VITEK® MS PRIME – Innovation & Next Level of Experience

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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
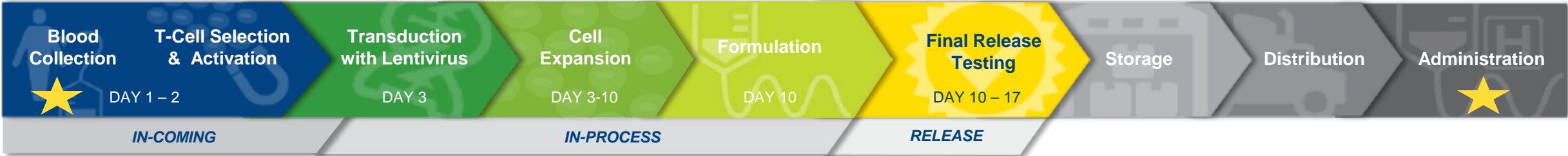- One Technology For All Bacteria, Fungi, and Mycobacteria
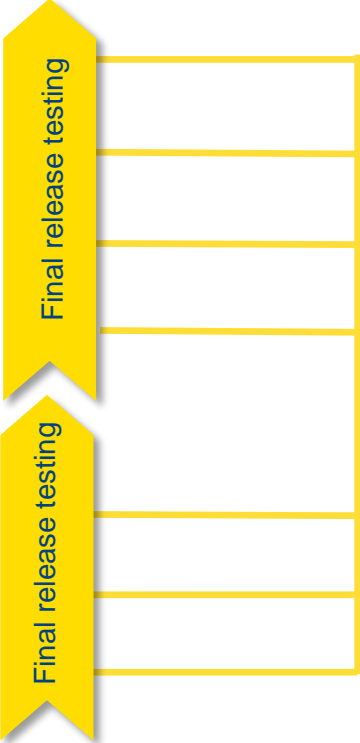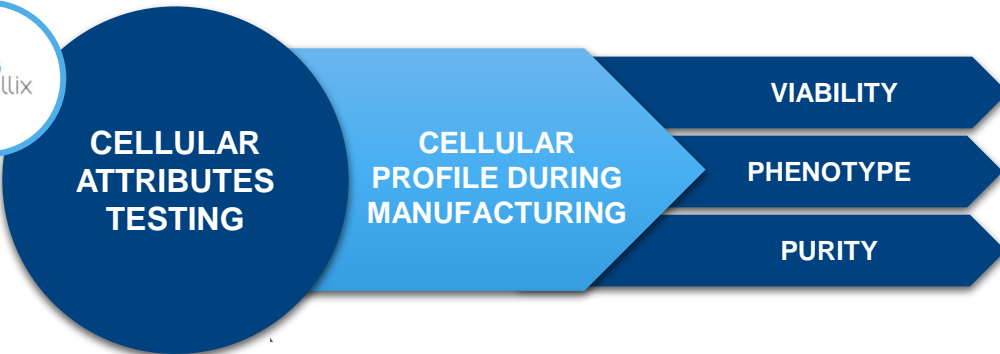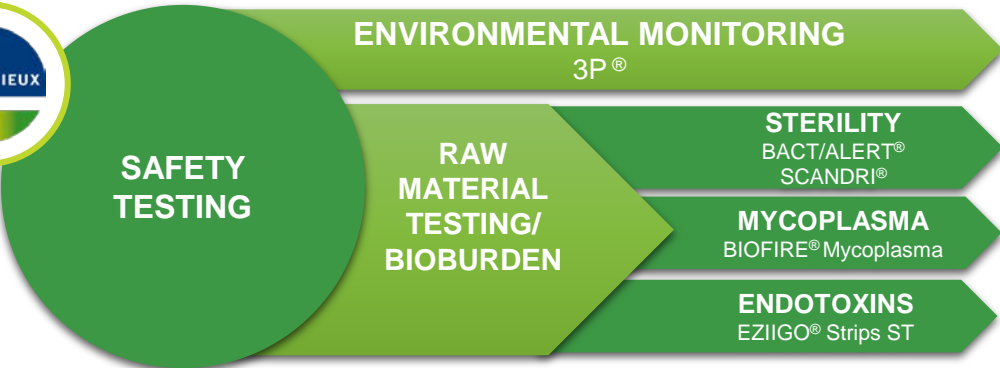- Accuracy
- Ease Of Use
- Cost Per Test

EARLIER Decision support

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

Blood Collection	T-Cell Selection & Activation	Transduction with Lentivirus	Cell Expansion	Formulation	Final Release Testing	Storage	Distribution	Administration
DAY 1 – 2		DAY 3	DAY 3-10	DAY 10	DAY 10 – 17			

