



December 21, 2018

bioMerieux, Inc.
Jennifer Jines
Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K181412

Trade/Device Name: Vitek MS
Regulation Number: 21 CFR 21 CFR 866.3378
Regulation Name: Clinical Mass Spectrometry Microorganism Identification and Differentiation System
Regulatory Class: Class II
Product Code: QBN
Dated: May 29, 2018
Received: May 30, 2018

Dear Jennifer Jines:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.

Director

Division of Microbiology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number (*if known*)
K181412

Device Name
VITEK® MS

Indications for Use (*Describe*)

VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens.

The VITEK® MS system is a qualitative in vitro diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections.

(See Attached for 'List of Claimed Organisms')

Type of Use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 1.5 (Continued)**Indications for Use Attachment****Gram Negative / Positive****Bacteria & Yeast**

Abiotrophia defectiva
Achromobacter denitrificans
Achromobacter xylosoxidans
Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffii
Acinetobacter nosocomialis
Acinetobacter pittii
Actinomyces bovis
Actinomyces israelii
Actinomyces meyeri
Actinomyces naeslundii
Actinomyces neuvi
Actinomyces odontolyticus
Actinotignum schaalii
Aerococcus viridans
Aeromonas hydrophila
Aeromonas jandaei
Aeromonas punctata (caviae)
Aeromonas sobria
Aggregatibacter actinomycetemcomitans
Aggregatibacter aphrophilus
Aggregatibacter segnis
Alcaligenes faecalis ssp faecalis
Bacteroides caccae
Bacteroides eggerthii
Bacteroides fragilis
Bacteroides ovatus / xylanisolvens
Bacteroides pyogenes
Bacteroides stercoris
Bacteroides thetaiotaomicron
Bacteroides uniformis
Bacteroides vulgatus
Bifidobacterium spp
Bilophila wadsworthia
Bordetella avium
Bordetella bronchiseptica
Bordetella parapertussis
Bordetella pertussis
Brevundimonas diminuta
Brevundimonas vesicularis
Brucella spp

Burkholderia cenocepacia
Burkholderia cepacia
Burkholderia contaminans
Burkholderia gladioli
Burkholderia multivorans
Burkholderia vietnamiensis
Campylobacter coli
Campylobacter jejuni
Campylobacter rectus
Candida albicans
Candida auris
Candida dubliniensis
Candida duobushaemulonii
Candida famata
Candida glabrata
Candida guilliermondii
Candida haemulonii
Candida inconspicua
Candida intermedia
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitanae
Candida metapsilosis
Candida norvegensis
Candida orthopsilosis
Candida parapsilosis
Candida pelliculosa
Candida rugosa
Candida tropicalis
Candida utilis
Candida zeylanoides
Cedecea davisae
Cedecea lapagei
Cedecea neteri
Chryseobacterium gleum
Chryseobacterium indologenes
Citrobacter amalonaticus
Citrobacter braakii
Citrobacter farmeri
Citrobacter freundii
Citrobacter koseri
Citrobacter youngae
Clostridium baratii
Clostridium beijerinckii
Clostridium butyricum
Clostridium cadaveris

Section 1.5 (Continued)

Clostridium clostridioforme
Clostridium difficile
Clostridium innocuum
Clostridium novyi
Clostridium perfringens
Clostridium ramosum
Clostridium septicum
Clostridium sporogenes
Clostridium tertium
Clostridium tetani
Comamonas testosteroni
Corynebacterium jeikeium
Cronobacter muytjensii
Cronobacter sakazakii
Cronobacter turicensis
Cryptococcus gattii
Cryptococcus neoformans
Curtobacterium flaccumfaciens
Delftia acidovorans
Edwardsiella hoshinae
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia anophelis
Elizabethkingia meningoseptica
Elizabethkingia miricola
Enterobacter aerogenes
Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter cloacae
Enterobacter hormaechei
Enterobacter kobei
Enterobacter ludwigii
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Escherichia coli
Escherichia fergusonii
Escherichia hermannii
Escherichia vulneris
Ewingella americana
Finegoldia magna
Fusobacterium mortiferum
Fusobacterium necrophorum
Fusobacterium nucleatum
Fusobacterium periodonticum
Gardnerella vaginalis

Gemella haemolysans
Gemella morbillorum
Granulicatella adiacens
Haemophilus influenzae
Haemophilus parahaemolyticus
Haemophilus parainfluenzae
Hafnia alvei
Hathewayia histolytica
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella variicola
Khuyvera ascorbata
Khuyvera cryocrescens
Khuyvera intermedia
Kocuria rhizophila
Kodamaea ohmeri
Lactococcus garvieae
Lactococcus lactis
Leclercia adecarboxylata
Legionella pneumophila
Lelliottia amnigena
Leuconostoc mesenteroides
Leuconostoc pseudomesenteroides
Listeria monocytogenes
Malassezia furfur
Malassezia pachydermatis
Mannheimia haemolytica
Micrococcus luteus
Mobiluncus curtisii
Moraxella catarrhalis
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Morganella morganii
Myroides spp
Neisseria cinerea
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria mucosa / sicca
Ochrobactrum anthropi
Oligella ureolytica
Oligella urethralis
Paeniclostridium sordellii
Pantoea agglomerans
Pantoea dispersa

Section 1.5 (Continued)

