





VITEK® MS PRIME – Innovation & Next Level of Experience

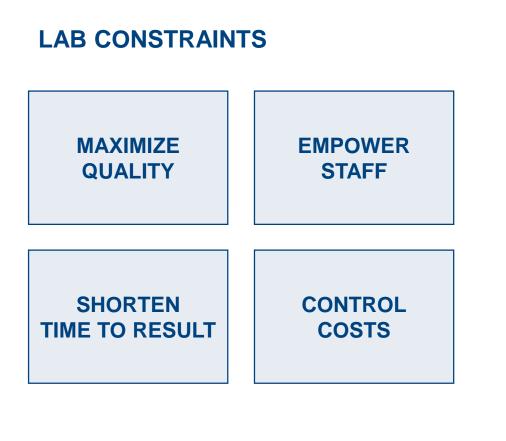
PHARMA LAB, 24 Nov 2021

Julie YANG Program Director ID&BTA, Health & Personal Care Business

> Victoria GIRARD R&D VITEK MS Program Director

> > **PIONEERING DIAGNOSTICS**

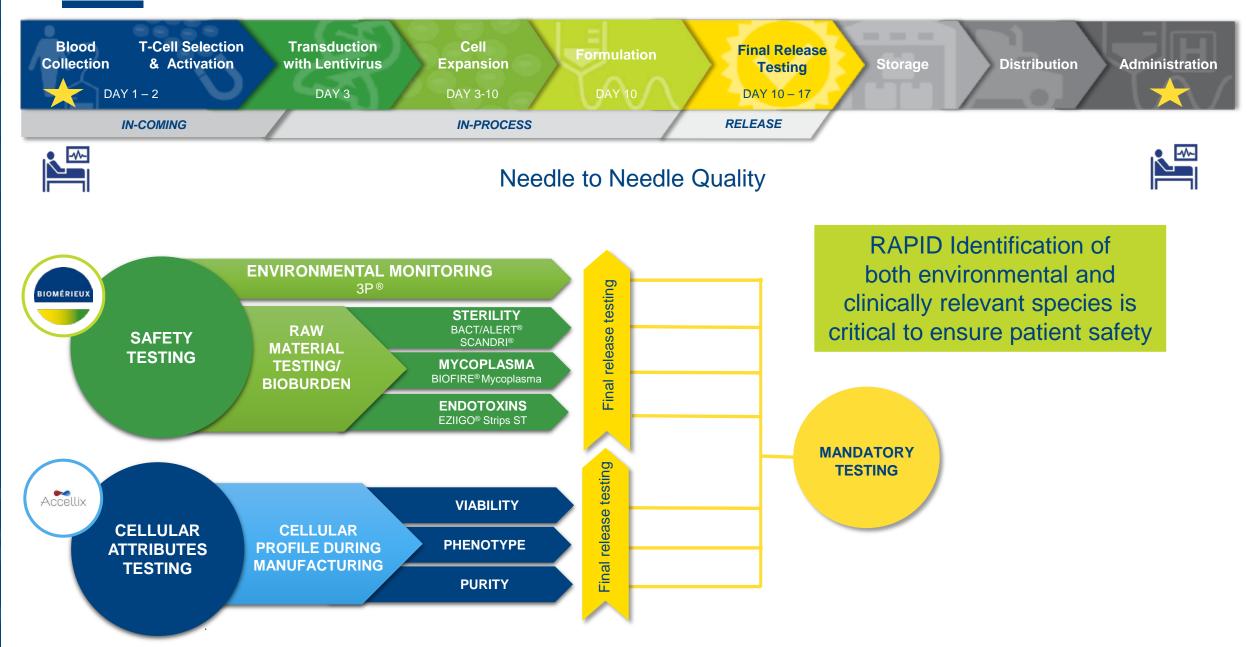
ADDRESSING KEY CHALLENGES WITH VITEK® MS PRIME



MASS SPECTROMETRY Ō Time To Result One Technology For All Bacteria, to Fungi, and Mycobacteria Accuracy The state Ease Of Use 2° **Cost Per Test**