IN-COMING — **IN-PROCESS** — **RELEASE**

Needle to Needle Quality

SAFETY TESTING

ENVIRONMENTAL MONITORING
3P®

RAW MATERIAL TESTING/ BIOBURDEN

STERILITY
BACT/ALERT® SCANDRI®

MYCOPLASMA
BIOFIRE® Mycoplasma

ENDOTOXINS
EZIIGO® Strips ST

Final release testing

CELLULAR ATTRIBUTES TESTING

CELLULAR PROFILE DURING MANUFACTURING

VIABILITY

PHENOTYPE

PURITY

Final release testing

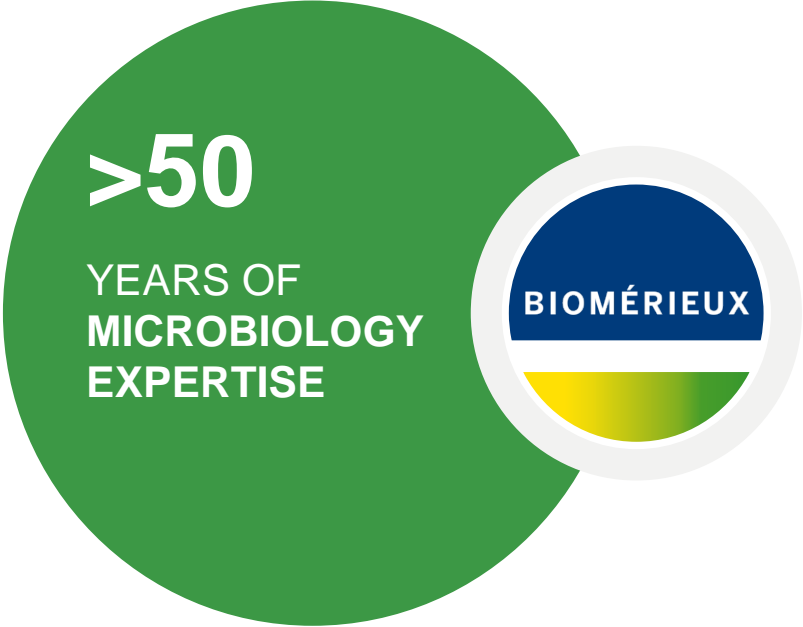**MANDATORY TESTING**

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

BIOMÉRIEUX

Accellix

MICROBIOLOGY EXPERTISE MEETS INNOVATION WITH VITEK® MS PRIME

>50 YEARS OF MICROBIOLOGY EXPERTISE

BIOMÉRIEUX

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

Superior Workflow Efficiency

Robust and Evolving Database

Designed for connectivity and integrated ID

A Committed Service Partner

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**

Benchtop system

Integrated adjustable monitor

Saves space, improves ergonomics, reduces lab constraints

Reduces lab constraints and improves user experience

BIOMÉRIEUX
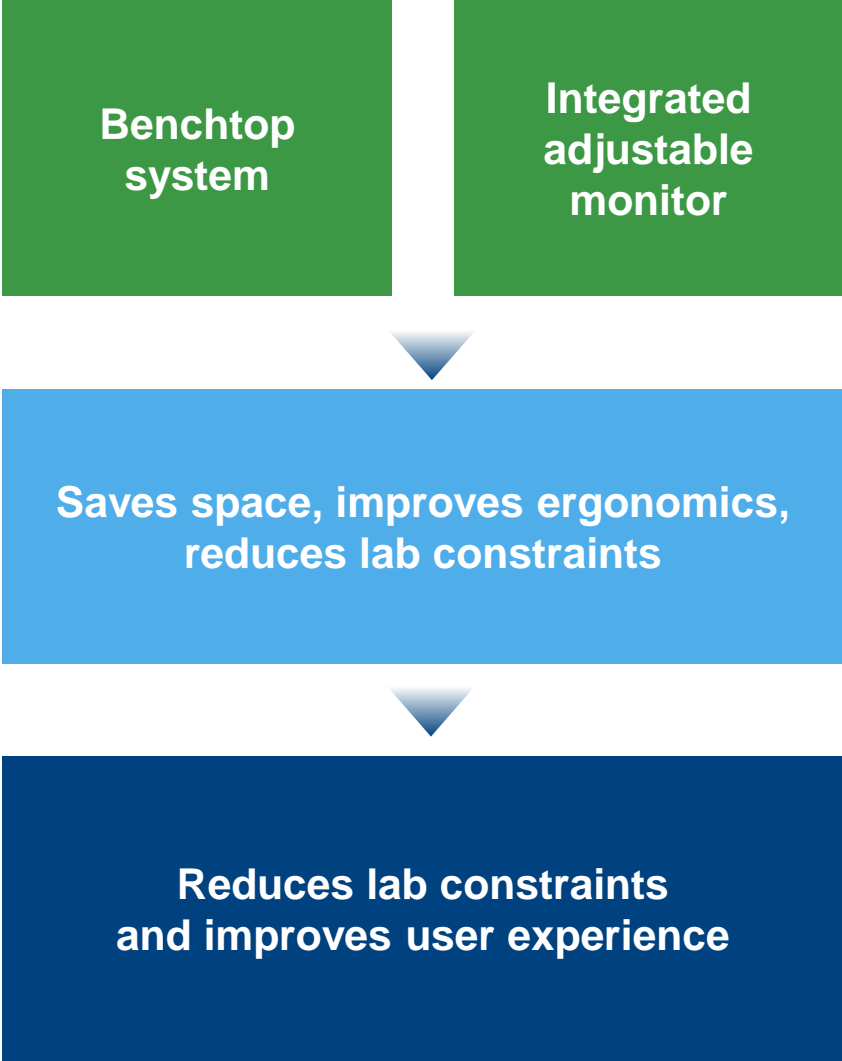
FROM SAMPLE PREPARATION TO RESULTS REVIEW, VITEK® MS PRIME TAKES YOUR WORKFLOW TO THE NEXT LEVEL TO INCREASE LABORATORY EFFICIENCY
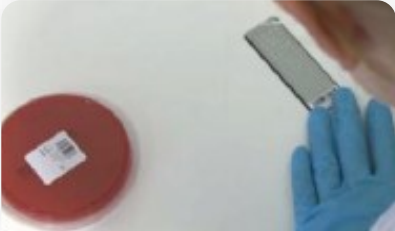
Validated protocols for easy, fast sample preparation

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

BIOMÉRIEUX

AUTOMATED CONTINUOUS LOAD AND GO
WORKFLOW EFFICIENCY IMPROVING TIME TO RESULT

LOAD

UNLOAD

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**

Icon represents prioritized slide

DS190615934

Urgent

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