<i>Paraclostridium bifermentans</i>	<i>Serratia fonticola</i>
<i>Parvimonas micra</i>	<i>Serratia grimesii</i>
<i>Pasteurella aerogenes</i>	<i>Serratia liquefaciens</i>
<i>Pasteurella multocida</i>	<i>Serratia marcescens</i>
<i>Pediococcus acidilactici</i>	<i>Serratia odorifera</i>
<i>Peptoniphilus asaccharolyticus</i>	<i>Serratia plymuthica</i>
<i>Peptostreptococcus anaerobius</i>	<i>Serratia proteamaculans</i>
<i>Plesiomonas shigelloides</i>	<i>Serratia quinivorans</i>
<i>Pluralibacter gergoviae</i>	<i>Serratia rubidaea</i>
<i>Porphyromonas asaccharolytica / uenonis</i>	<i>Shewanella putrefaciens</i>
<i>Porphyromonas gingivalis</i>	<i>Sphingobacterium multivorum</i>
<i>Prevotella bivia</i>	<i>Sphingobacterium spiritivorum</i>
<i>Prevotella buccae</i>	<i>Sphingomonas paucimobilis</i>
<i>Prevotella denticola</i>	<i>Staphylococcus aureus</i>
<i>Prevotella intermedia</i>	<i>Staphylococcus auricularis</i>
<i>Prevotella loescheii</i>	<i>Staphylococcus capitis</i>
<i>Prevotella melaninogenica</i>	<i>Staphylococcus chromogenes</i>
<i>Prevotella oralis</i>	<i>Staphylococcus cohnii ssp cohnii</i>
<i>Prevotella oris</i>	<i>Staphylococcus cohnii ssp urealyticus</i>
<i>Propionibacterium acidipropionici</i>	<i>Staphylococcus epidermidis</i>
<i>Propionibacterium acnes</i>	<i>Staphylococcus haemolyticus</i>
<i>Propionibacterium avidum</i>	<i>Staphylococcus hominis</i>
<i>Propionibacterium granulosum</i>	<i>Staphylococcus hyicus</i>
<i>Propionibacterium propionicum</i>	<i>Staphylococcus intermedius</i>
<i>Proteus mirabilis</i>	<i>Staphylococcus kloosii</i>
<i>Proteus penneri</i>	<i>Staphylococcus lentus</i>
<i>Proteus vulgaris</i>	<i>Staphylococcus lugdunensis</i>
<i>Providencia alcalifaciens</i>	<i>Staphylococcus pseudintermedius</i>
<i>Providencia rettgeri</i>	<i>Staphylococcus saprophyticus</i>
<i>Providencia rustigianii</i>	<i>Staphylococcus schleiferi</i>
<i>Providencia stuartii</i>	<i>Staphylococcus sciuri</i>
<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus simulans</i>
<i>Pseudomonas alcaligenes</i>	<i>Staphylococcus warneri</i>
<i>Pseudomonas fluorescens</i>	<i>Staphylococcus xylosus</i>
<i>Pseudomonas luteola</i>	<i>Stenotrophomonas maltophilia</i>
<i>Pseudomonas mendocina</i>	<i>Streptococcus agalactiae</i>
<i>Pseudomonas oryzihabitans</i>	<i>Streptococcus alactolyticus</i>
<i>Pseudomonas putida</i>	<i>Streptococcus anginosus</i>
<i>Pseudomonas stutzeri</i>	<i>Streptococcus canis</i>
<i>Ralstonia pickettii</i>	<i>Streptococcus constellatus</i>
<i>Raoultella ornithinolytica</i>	<i>Streptococcus cristatus</i>
<i>Raoultella planticola</i>	<i>Streptococcus dysgalactiae ssp dysgalactiae</i>
<i>Raoultella terrigena</i>	<i>Streptococcus dysgalactiae ssp equisimilis</i>
<i>Rhizobium radiobacter</i>	<i>Streptococcus equi ssp equi</i>
<i>Rhodotorula mucilaginosa</i>	<i>Streptococcus equi ssp zooepidemicus</i>
<i>Rothia mucilaginosa</i>	<i>Streptococcus equinus</i>
<i>Saccharomyces cerevisiae</i>	<i>Streptococcus gallolyticus ssp gallolyticus</i>
<i>Salmonella enterica ssp enterica</i>	<i>Streptococcus gallolyticus ssp pasteurianus</i>
<i>Saprochaete capitata</i>	<i>Streptococcus gordonii</i>
<i>Serratia ficaria</i>	

Section 1.5 (Continued)

Streptococcus infantarius ssp *coli* (*Str.lutetiensis*)
Streptococcus infantarius ssp *infantarius*
Streptococcus intermedius
Streptococcus mitis / *Streptococcus oralis*
Streptococcus mutans
Streptococcus parasanguinis
Streptococcus pneumoniae
Streptococcus pseudoporcinus
Streptococcus pyogenes
Streptococcus salivarius ssp *salivarius*
Streptococcus sanguinis
Streptococcus sobrinus
Streptococcus suis
Streptococcus uberis
Streptococcus
vestibularis
Tannerella forsythia
Veillonella dispar
Vibrio alginolyticus
Vibrio cholerae
Vibrio fluvialis
Vibrio metschnikovii
Vibrio mimicus
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia aldovae
Yersinia enterocolitica
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis
Yersinia ruckeri

