



VITEK® MS PRIME – Innovation & Next Level of Experience



PHARMA LAB , 24 Nov 2021

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PIONEERING DIAGNOSTICS

ADDRESSING KEY CHALLENGES WITH VITEK[®] MS PRIME

LAB CONSTRAINTS

MAXIMIZE
QUALITY

EMPOWER
STAFF

SHORTEN
TIME TO RESULT

CONTROL
COSTS

MASS SPECTROMETRY



Time To Result



One Technology For All Bacteria,
Fungi, and Mycobacteria



Accuracy



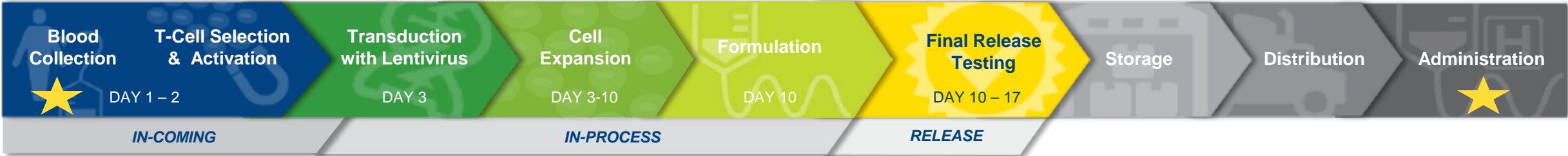
Ease Of Use



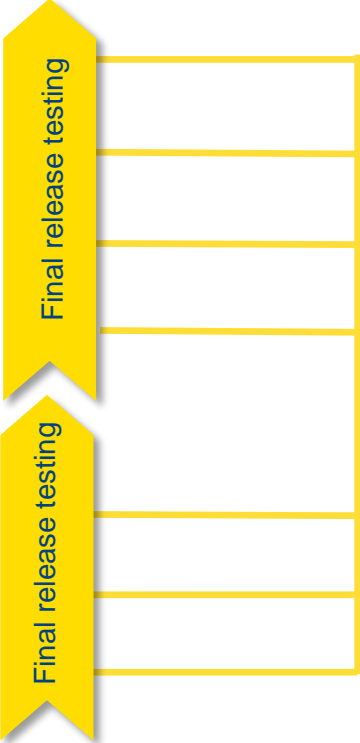
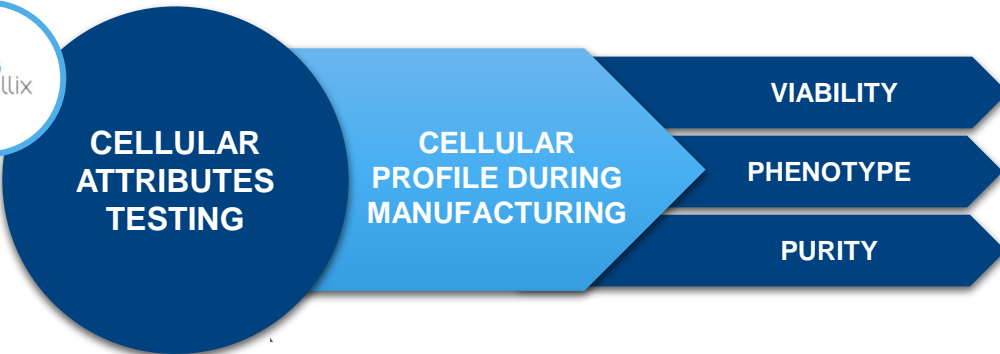
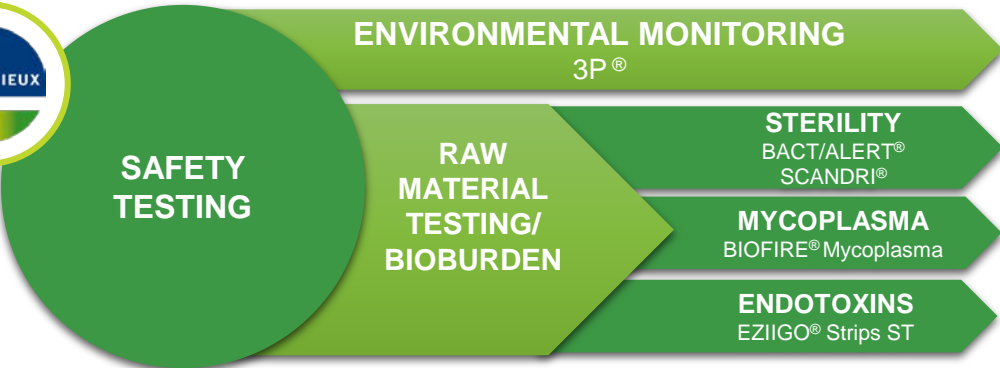
Cost Per Test

