of *M. abscessus* spp. *abscessus* and 19 strains of *M. abscessus* spp. *massiliense*. The remaining 116 isolates were used to validate the customized database.

RESULTS

99.1% of the 116 isolates (115/116) used to validate the expanded database were identified at subspecies level, demonstrating the utility of SARAMIS to go beyond species level.

Two peaks were specific for *M. abscessus* spp. *abscessus* and four peaks were specific to *M. abscessus* spp. *massiliense*.

CONCLUSIONS

The expansion of the RUO SARAMIS database with well-characterized strains of the two subspecies of *M. abscessus* enabled their differentiation.

"The present study demonstrated the potential use of the MALDI-TOF MS RUO Saramis Knowledge Base database to identify M. abscessus at the subspecies level."

RUO APPLICATIONS TYPING

EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES 2019;38(3):581-591

Use of MALDI-TOF mass spectrometry to detect nosocomial outbreaks of Serratia marcescens and Citrobacter freundii

Rödel J, Mellmann A, Stein C, Alexi M, Kipp F, Edel B, Dawczynski K, Brandt C, Seidel L, Pfister W, Löffler B, Straube E.

OBJECTIVE

This study evaluated the use of VITEK® MS PLUS as a first-line typing tool to identify clonal clusters from outbreak-associated isolates of *Serratia marcescens* and *Citrobacter freundii*.

STUDY DESIGN

The authors investigated MALDI-TOF MS for typing of two different clinical species and compared the results with Whole Genome Sequencing (WGS) which was used as the reference method.

First, 21 isolates of *S. marcescens* with seven different genotypes were used to define typing criteria for MALDI-TOF MS. The defined criteria were then applied to subtype another set of *S. marcescens* and *C. freundii* isolates from a nosocomial outbreak.

RESULTS

The typing criteria for MALDI-TOF MS were the following: use of fresh cultures, direct smear preparation, measurement in the 3000 to 15000 Da range and generation of a consensus spectrum containing only peaks detected in three parallel single spectra. When the similarity cutoff was set to 90% for MALDI-TOF MS dendograms, the spectra clustering for the first 21 *S. marcescens* isolates corresponded to the distribution of genotypes with only one exception.

The same criteria were applied to discriminate the S. *marcescens* isolates from the neonatology intensive care unit (NICU). Three MALDI-TOF MS clusters were found and confirmed by WGS analysis.

The same approach was performed on *C. freundii* isolates during an outbreak and allowed the verification of the infection source. Once again, isolates that showed the same WGS type were grouped in the same MALDI-TOF MS cluster.

CONCLUSIONS

MALDI-TOF MS analysis can contribute to identifying clonal clusters of the opportunistic pathogens *S. marcescens* and *C. freundii* if defined typing criteria, such as use of fresh cultures and generation of consensus spectra, are applied to reduce the intrinsic variability of single spectra.

"...consensus spectra-based MALDI-TOF typing has the potential to serve as a screening method for identification of clonal clusters of S. marcescens and C. freundii"

KEY FINDINGS

Mycobacterium abscessus subspecies can be differentiated at subspecies level using the RUO SARAMIS[®] database.

This study confirms that differential peaks exist for each of the subspecies.

KEY FINDINGS

A first-line epidemiological screening by MALDI-TOF MS isolates that require analysis by WGS.

An advantage of MALDI-TOF typing is the availability of the results within 24 hours compared with WGS.



A first-line epidemiological screening by MALDI-TOF MS is possible and may contribute to reduce the number of

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