Mycobacterium

Mycobacterium abscessus
Mycobacterium avium
Mycobacterium chelonae
Mycobacterium fortuitum group
Mycobacterium gordonae
Mycobacterium haemophilum
Mycobacterium immunogenum
Mycobacterium intracellulare
Mycobacterium kansasii
Mycobacterium lentiflavum
Mycobacterium malmoense
Mycobacterium marinum
Mycobacterium mucogenicum
Mycobacterium scrofulaceum
Mycobacterium simiae

Mycobacterium smegmatis
Mycobacterium szulgai
Mycobacterium tuberculosis complex
Mycobacterium xenopi

Nocardia

Nocardia abscessus
Nocardia africana / *nova*
Nocardia asteroides
Nocardia brasiliensis
Nocardia cyriacigeorgica
Nocardia farcinica
Nocardia otitidiscaviarum
Nocardia paucivorans
Nocardia pseudobrasiliensis
Nocardia transvalensis
Nocardia veterana
Nocardia wallacei

Mould

Acremonium sclerotigenum
Alternaria alternata
Aspergillus brasiliensis
Aspergillus calidoustus / *ustus*
Aspergillus flavus / *oryzae*
Aspergillus fumigatus
Aspergillus lentulus
Aspergillus nidulans
Aspergillus niger complex
Aspergillus sydowii
Aspergillus terreus complex
Aspergillus versicolor
Blastomyces dermatitidis
Cladophialophora bantiana
Coccidioides immitis / *posadasii*
Curvularia hawaiiensis
Curvularia spicifera
Epidermophyton floccosum
Exophiala dermatitidis
Exophiala xenobiotica
Exserohilum rostratum
Fusarium oxysporum complex
Fusarium proliferatum
Fusarium solani complex
Histoplasma capsulatum
Lecythophora hoffmannii
Lichtheimia corymbifera
Microsporum audouinii

Section 1.5 (Continued)

Microsporum canis
Microsporum gypseum
Mucor racemosus complex
Paecilomyces variotii complex
Penicillium chrysogenum
Pseudallescheria boydii
Purpureocillium lilacinum
Rasamsonia argillacea complex
Rhizopus arrhizus complex
Rhizopus microsporus complex
Sarocladium kiliense
Scedosporium apiospermum

Scedosporium prolificans
Sporothrix schenckii complex
Trichophyton interdigitale
Trichophyton rubrum
Trichophyton tonsurans
Trichophyton verrucosum
Trichophyton violaceum
Trichosporon asahii
Trichosporon dermatis / *mucoides*
Trichosporon inkin

510(k) SUMMARY**VITEK® MS****A. 510(k) Number:** K181412**B. Purpose for Submission:** Update to the VITEK® MS clinical Knowledge Base v3.2.0 to add new indications for use to the previously cleared device K162950 and DEN130013 (K124067)**C. Measurand:** See Intended Use**D. Type of Test:** A mass spectrometer system for clinical use for the identification of microorganisms is a qualitative *in vitro* diagnostic device intended for the identification of microorganisms cultured from human specimens. The device is comprised of an ionization source, a mass analyzer and a spectral database. The device is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections.**E. Applicant:**

Submitter's Name:	bioMérieux, Inc. on behalf of bioMérieux, SA
Address:	bioMérieux SA 3 Route de Port Michaud. La Balme les Grottes, 38390 (France)
Contact Person:	Jennifer Jines Regulatory Affairs Specialist
Phone Number:	314 -731-8352
Fax Number:	314-731-8689
Date of Preparation:	May 18, 2018

F. Proprietary and Established Names:

Formal/Trade Name:	VITEK® MS
Common Name:	VITEK® MS, VITEK MS

G. Regulatory Information:

1. <u>Regulation Section:</u>	21 CFR 866.3378
2. <u>Classification Name:</u>	Clinical mass spectrometry microorganism identification and differentiation system
3. <u>Product Code:</u>	QBN
4. <u>Panel:</u>	Microbiology

H. Intended Use:1. Intended use(s):

VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens.

The VITEK® MS is a qualitative *in vitro* diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections.

2. Indication(s) for use:

The following organisms are claimed:

Gram Negative / Positive**Bacteria & Yeast**

<i>Abiotrophia defectiva</i>	<i>Burkholderia cenocepacia</i>
<i>Achromobacter denitrificans</i>	<i>Burkholderia cepacia</i>
<i>Achromobacter xylosoxidans</i>	<i>Burkholderia contaminans</i>
<i>Acinetobacter baumannii</i>	<i>Burkholderia gladioli</i>
<i>Acinetobacter calcoaceticus</i>	<i>Burkholderia multivorans</i>
<i>Acinetobacter haemolyticus</i>	<i>Burkholderia vietnamiensis</i>
<i>Acinetobacter johnsonii</i>	<i>Campylobacter coli</i>
<i>Acinetobacter junii</i>	<i>Campylobacter jejuni</i>
<i>Acinetobacter lwoffii</i>	<i>Campylobacter rectus</i>
<i>Acinetobacter nosocomialis</i>	<i>Candida albicans</i>
<i>Acinetobacter pittii</i>	<i>Candida auris</i>
<i>Actinomyces bovis</i>	<i>Candida dubliniensis</i>
<i>Actinomyces israelii</i>	<i>Candida duobushaemulonii</i>
<i>Actinomyces meyeri</i>	<i>Candida famata</i>
<i>Actinomyces naeslundii</i>	<i>Candida glabrata</i>
<i>Actinomyces neuui</i>	<i>Candida guilliermondii</i>
<i>Actinomyces odontolyticus</i>	<i>Candida haemulonii</i>
<i>Actinotignum schaalii</i>	<i>Candida inconspicua</i>
<i>Aerococcus viridans</i>	<i>Candida intermedia</i>
<i>Aeromonas hydrophila</i>	<i>Candida kefyr</i>
<i>Aeromonas jandaei</i>	<i>Candida krusei</i>
<i>Aeromonas punctata (caviae)</i>	<i>Candida lambica</i>
<i>Aeromonas sobria</i>	<i>Candida lipolytica</i>
<i>Aggregatibacter actinomycetemcomitans</i>	<i>Candida lusitanae</i>
<i>Aggregatibacter aphrophilus</i>	<i>Candida metapsilosis</i>
<i>Aggregatibacter segnis</i>	<i>Candida norvegensis</i>
<i>Alcaligenes faecalis ssp faecalis</i>	<i>Candida orthopsilosis</i>
<i>Bacteroides caccae</i>	<i>Candida parapsilosis</i>
<i>Bacteroides eggerthii</i>	<i>Candida pelliculosa</i>
<i>Bacteroides fragilis</i>	<i>Candida rugosa</i>
<i>Bacteroides ovatus / xylanisolvens</i>	<i>Candida tropicalis</i>
<i>Bacteroides pyogenes</i>	<i>Candida utilis</i>
<i>Bacteroides stercoris</i>	<i>Candida zeylanoides</i>
<i>Bacteroides thetaiotaomicron</i>	<i>Cedecea davisae</i>
<i>Bacteroides uniformis</i>	<i>Cedecea lapagei</i>
<i>Bacteroides vulgatus</i>	<i>Cedecea neteri</i>
<i>Bifidobacterium spp</i>	<i>Chryseobacterium gleum</i>
<i>Bilophila wadsworthia</i>	<i>Chryseobacterium indologenes</i>
<i>Bordetella avium</i>	<i>Citrobacter amalonaticus</i>
<i>Bordetella bronchiseptica</i>	<i>Citrobacter braakii</i>
<i>Bordetella parapertussis</i>	<i>Citrobacter farmeri</i>
<i>Bordetella pertussis</i>	<i>Citrobacter freundii</i>
<i>Brevundimonas diminuta</i>	<i>Citrobacter koseri</i>
<i>Brevundimonas vesicularis</i>	<i>Citrobacter youngae</i>
<i>Brucella spp</i>	<i>Clostridium baratii</i>
	<i>Clostridium beijerinckii</i>
	<i>Clostridium butyricum</i>
	<i>Clostridium cadaveris</i>

Clostridium clostridioforme
Clostridium difficile
Clostridium innocuum
Clostridium novyi
Clostridium perfringens
Clostridium ramosum
Clostridium septicum
Clostridium sporogenes
Clostridium tertium
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Comamonas testosteroni
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Curtobacterium flaccumfaciens
Delftia acidovorans
Edwardsiella hoshinae
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia anophelis
Elizabethkingia meningoseptica
Elizabethkingia miricola
Enterobacter aerogenes
Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter cloacae
Enterobacter hormaechei
Enterobacter kobei
Enterobacter ludwigii
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Escherichia coli
Escherichia fergusonii
Escherichia hermannii
Escherichia vulneris
Ewingella americana
Finegoldia magna
Fusobacterium mortiferum
Fusobacterium necrophorum
Fusobacterium nucleatum
Fusobacterium periodonticum
Gardnerella vaginalis

Gemella haemolysans
Gemella morbillorum
Granulicatella adiacens
Haemophilus influenzae
Haemophilus parahaemolyticus
Haemophilus parainfluenzae
Hafnia alvei
Hathewayia histolytica
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella variicola
Kluyvera ascorbata
Kluyvera cryocrescens
Kluyvera intermedia
Kocuria rhizophila
Kodamaea ohmeri
Lactococcus garvieae
Lactococcus lactis
Leclercia adecarboxylata
Legionella pneumophila
Lelliottia amnigena
Leuconostoc mesenteroides
Leuconostoc pseudomesenteroides
Listeria monocytogenes
Malassezia furfur
Malassezia pachydermatis
Mannheimia haemolytica
Micrococcus luteus
Mobiluncus curtisii
Moraxella catarrhalis
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Morganella morganii
Myroides spp
Neisseria cinerea
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria mucosa / sicca
Ochrobactrum anthropi
Oligella ureolytica
Oligella urethralis
Paeniclostridium sordellii
Pantoea agglomerans
Pantoea dispersa