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



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



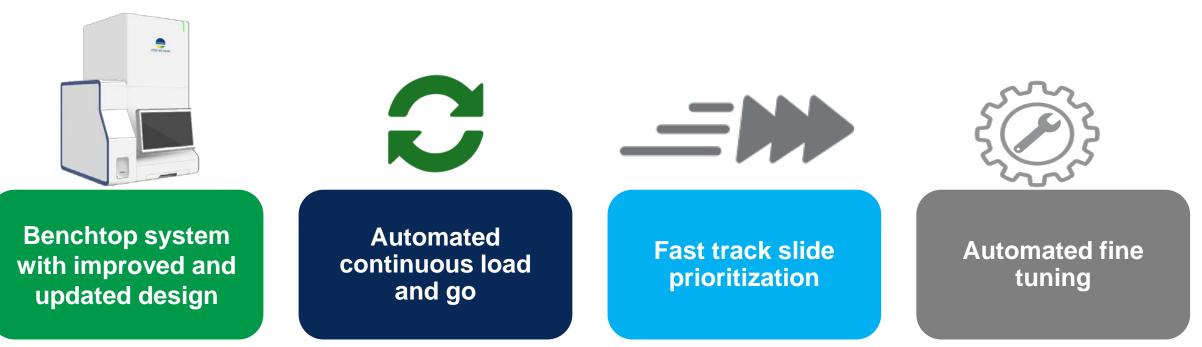
IMPROVING EFFICIENCY & PRODUCTIVITY



NEW FUNCTIONALITY MAXIMIZES THE IMPACT OF DAILY LABORATORY WORKFLOW



NEW WITH VITEK® MS PRIME



VITEK® MS PRIME IS A BENCHTOP SYSTEMTO EASILY FIT INTO YOUR LAB





Saves space, improves ergonomics, reduces lab constraints

Reduces lab constraints and improves user experience

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



AUTOMATED CONTINUOUS LOAD AND GO WORKFLOW EFFICIENCY IMPROVING TIME TO RESULT



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**

	DS190615932	fse		•	А		\bullet		Accession ID:	N/A
Ŧ	DS190615934	fse		3 🛛	в				ZACK	
Ŧ	DS190615931	fse			с				Status:	Waiting to be Acquired
Ŧ	DS190615935	fse		2	D	\mathbf{O}		0	Spot:	
			AVAILABLE		Е					
			AVAILABLE							
			AVAILABLE		F					and the
			AVAILABLE		G				Profiles passed:	N/A
			AVAILABLE	Icon represents prioritized slide	н	\bigcirc	00	0	Spectrum:	
			AVAILABLE		1					
			AVAILABLE		J			0		
			AVAILABLE							
			AVAILABLE		ĸ					
			AVAILABLE		L	\bigcirc				
			AVAILABLE		[DS190	0615934			
			AVAILABLE			Urgen				
							3			

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

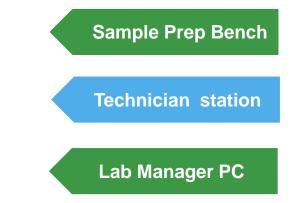






中 EE

LIMS



	Results Silves	Reports	Results to Rev	view	Spectren Search
	Escherichie zolikierelikel zooodsity of Singele date high confideres values (11) 🚳 Validati	and the second	er 🚓 Ratas 🔊		Search Drians 315/315
	Accession ID Q	Side ID V	Organisari Noree	Confidence Level	Centificence Value
	HED3TR_121328_736873-1	10370_121326_96862 (A1)	Pastauralla matocida		42
	tui0379_121328_738673-2	wiD379_121320_66662 (A2)	htycobacterium lentitavum		243
	(siD379_121324_736873-3	10179_121326_99662 (A3)	Rohia muckaginoka		40.
	WD370_121326_738875.4	NI0370_121328_00862 (A4)	Matassezia furfur		12.
٥	121324_736870-1	121324_00000 (A1)	Sphingomanas paucimobilis		60.
	H/0370_121328_738875-4	%10379_121326_09662 (A4)	Malappozia farfur		12.
	121334_736870-1	121324_00050 (A1)	Sphingomonas paucincobils		99.
	HED3179_121320_738873-1	%10379_121326_96662 (A1)	Pastaurelle multocide		42
0	tui0379_121328_738873-2	wiD379_121320_66662 (A2)	Mycobacterium lentitavum		240
	lex0379_121326_736873-3	x10379_131326_99662 (A3)	Robia mackaginosa		40
	isi0370_121328_738873-4	k40370_121328_00662 (A4)	Matassezia furfur		12.
3	121324_736870-1	121324_66009 (A1)	Sphingomanas paucinobilis		
	121330_738084-1	121300_66654 (A1)	Prevotella denticola		75.