EARLIER
Decision
support

VITEK® MS PRIME CAN HELP MICROBIAL IDENTIFICATION IN CELL & GENE THERAPIES



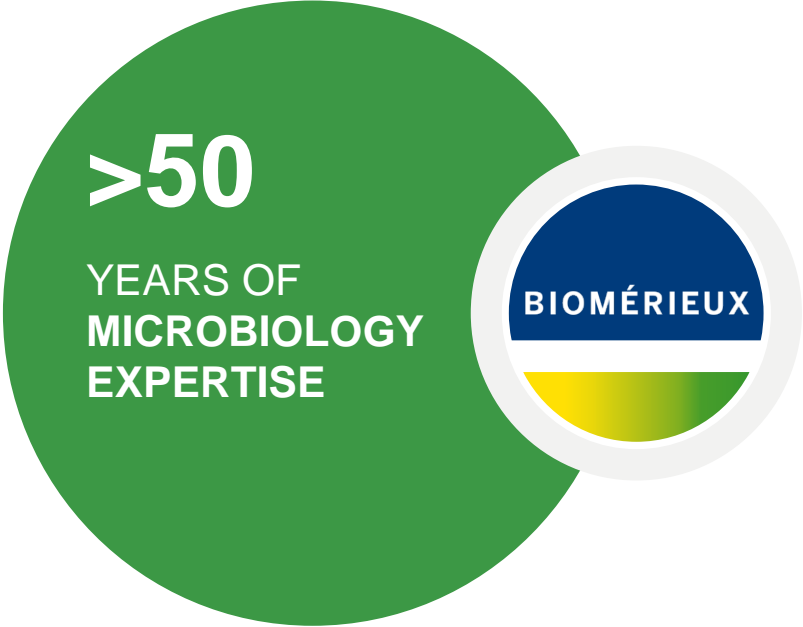
Needle to Needle Quality



RAPID Identification of both environmental and clinically relevant species is critical to ensure patient safety

MANDATORY TESTING

MICROBIOLOGY EXPERTISE MEETS INNOVATION WITH VITEK® MS PRIME



WITH VITEK® MS PRIME, BIOMÉRIEUX TAKES MASS SPECTROMETRY TO THE NEXT LEVEL, BUILDING ON A FOUNDATION YOU KNOW AND TRUST

NOT JUST AN INSTRUMENT VITEK® MS PRIME IS AN INTEGRATED, COMPREHENSIVE SOLUTION WITH SUPERIOR WORKFLOW EFFICIENCY DESIGNED TO BRING PRIME RESULTS FOR MAXIMUM PRODUCTIVITY IMPACT