<i>Paraclostridium bifermentans</i>	<i>Serratia fonticola</i>
<i>Parvimonas micra</i>	<i>Serratia grimesii</i>
<i>Pasteurella aerogenes</i>	<i>Serratia liquefaciens</i>
<i>Pasteurella multocida</i>	<i>Serratia marcescens</i>
<i>Pediococcus acidilactici</i>	<i>Serratia odorifera</i>
<i>Peptoniphilus asaccharolyticus</i>	<i>Serratia plymuthica</i>
<i>Peptostreptococcus anaerobius</i>	<i>Serratia proteamaculans</i>
<i>Plesiomonas shigelloides</i>	<i>Serratia quinivorans</i>
<i>Pluralibacter gergoviae</i>	<i>Serratia rubidaea</i>
<i>Porphyromonas asaccharolytica / uenonis</i>	<i>Shewanella putrefaciens</i>
<i>Porphyromonas gingivalis</i>	<i>Sphingobacterium multivorum</i>
<i>Prevotella bivia</i>	<i>Sphingobacterium spiritivorum</i>
<i>Prevotella buccae</i>	<i>Sphingomonas paucimobilis</i>
<i>Prevotella denticola</i>	<i>Staphylococcus aureus</i>
<i>Prevotella intermedia</i>	<i>Staphylococcus auricularis</i>
<i>Prevotella loescheii</i>	<i>Staphylococcus capitis</i>
<i>Prevotella melaninogenica</i>	<i>Staphylococcus chromogenes</i>
<i>Prevotella oralis</i>	<i>Staphylococcus cohnii ssp cohnii</i>
<i>Prevotella oris</i>	<i>Staphylococcus cohnii ssp urealyticus</i>
<i>Propionibacterium acidipropionici</i>	<i>Staphylococcus epidermidis</i>
<i>Propionibacterium acnes</i>	<i>Staphylococcus haemolyticus</i>
<i>Propionibacterium avidum</i>	<i>Staphylococcus hominis</i>
<i>Propionibacterium granulosum</i>	<i>Staphylococcus hyicus</i>
<i>Propionibacterium propionicum</i>	<i>Staphylococcus intermedius</i>
<i>Proteus mirabilis</i>	<i>Staphylococcus kloosii</i>
<i>Proteus penneri</i>	<i>Staphylococcus lentus</i>
<i>Proteus vulgaris</i>	<i>Staphylococcus lugdunensis</i>
<i>Providencia alcalifaciens</i>	<i>Staphylococcus pseudintermedius</i>
<i>Providencia rettgeri</i>	<i>Staphylococcus saprophyticus</i>
<i>Providencia rustigianii</i>	<i>Staphylococcus schleiferi</i>
<i>Providencia stuartii</i>	<i>Staphylococcus sciuri</i>
<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus simulans</i>
<i>Pseudomonas alcaligenes</i>	<i>Staphylococcus warneri</i>
<i>Pseudomonas fluorescens</i>	<i>Staphylococcus xylosus</i>
<i>Pseudomonas luteola</i>	<i>Stenotrophomonas maltophilia</i>
<i>Pseudomonas mendocina</i>	<i>Streptococcus agalactiae</i>
<i>Pseudomonas oryzihabitans</i>	<i>Streptococcus alactolyticus</i>
<i>Pseudomonas putida</i>	<i>Streptococcus anginosus</i>
<i>Pseudomonas stutzeri</i>	<i>Streptococcus canis</i>
<i>Ralstonia pickettii</i>	<i>Streptococcus constellatus</i>
<i>Raoultella ornithinolytica</i>	<i>Streptococcus cristatus</i>
<i>Raoultella planticola</i>	<i>Streptococcus dysgalactiae ssp dysgalactiae</i>
<i>Raoultella terrigena</i>	<i>Streptococcus dysgalactiae ssp equisimilis</i>
<i>Rhizobium radiobacter</i>	<i>Streptococcus equi ssp equi</i>
<i>Rhodotorula mucilaginosa</i>	<i>Streptococcus equi ssp zooepidemicus</i>
<i>Rothia mucilaginosa</i>	<i>Streptococcus equinus</i>
<i>Saccharomyces cerevisiae</i>	<i>Streptococcus gallolyticus ssp gallolyticus</i>
<i>Salmonella enterica ssp enterica</i>	<i>Streptococcus gallolyticus ssp pasteurianus</i>
<i>Saprochaete capitata</i>	<i>Streptococcus gordonii</i>
<i>Serratia ficaria</i>	

Streptococcus infantarius ssp *coli* (*Str.lutetiensis*)
Streptococcus infantarius ssp *infantarius*
Streptococcus intermedius
Streptococcus mitis / *Streptococcus oralis*
Streptococcus mutans
Streptococcus parasanguinis
Streptococcus pneumoniae
Streptococcus pseudoporcinus
Streptococcus pyogenes
Streptococcus salivarius ssp *salivarius*
Streptococcus sanguinis
Streptococcus sobrinus
Streptococcus suis
Streptococcus uberis
Streptococcus
vestibularis
Tannerella forsythia
Veillonella dispar
Vibrio alginolyticus
Vibrio cholerae
Vibrio fluvialis
Vibrio metschnikovii
Vibrio mimicus
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia aldovae
Yersinia enterocolitica
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis
Yersinia ruckeri

Mycobacterium

Mycobacterium abscessus
Mycobacterium avium
Mycobacterium chelonae
Mycobacterium fortuitum group
Mycobacterium gordonae
Mycobacterium haemophilum
Mycobacterium immunogenum
Mycobacterium intracellulare
Mycobacterium kansasii
Mycobacterium lentiflavum
Mycobacterium malmoense
Mycobacterium marinum
Mycobacterium mucogenicum
Mycobacterium scrofulaceum
Mycobacterium simiae

Mycobacterium smegmatis
Mycobacterium szulgai
Mycobacterium tuberculosis complex
Mycobacterium xenopi