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

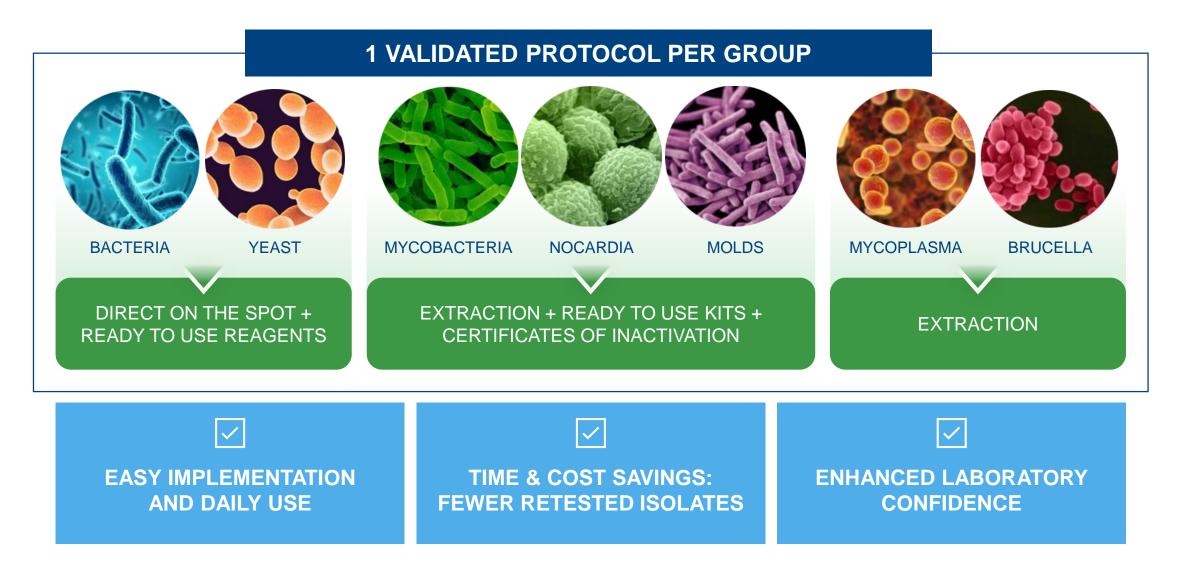
Import CSV into offline software

Trending and statistical analysis

PROVIDING ACCURATE IDENTIFICATION



VALIDATED PROTOCOLS FOR SIMPLE AND RAPID PREPARATION



VITEK® MS PRIME KNOWLEDGE BASE QUALITY AND ROBUSTNESS FOR ACCURATE IDENTIFICATION



MICROBIAL VARIABILITY	TECHNICAL VARIABILITY	
Global Variability	Different Media	
		SINGLE
Strains included	Operators & Systems	CHOICE RESULT
from different sources Population based 12 strains/species	Representative collection of spectra > 40 000 spectra	
Powe <u>rful</u>	Algorithm	

Identifying presence and absence of species specific peaks

VITEK® MS PRIME KNOWLEDGE BASE QUALITY AND ROBUSTNESS FOR ACCURATE IDENTIFICATION

- A recent published study of 246 isolates from environmental monitoring programs found that VITEK[®] MS KB v3.2 included 94.5% of the species isolated.
- 88.1% were identified to species level using VITEK[®] MS KB v3.2
- Poster presented at PDA Pharmaceutical Microbiology Conference 2019