IMPROVING EFFICIENCY & PRODUCTIVITY



NEW FUNCTIONALITY MAXIMIZES THE IMPACT OF DAILY LABORATORY WORKFLOW



NEW WITH VITEK[®] MS PRIME



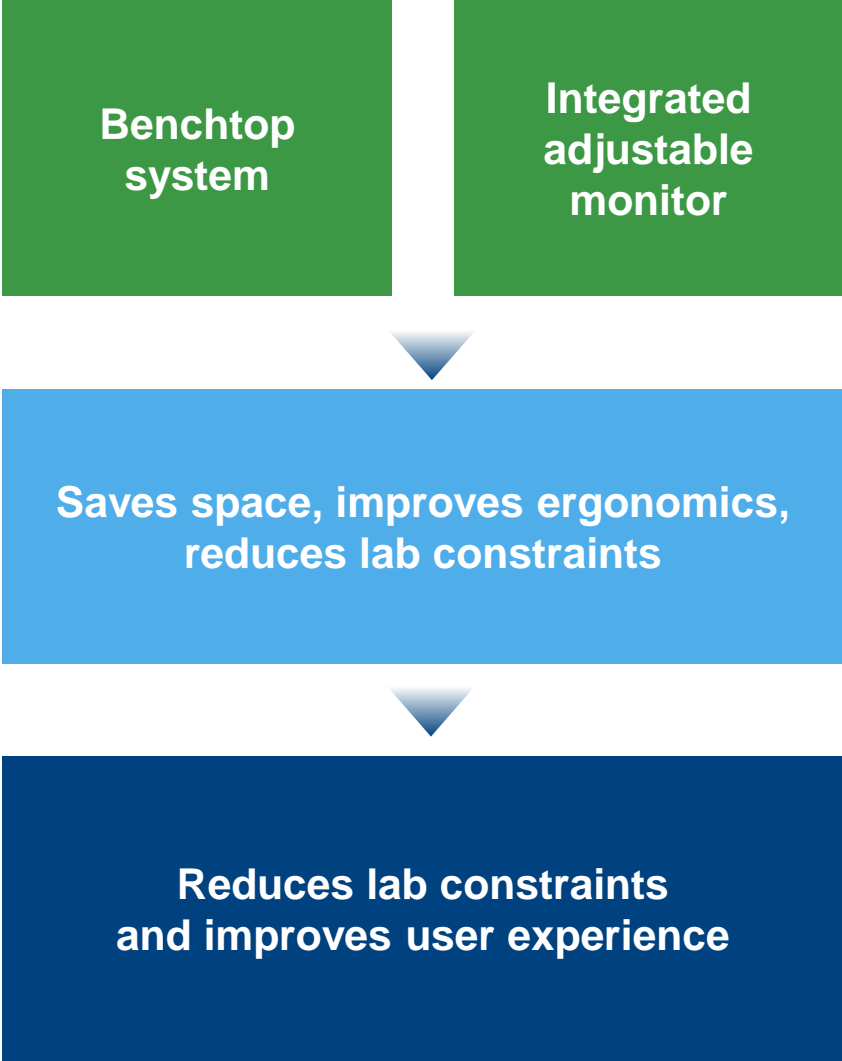
Benchtop system with improved and updated design

Automated continuous load and go

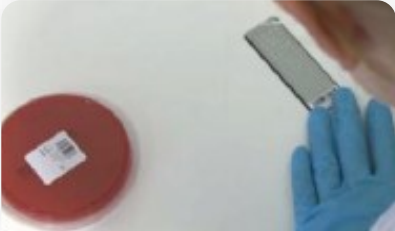
Fast track slide prioritization

Automated fine tuning

VITEK[®] MS PRIME IS A BENCHTOP SYSTEM TO EASILY FIT INTO YOUR LAB



FROM SAMPLE PREPARATION TO RESULTS REVIEW, VITEK® MS PRIME TAKES YOUR WORKFLOW TO THE NEXT LEVEL TO INCREASE LABORATORY EFFICIENCY



Validated protocols for easy, fast sample preparation



Multiple bench sample preparation with VITEK® FLEXPREP®



Urgent Slide Prioritization



Continuous Load and Go



Results review at multiple benches



LIMS

Auto releasing high confidence results

19 minutes

Time savings & Easy implementation and daily use

Greater productivity, faster time to reported result

Distribute workload + improve time to result

Transfer ID results to LIMS with seamless connectivity

AUTOMATED CONTINUOUS LOAD AND GO WORKFLOW EFFICIENCY IMPROVING TIME TO RESULT



VITEK® MS PRIME LOAD AND UNLOAD

Load and unload slides individually or by batch (capacity=16 slides) with no waiting time and no impact to the slide currently processing

Automated barcode scanning ensures sample traceability and reduces error



Increased workflow flexibility, time savings and faster reporting

URGENT SLIDE PRIORITIZATION ALLOWS SAMPLES TO BE **AUTOMATICALLY PRIORITIZED WITH NO INTERRUPTION TO SLIDES CURRENTLY PROCESSING**

The screenshot displays a software interface for slide management. On the left, a table lists slides with IDs (DS190615932-35) and 'fse' status. The second row (DS190615934) is highlighted in yellow and has a blue lightning bolt icon. A green callout box with a warning triangle icon points to this icon, containing the text 'Icon represents prioritized slide'. To the right is a slide tray grid with rows A-L and columns 1-4. The second row (B) and second column (2) are highlighted in yellow. Below the tray is a yellow button labeled 'Urgent' with the lightning bolt icon. On the far right, a panel shows 'ACCESSION ID: N/A', 'ZACK', 'Status: Waiting to be Acquired', 'Spot: [Micrograph]', 'Profiles passed: N/A', and 'Spectrum:'. A green line connects the 'Urgent' button to the first flowchart box below.