Nocardia

Nocardia abscessus
Nocardia africana / *nova*
Nocardia asteroides
Nocardia brasiliensis
Nocardia cyriacigeorgica
Nocardia farcinica
Nocardia otitidiscaviarum
Nocardia paucivorans
Nocardia pseudobrasiliensis
Nocardia transvalensis
Nocardia veterana
Nocardia wallacei

Mould

Acremonium sclerotigenum
Alternaria alternata
Aspergillus brasiliensis
Aspergillus calidoustus / *ustus*
Aspergillus flavus / *oryzae*
Aspergillus fumigatus
Aspergillus lentulus
Aspergillus nidulans
Aspergillus niger complex
Aspergillus sydowii
Aspergillus terreus complex
Aspergillus versicolor
Blastomyces dermatitidis
Cladophialophora bantiana
Coccidioides immitis / *posadasii*
Curvularia hawaiiensis
Curvularia spicifera
Epidermophyton floccosum
Exophiala dermatitidis
Exophiala xenobiotica
Exserohilum rostratum
Fusarium oxysporum complex
Fusarium proliferatum
Fusarium solani complex
Histoplasma capsulatum
Lecythophora hoffmannii
Lichtheimia corymbifera
Microsporum audouinii

Microsporum canis
Microsporum gypseum
Mucor racemosus complex
Paecilomyces variotii complex
Penicillium chrysogenum
Pseudallescheria boydii
Purpureocillium lilacinum
Rasamsonia argillacea complex
Rhizopus arrhizus complex
Rhizopus microsporus complex
Sarocladium kiliense
Scedosporium apiospermum

Scedosporium prolificans
Sporothrix schenckii complex
Trichophyton interdigitale
Trichophyton rubrum
Trichophyton tonsurans
Trichophyton verrucosum
Trichophyton violaceum
Trichosporon asahii
Trichosporon dermatitis / *mucooides*
Trichosporon inkin



3. Special conditions for use statement(s):

The VITEK MS is for prescription use only in accordance with 21 CFR 801.109

4. Special instrument requirements:

VITEK[®] MS: Shimadzu AXIMA[®] Assurance mass spectrometer
VITEK[®] MS Prep Station
VITEK[®] MS-DS Target Slides

Reagents:

VITEK[®] MS-CHCA (Alpha-cyano-4-hydroxy-cinnamic acid) solution
VITEK[®] MS-FA (Formic acid) reagent
VITEK[®] MS MYCOBACTERIUM/NOCARDIA KIT
VITEK[®] MS LIQUID MYCO SUPPLEMENTAL KIT
VITEK[®] MS MOULD KIT

Database:

VITEK[®] MS v3.2.0 Knowledge Base (KB)

Software:

VITEK[®] MS Sample Prep Station software
VITEK[®] MS Acquisition Station
VITEK[®] MS Analysis Server / Software
VITEK[®] MS Computation Engine
Myla[®] Middleware

I. Device Description:

The VITEK[®] MS v3.0 system is a system consisting of kit reagents (VITEK[®] MS-CHCA, VITEK[®] MS-FA, VITEK[®] MS Mycobacterium/Nocardia Kit, VITEK[®] MS Mould Kit), VITEK[®] MS-DS target slides, VITEK[®] MS Prep Station, Knowledge Base v3.2.0, software, and the VITEK[®] MS (original equipment manufacturer (OEM)-labeled Shimadzu AXIMA[®] Assurance mass spectrometer).

Reagent Description:

VITEK[®] MS-CHCA (Alpha-cyano-4-hydroxy-cinnamic acid) is the solution that serves as a matrix which will crystalize with the microbial sample on the target slide spot. 1.0 µl of the matrix is added to the spot with the sample and allowed to dry forming crystals.

The VITEK[®] MS-FA (Formic acid) reagent is used to pre-treat yeast in order to extract protein before the VITEK MS-CHCA matrix is added to the spot containing the sample.

VITEK[®] MS-DS target slides are single-use disposables which contain 3 acquisition groups of 16 sample spots. Each group includes 1 calibration spot. Target slides are for single use only.

VITEK[®] MS MYCOBACTERIUM/NOCARDIA KIT includes ethanol and vials with glass beads to inactivate mycobacteria and nocardia by disrupting the cells. The kit also includes formic acid and acetonitrile to complete the extraction of proteins.

VITEK[®] MS LIQUID MYCO SUPPLEMENTAL KIT includes the additional consumables (i.e., 5 mL conical bottom tubes and safety backed absorbent pads) needed to process samples for mycobacterium with liquid media.



VITEK[®] MS MOULD KIT provides ethanol, formic acid and acetonitrile to inactivate moulds and extract their proteins.

Knowledge Base:

The reference database for the VITEK[®] MS system includes data representing 1316 species and 1158 taxa displayed. VITEK[®] MS Knowledge Base v3.2.0 includes 1095 species of bacteria (863 single species and 77 groups including 232 species) and 221 species of fungi (195 single species and 12 groups including 26 species).

Additional laboratory tests as determined by Microbiology laboratory protocols for low discrimination results or non-clinically validated organisms are necessary for the completion of the organism identification. Non-clinically validated organisms are displayed as (N) in the report.

Testing of non-clinically validated species or species not found in the database may result in an unidentified result or a misidentification.

Note: Interpretation of results and use of the VITEK[®] MS system require a competent laboratorian who should judiciously make use of experience, specimen information, and other pertinent procedures before reporting the identification of test organisms. Additional information known to the user, such as Gram stain reaction, colonial and cellular morphology, and growth aerobically or in CO₂ should be considered when accepting VITEK[®] MS results.