ACCURATE IDENTIFICATION OF ENVIRONMENTAL BACTERIA BY MALDI-TOF MASS SPECTROMETRY USING VITEK® MS

Victoria Girard^a, Valérie Monnin^a, Marie-Christine Saccomen², Felix Montero-Julian⁴ and Arnaud Carlotti² *bioMérieux, La balme les Grottes , France, *Eurofins, Dardilly, France

The relevance of a robust knowledge base for routine environmental monitoring

ABSTRACT

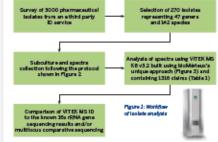
Use din contenni stati ni mer digattare ana dis understand the mis table socialey of a marsukati ingleding, succelle microsofti di softici di mi (c) ia men sundi algori di platemasculari quella grafita da la fini fini antaly ev-demantari da fini anta con regi of biolofica un'histo di VICIO Microsofti que ana (Mi) Anthi suasi Matta Analoida Lianz Description in tabletan – Time of Fight Mass Spectromatry (MAL-10 Tog) fanto di microsognaliane in glamama Liada advocenta.

Datagenerated in this partice till one the sites of VERX MASS in 22 that was built with multiple well-care and include and encounted in sites, where using a matcura match in the sites and counted for the different regions of the work. In this study, we assess the performance of this may knowledge base using 270 studied anyone multiple of genes and M2 spectra holding organization system (see the pharma and cale and counterparts).

The VITEXAS' results were in concordance with gave sequencing for 246 isolates (90, 444) to the gatrue level and for 256 isolates (86, 164) for the species level. 22 isolates (86%) were not identified and 9 isolates (24%) were middle titled. Among the 22 not identified isolates, 15 isolates (5.5% of all isolates) were not identified.

These data demonstrates that the VTDX MS provides relative identification of notice pharmaceutical instates as ing the latest notest increasing issues 22 and can the relate be used as an accounter identification global states in pharmaceutical companies.





FALCEDY DATA SUCH SER

Figure 3: Unique appresents hobitaliting andust insertingen base. VTERM MGV 32: destatuos taxed in difa a titudy was destigned to incorporate informacess and technical instability and use the field. Development caused well-operaterized strategies contrage from different ingense of the world, of thermit samples, including environmental anduse which were leaded using various needed and incubation times, in order to make a robust involved relations.



Table 2. KB V3.2 species claims. VT(RV9 MS x3.2 KB contains a variety of organizing from both clinical and industrial antitigger including myone table 300 species of backeting and fungt. This study focuses of backets from environmental specificiting programs with frequently observed aped as inducted in the a bioly.

VITEXINS Knowledge Base v2.2	Claims
Tatal species bectaris + fungi (including groups)	1,916
Recteria	1,095
Fengi	221

R	-	~	п	
ю	-	-		

Table 2: Species tested during the study.

Top 10 Most Requestly Identified Genera	Species identified within the genus					
Marececas	HE External					
Pacifius	ill cereasgroop, ill licheoidorrais, ill subtills, ill structuress. Ill simpler, ill circulare, ill firmus, ill mogeterium, ill mycoides					
Stephylosocas	5. hastychficza, 5. cohráj 5. aorean, 5. epiderosida, 5. horrista, 5. warrani, 5. capita, 5. kajdanezak, 5. seprephyticas					
Personana	Rywei					
Paeadomonee	Rierogioase, Ristatori					
Stecotrophorease	S. nuðophila,					
Funktolderig	R capacia-group					
Cogratedwises	C. antycolaturo, C. diphther iee, C. striaturo, C. (Weison, C. rosoffacieno, C. anticelecinomo					
Rektorie	R picketti, R inskinse					
Sphingumonas	5.peaclockle					

TS

BOMÉRIEUX



Figures: VITEK MS Knowledge Base K3.2 Performance



These data demonstrates the HTML WEX MS is 2 showing a base possible in black-intertitie atom of reating pharma with all isolates and constituent on the scaned are in tight-through part. MALDI FDF identification glidterm in pharma and take on partial environmental most bring programs.