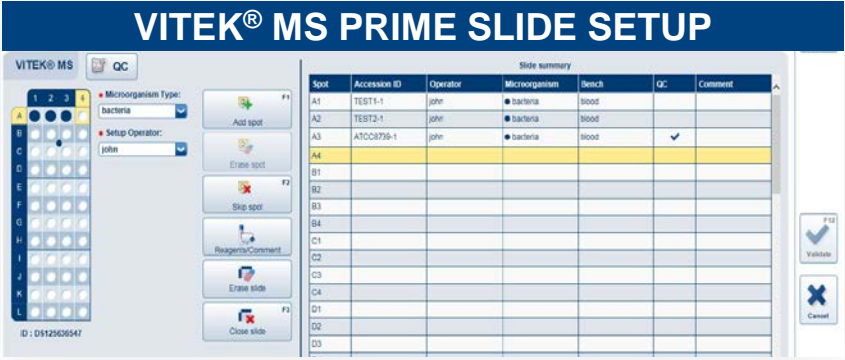
Slides can be marked "urgent" after loading

Urgent slides are processed as soon as the current slide processing is completed

Once processed, analysis resumes on the previous slide*or moves to the next slide in the queue

*If acquisition groups remain

PREPARE ID SAMPLES & REVIEW RESULTS WITH VITEK® FLEXPREP™ TO ENSURE TRACEABILITY, IMPROVE TIME TO RESULT AND SAVE TECH TIME

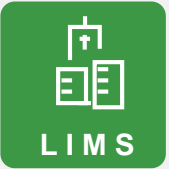


Sample Prep Bench

Technician station

Lab Manager PC

Accession ID	Slide ID	Organism Name	Confidence Level	Confidence Value
te0070_121326_738873-1	te0070_121326_86602 (A1)	Paeturella multocida	■	42.0
te0070_121326_738873-2	te0070_121326_86602 (A2)	Mycobacterium lentiformis	■	24.0
te0070_121326_738873-3	te0070_121326_86602 (A3)	Rothia mucilaginosa	■	40.0
te0070_121326_738873-4	te0070_121326_86602 (A4)	Malaesoba furfur	■	12.0
121324_738870-1	121324_86609 (A1)	Sphingomonas paucimobis	■	99.0
te0070_121326_738873-4	te0070_121326_86602 (A4)	Malaesoba furfur	■	12.0
121324_738870-1	121324_86609 (A1)	Sphingomonas paucimobis	■	99.0
te0070_121326_738873-1	te0070_121326_86602 (A1)	Paeturella multocida	■	42.0
te0070_121326_738873-2	te0070_121326_86602 (A2)	Mycobacterium lentiformis	■	24.0
te0070_121326_738873-3	te0070_121326_86602 (A3)	Rothia mucilaginosa	■	40.0
te0070_121326_738873-4	te0070_121326_86602 (A4)	Malaesoba furfur	■	12.0
121324_738870-1	121324_86609 (A1)	Sphingomonas paucimobis	■	99.0
121324_738864-1	121324_86604 (A1)	Prevotella dentata	■	75.0



Auto releasing high confidence results helps technicians focus on critical and challenging isolates

INTEGRATE YOUR RESULTS INTO EXTERNAL APPLICATIONS

CONNECT TO LIMS

BCI Connect uses bi-directional communication between VITEK[®] MS and your LIMS

Requires network access

21 CFR Part 11 compliance features

Trending and statistical analysis

EXPORT RESULTS

Export results to CSV file

Import CSV into offline software

Trending and statistical analysis

PROVIDING ACCURATE IDENTIFICATION



VALIDATED PROTOCOLS FOR SIMPLE AND RAPID PREPARATION

1 VALIDATED PROTOCOL PER GROUP



✓
**EASY IMPLEMENTATION
AND DAILY USE**

✓
**TIME & COST SAVINGS:
FEWER RETESTED ISOLATES**

✓
**ENHANCED LABORATORY
CONFIDENCE**

VITEK[®] MS PRIME KNOWLEDGE BASE

QUALITY AND ROBUSTNESS FOR ACCURATE IDENTIFICATION

UNIQUE DEVELOPMENT STRATEGY

MICROBIAL VARIABILITY



Strains included from different sources

Population based
12 strains/species

TECHNICAL VARIABILITY



Representative collection
of spectra > 40 000 spectra

Powerful Algorithm

Identifying presence and absence of species specific peaks



**SINGLE
CHOICE
RESULT**

VITEK® MS PRIME HAS COMPLETED BIOLOGICAL VERIFICATION AND PROVIDES EQUIVALENT DATABASE PERFORMANCE TO VITEK® MS



One strain from the 479 current FDA-cleared species was run in triplicate on VITEK MS PRIME and compared to the reference identification