Software:

The VITEK[®] MS system consists of a suite of applications that perform the overall system function. The system functions as a kiosk, not allowing the end-user to access any operating system functions. The end-user cannot access the native operating system or any system configuration panels. The software application contains several processes that include handling all user interactions, all network activity, communication, and synchronization with all the components. The VITEK[®] MS system software is comprised of four software components and MYLA middleware.

1. VITEK[®] MS Sample Prep Station software: The VITEK MS Prep Station is used to prepare VITEK[®] MS-DS target slides. It consists of a computer workstation equipped with a barcode reader, Touch Screen and Virtual Keyboard.
2. VITEK[®] MS acquisition station: The Acquisition Station Software controls the VITEK MS to acquire spectral data from each sample in turn and displays the spectra for the operator to review. The Acquisition Station displays the spectra and peak lists and transfers the peak lists to the VITEK MS Analysis Server.
3. VITEK[®] MS Analysis Server / Software: The VITEK MS Analysis Server is the software that manages the VITEK MS workflow and computes VITEK MS identification results. It is a software component that resides on the Myla Server (PC).
4. VITEK[®] MS Computation Engine: The VITEK MS analysis server sends to the computation engine that calculates the identification results. The algorithms and mapping files required for identification are contained within the computation engine.
5. Myla[®] Middleware: Myla is a computer application ("Middleware"), based on Web technology, which allows data related to the laboratory workflow, laboratory instruments, Laboratory Information System (LIS), analysis results, etc. to be grouped together. Myla[®] interfaces between the bioMérieux instruments connected to the application (e.g., VITEK MS) and the Laboratory Information System (LIS). Myla[®] is the user interface for the review and approval of the VITEK[®] MS identification results.

VITEK[®] MS:

bioMérieux's VITEK[®] MS, is the same instrument as the Shimadzu Axima Assurance MALDI TOF spectrometer. The VITEK MS is manufactured for bioMérieux by Kratos Analytical (a Shimadzu subsidiary) in Manchester, UK. The VITEK MS contains a Class 1 laser product containing a Class 3b invisible-light laser. The laser is a 337 nm nitrogen laser, fixed focus. This speed depends on the mass of the ions with heavier molecules having a higher moment



of inertia resulting in a lower velocity. The time of transit is measured precisely by the ions' arrival at a particle detector. Based on the time of flight, the m/z ratio of each particle can be determined, and a mass spectrum of the sample mixture is generated. The recorded signal is processed by the Acquisition Station software and presented as a spectrum of intensity versus mass in Daltons (Da).

J. Substantial Equivalence Information:

1. Predicate Device Name:

MALDI Biotyper CA System

2. Predicate Device De Novo Submission Number:

DEN170081

3. Comparison with predicate:

Similarities		
Characteristic	New Device VITEK [®] MS v3 / KB v3.2.0	Predicate Device MALDI Biotyper CA System (DEN170081)
Classification	Classification Name: Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured isolates Regulation Number: 21 CFR 866.3378	Classification Name: Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured isolates Regulation Number: 21 CFR 866.3378
Product Code	QBN	QBN
Intended Use	VITEK [®] MS is a mass spectrometry system using matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK [®] MS is a qualitative <i>in vitro</i> diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections.	The MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ionization - time of flight (MALDI-TOF) for the identification and differentiation of microorganisms cultured from human specimens. The MALDI Biotyper CA System is a qualitative <i>in vitro</i> diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections
Sample Type	Isolated colony from a patient sample source, from media including: - BacT/ALERT[®] MP (liquid culture media bottle) - Brucella agar base - Buffered charcoal yeast extract - Campylosel agar - Chocolate polyvitex agar - chromID CPS - Coletsos	Isolated colony from any patient sample source. Acceptable media: -Columbia blood agar with 5% sheep blood (Gram-negative bacteria) -Columbia CNA agar with 5% sheep blood (Gram-positive bacteria) - Trypticase soy agar with 5% sheep blood (Gram-negative