BIOMÉRIEUX

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

VITEK® MS PRIME SLIDE SETUP
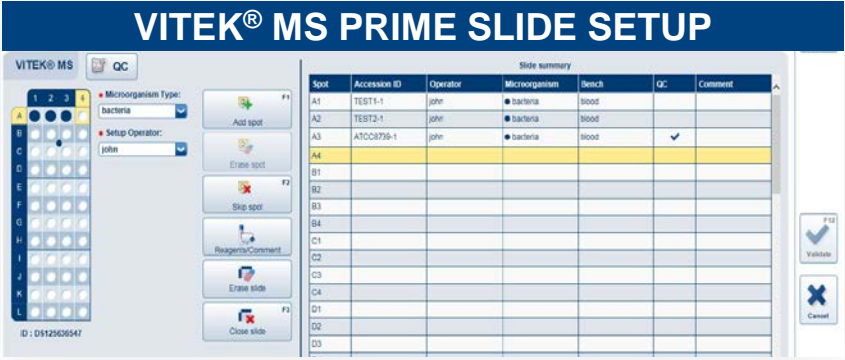
Sample Prep Bench

Technician station

Lab Manager PC

Results to Review

LIMS

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

BIOMÉRIEUX

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

BACTERIA   YEAST

MYCOBACTERIA   NOCARDIA   MOLDS

MYCOPLASMA   BRUCELLA

DIRECT ON THE SPOT + READY TO USE REAGENTS

EXTRACTION + READY TO USE KITS + CERTIFICATES OF INACTIVATION

EXTRACTION

☑ **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

Global Variability

Strains included
from different sources

**Population based
12 strains/species**

TECHNICAL VARIABILITY

Different Media

Operators & Systems

Incubation Time

**Representative collection
of spectra > 40 000 spectra**

Powerful Algorithm
Identifying presence and absence of species specific peaks

SINGLE CHOICE RESULT

BIOMÉRIEUX

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

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

A POSTER ON VITEK® MS PRIME PERFORMANCE IS AVAILABLE

BIOMÉRIEUX

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

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AN **OPEN DATABASE IS AVAILABLE** WITH VITEK® MS PRIME

BIOMÉRIEUX IVD DATABASE

- › **15 556** strains
- › **1 316** species
- › **12** strains/species

2 COMPLEMENTARY DATABASES

RUO SARAMIS® KB

- › Open database : **1 859** species
- › Database creation and customization

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

BIOMÉRIEUX

PIONEERING DIAGNOSTICS

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