Using internal well-characterized strains from our stock collection



Overall performance of :

- **98.4% correct ID**
- 0.21% Discordant ID
 - 1.37% No ID

VITEK® MS PRIME HAS COMPLETED CLINICAL TRIALS WITH EXCELLENT PERFORMANCE



5 replicates of the 100 most common clinically relevant species were run on VITEK MS PRIME at 3 internal sites and compared to the reference identification



Using well-characterized stock strains from previous trials



Overall performance of :

- **98,4% correct ID**
- 0,4% discordant ID
 - 1,2% No ID

A POSTER ON VITEK® MS PRIME PERFORMANCE IS AVAILABLE



Identification performance of the VITEK® MS PRIME MALDI-TOF system

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¹BIOMÉRIEUX, LA BALME-LES-GROTTES, FRANCE, ²CADUCEUM, LYON, FRANCE, ³BIOMÉRIEUX, INC., HAZELWOOD, MO, ⁴BIOMÉRIEUX, INC. DURHAM, NC,



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INTRODUCTION

The development of matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI-TOF MS) has revolutionized the routine identification of microorganisms in clinical microbiology laboratories and has been beneficial in decreasing time to identification of causative organisms compared to traditional methods.

VITEK MS PRIME is a new MALDI-TOF MS microbial identification system. This work presents biological performance of VITEK MS PRIME over a broad range of species as well as clinical trials showing consistent performance between different strains of the same species.

The performance study covers all claimed microorganisms on VITEK MS system while the clinical trials focus on a subset of representative microorganisms in a clinical setting.

METHODS

A broad performance study was conducted on 477^a species (one strain per species): 135 Gram-positive bacteria, 211 Gram-negative bacteria, 36 yeasts, 52 moulds, 30 mycobacteria and 13 *Nocardia*. Clinical trials were performed on a set of 100 species (five strains per species) of the most common and/or clinically relevant species/group/complex from Gram-positive (29) and Gram-negative (32) bacteria, yeasts (17) and moulds (10), mycobacteria (8) and *Nocardia* (4). Biological performance was determined by comparing VITEK MS PRIME identification using knowledge base V3.2.0 to a reference identification.

	Performance study		Clinical trials	
	species	strains	species	strains
Gram-positive bacteria	135	135	29	145
Gram-negative bacteria	211	211	32	160
Moulds	52	52	10	50
Yeasts	36	36	17	85
Mycobacteria	30	30	8	40
<i>Nocardia</i>	13	13	4	20
Total	477	477	100	500

Table 1. Species and strains distribution for performance study and clinical trials

Each strain have been previously well-characterized and no additional reference testing was required. For clinical trials, five unique clinical isolates for each of the 100 species were tested as far as possible.

PERFORMANCE STUDY RESULTS

The global biological performance is calculated from 1458 samples. The study covers 400 displayed labels and 477 species, for a total of 486 unique tests (9 mycobacteria species were tested both on solid and liquid media).

Microorganism	Overall Correct ID		No ID		Wrong Identification		Total
	N	%	N	%	N	%	
Gram-positive bacteria	401	99.0	4	0.99	0	0	405
Gram-negative bacteria	620	98.0	10	1.58	3	0.47	633
Yeasts	108	100.00	0	0	0	0	108
Moulds	152	97.4	4	2.56	0	0	156
Mycobacteria	115	98.3	2	1.7	0	0	117
<i>Nocardia</i>	39	100.00	0	0	0	0	39
Total	1435	98.42	20	1.37	3	0.21	1458

Table 2. Identification results of performance study after repeat testing

A global correct identification rate of 98.4% (1435/1458) was obtained, with 0.2% (3/1458) discordant ID and 1.4% (20/1458) no ID. In more detail, identification performance was 99.0% (401/405) for Gram-positive, 98.0% (620/633) for Gram-negative, 100.0% (108/108) for yeasts, 97.4% (152/156) for moulds, 98.3% (115/117) for mycobacteria and 100.0% (39/39) for *Nocardia*.