VITEK[®] MS covers the vast majority of industrial customers' ID needs

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

• 1,2% No ID

A POSTER ON VITEK[®] MS PRIME PERFORMANCE IS AVAILABLE

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

D. JACOB¹, M. WANHAM², S. BLAMEY³, E. MILLER⁴, C. CANTRELL⁴, P-J. COTTE-PATTAT¹, R. BIRCH³, S. ELIZABETH³, T. TROST³, V. GIRARD¹ ¹BIOMÉRIEUX, LA BALME-LES-GROTTES, FRANCE, ²CADUCEUM, LYON, FRANCE, ³BIOMÉRIEUX, INC., HAZELWOOD, MO, ⁴BIOMÉRIEUX, INC. DURHAM, NC,

BIOMÉRIEUX

ECCMID 2021 – 9-12 July 2021

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 Gramnegative 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.

	Performa	nce study			
	species	strains	species	strains	
Gram-positive bacteria	135	135	29	145	
Gram-negative bacteria	211	211	211 32		
Moulds	52	52	10	50	
Yeasts	36	36	17	85	
Mycobacteria	30	30	8	40	
Nocordia	13	13	4	20	
Total	477	477	100	500	

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		D	Wrong Identification		Total	
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	
Nocardia	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 Gramnegative, 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), Gramnegative 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		erall ect ID			Wrong Identification		Total
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
Nocardia	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 *Two strains were not able to be tested

BIOMÉRIEUX

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

PERFORMANCE ON FREQUENTLY ENCOUNTERED SPECIES WITH VITEK ® MS PRIME

	One choice
Species	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

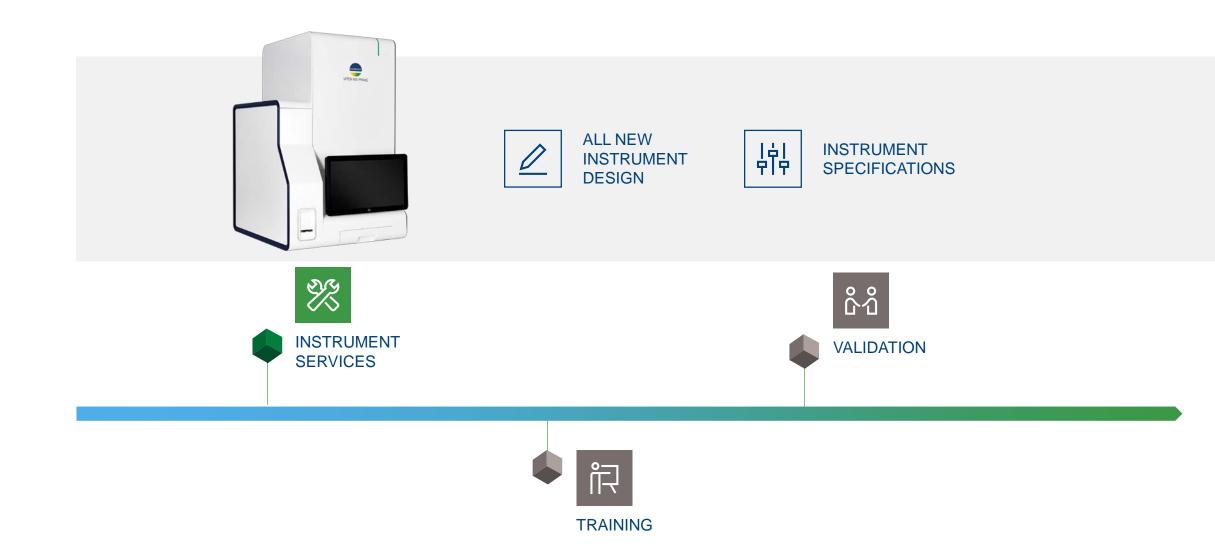
AN OPEN DATABASE IS AVAILABLE WITH VITEK® MS PRIME



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



VITEK[®] MS PRIME, **HIGH-THROUGHPUT AUTOMATED IDENTIFICATION FOR** RAPID, <u>SIMPLE</u>, 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