Klebsiella variicola wrongly identified to *Klebsiella pneumoniae* was the sole misidentification in this study.

CLINICAL TRIALS RESULTS

Clinical strains for all isolates tested showed a global agreement rate of 98.4% (492/500). The agreement rate within each organism group is above 95.3%.

In detail, Gram-positive bacteria at 99.3% (144/145), Gram-negative bacteria at 98.8% (158/160), yeast at 95.3% (81/85), moulds at 98.0% (49/50), mycobacteria at 100.0% (40/40) and *Nocardia* at 100.0% (20/20) proper identification. An error rate of 0.4% (2/500) was obtained overall, and the combined no identification rate was at 1.2% (6/500).

Microorganism	Overall Correct ID		No ID		Wrong Identification		Total
	N	%	N	%	N	%	
Gram-positive bacteria	144	99.3	0	0.0	1	0.7	145
Gram-negative bacteria	158	98.8	2	1.3	0	0.0	160
Yeasts	81	95.3	4	4.7	0	0.0	85
Moulds	49	98.0	0	0.0	1	2.0	50
Mycobacteria	40	100.0	0	0.0	0	0.0	40
<i>Nocardia</i>	20	100.0	0	0.0	0	0.0	20
Total	492	98.4	6	1.2	2	0.4	500

Table 3. Identification results of clinical trials after repeat testing

Only two misidentifications were observed, with one strain of *Trichophyton rubrum* wrongly identified as *Trichophyton violaceum* and one strain of *Listeria monocytogenes* wrongly identified as *Listeria innocua*, although they were correctly identified at genus level.

CONCLUSIONS

These studies showed that the new VITEK MS PRIME system provides reliable identification on a diverse panel of species and microorganisms, with a correct identification rate of 98.4% in both performance study and clinical trials. This performance combined to new features improving workflow efficiency will allow rapid and accurate identifications and help drive informed clinical decisions to optimize patient outcomes.

Footnotes

^aTwo strains were not able to be tested

PERFORMANCE ON FREQUENTLY ENCOUNTERED SPECIES WITH VITEK® MS PRIME

Species	One choice reference result
Burkholderia cenocepacia	100.0% (5/5)
Burkholderia multivorans	100.0% (5/5)
Micrococcus luteus	100.0% (5/5)
Pseudomonas aeruginosa	100.0% (5/5)
Staphylococcus aureus	100.0% (5/5)
Staphylococcus capitis	100.0% (5/5)
Staphylococcus epidermidis	100.0% (5/5)
Staphylococcus haemolyticus	100.0% (5/5)
Staphylococcus hominis ssp hominis	100.0% (5/5)
Staphylococcus lugdunensis	100.0% (5/5)
Staphylococcus saprophyticus	100.0% (5/5)
Stenotrophomonas maltophilia	100.0% (5/5)

100% correct identification for each species on 5 unique strains

AN OPEN DATABASE IS AVAILABLE WITH VITEK® MS PRIME



Streamlined analysis

- › **Common software** for easy setup of IVD or RUO samples
- › **Direct transfer of spectra** possible from the IVD database to the RUO database **with one click**

VITEK® MS PRIME IS PART OF A COMPREHENSIVE SERVICE OFFER FROM A COMMITTED PARTNER



ALL NEW INSTRUMENT DESIGN



INSTRUMENT SPECIFICATIONS



INSTRUMENT SERVICES



VALIDATION



TRAINING

VITEK® MS PRIME, **HIGH-THROUGHPUT AUTOMATED IDENTIFICATION FOR RAPID, SIMPLE, ROBUST ID & SEAMLESS INTEGRATION INTO YOUR DAILY ROUTINE**



71 cm x 70 cm x 110 cm (W/D/H)
28 in x 27.6 in x 43.3 in (W/D/H)

SUMMARY

Flexible High Throughput: from 1 to 768 samples per run, up to 16 slides!

Designed for convenience and uptime

MALDI-TOF Technology with Data Integrity & all features allowing 21 CFR 11 compliance

Simple and effective routine workflows, compatible with VITEK® FLEXPREP™, and optimized design for routine microbiology needs

Same reagents and Standardized protocols for organisms needing extractions/deactivation like Moulds, Mycoplasma, and others

Broad coverage of industry relevant organisms, powered by technical and microbial variability **98.4% correct ID**

Use as standalone or connected to LIMS

CE marked



PIONEERING DIAGNOSTICS