	- Columbia blood agar with 5% sheep blood - Lowenstein-Jensen - MacConkey agar - MGIT™ (liquid culture media bottle) - Middlebrook 7H10 agar - Middlebrook 7H11 agar - Modified Sabouraud dextrose agar (glucose: 20 g/l - pH: 6.1) - Potato dextrose agar - Sabouraud dextrose agar (glucose: 40 g/l - pH: 5.6) - Sabouraud dextrose agar with Gentamicin & Chloramphenicol - Trypticase soy agar - Trypticase soy agar with 5% sheep blood - Trypticase soy agar with neutralizers - BacT/ALERT® MP - Campylosel agar - chromID CPS - Coletsos - Lowenstein-Jensen* - MGIT™* - Middlebrook 7H10 agar* - Middlebrook 7H11 agar* - Modified Sabouraud dextrose agar (glucose: 20 g/l - pH: 6.1) - Potato dextrose agar - Sabouraud dextrose agar with Gentamicin & Chloramphenicol - Trypticase soy agar with neutralizers * Non-bioMérieux media Note: Some media are different than the media for the predicate device.	bacteria, Gram-positive bacteria, yeasts) -Chocolate agar (Gram-negative bacteria, Gram-positive bacteria) -MacConkey Agar (Gram-negative bacteria) -Brucella Agar with 5% horse blood (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) -Sabouraud-Dextrose Agar (Yeasts) -CDC anaerobe Agar with 5% sheep blood (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) -CDC anaerobe 5% sheep blood Agar with phenylethyl alcohol (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) -CDC anaerobe laked sheep blood Agar with kanamycin and vancomycin (Gram-negative anaerobic bacilli) -Bacteroides bile esculin Agar with amikacin (Bacteroides species) -Clostridium difficile Agar with 7% sheep blood (Clostridium difficile) -Brain Heart Infusion Agar (Yeasts) -Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood (Campylobacter species) -Bordet Gengou Agar with 15% sheep blood (Bordetella species)
Type of Test	Automated Mass Spectrometry System	Automated Mass Spectrometry System
Matrix	alpha-cyano-4-hydroxy-cinnamic acid	alpha-cyano-4-hydroxy-cinnamic acid
Method of Testing	The sample prep for bacteria and yeast is direct testing from isolated colonies. Inactivation of the sample occurs during the addition of the CHCA Matrix. For sample prep of Mycobacteria, <i>Nocardia</i> and mould, an inactivation and extraction process is required prior to spotting the sample to the VITEK® MS-DS Target Slide.	Bacteria & Yeast: Direct testing If after initial analysis the log(score) is reported at <2.00, organisms may be processed using the Extraction (Ext) procedure or extended Direct Transfer (eDT, 70% aqueous formic acid). If eDT method still yields log(score) <2.0, organism may be processed via Ext procedure.



	For <i>Brucella</i> sample prep, an inactivation process is required prior to spotting the sample to the VITEK® MS-DS Target Slide.	
Result Reporting	To detect microbial growth, the VITEK MS System uses a knowledge base developed from spectra of a number of microbial species. The resulting spectra from the VITEK MS / Acquisition Station are evaluated against this knowledge. Identification are displayed, with a confidence value when an organism or organism group is identified. Low-discrimination identifications are displayed when more than one, but not more than four identifications, are made. When more than four identifications are made, or when no match is found, the organism is considered unidentified. Data analysis is performed using software embedded on the MYLA® Server.	Organism identification is reported with high confidence if the log(score) is >2.0. An organism identification is reported with low confidence if the log(score) is between 1.70 and <2.00.
Algorithm	An algorithm process known as "mass binning" is used for the differentiation of the species included in the knowledge base.	Calculates matches by comparing a new spectrum against each single reference entry of a reference database.
Recorded Mass Range	2,000 - 20,000 m/z	2,000 - 20,000 m/z
Laser	Class 1 Laser Product - 337 nm fixed focus, nitrogen laser	Class 1 Laser product (class 4 with safety cover opened) - 337 nm fixed focus, nitrogen laser

Differences		
Characteristic	New Device VITEK® MS v3 / KB v3.2.0	Predicate Device MALDI Biotyper CA System (DEN170081)
Knowledge Base and Indications for Use	VITEK® MS v3.2 Knowledge Base	MALDI Biotyper Reference Library for Clinical Applications (MBT-CA)
MALDI-TOF MS instrument	Shimadzu AXIMA® Assurance MS	Bruker microflex LT/SH (benchtop) Bruker microflex LT/SH smart (benchtop)
System Components, Software, Reagents	The VITEK® MS system consists of a number of components, - a Prep Station - the MS Instrument - an Acquisition Station - software/middleware solutions including,	The MBT-CA System consists of the microflex LT/SH mass spectrometer, reference library, kit reagents, US IVD 48 Spot Target or MBT Biotarget 96 US IVD plate, and software. Software:



	○ Acquisition Station Software, ○ an Analysis Server, ○ a Computation Engine, ○ MYLA[®] - disposables/consumables ○ the VITEK[®] MS-DS Target Slides, ○ CHCA Matrix, ○ Formic Acid, ○ VITEK[®] MS Mycobacterium/Nocardia Kit, ○ VITEK[®] MS Mould Kit	• MBT-CA System Software Package: MBT-CA System client software displaying the user interface, MBT-CA System Server, and MBT-CA System DB Server • flexControl Software Package: GTPS firmware and flexControl acquisition software - Reagents: • US IVD Bacterial Test Standard (BTS) • US IVD HCCA portioned (α-Cyano-4-hydroxycinnamic acid)
Calibration	<i>E. coli</i> ATCC 8739	Bruker US IVD Bacterial Test Standard

K. Standard/Guidance Document Referenced (if applicable):

- FDA/CDRH/ODE Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff (February 19, 1998)
- FDA Guidance Document, "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable" (April 25, 2006)
- Statistical Guidance on Reporting Results From Studies Evaluation Diagnostic Tests (March 13, 2007)
- CLSI C50-A Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance; Approved Guideline, 1st edition (October 29, 2007)
- CLSI MM09-A Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline, 2nd edition (August 14, 2015)
- CLSI MM18-A Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline, 1st edition (April 28, 2008)
- CLSI M35-A2 Abbreviated Identification of Bacteria and Yeast, Approved Guideline, 2nd edition (November 24, 2008)
- CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, 3rd edition (August 30, 2013)
- CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, 2nd edition (January 25, 2008)

L. Test Principle:

The VITEK MS system is based on a matrix-assisted laser desorption ionization-time of flight mass spectrometer (MALDI-TOF MS). The colony is mixed with a saturated matrix solution and forms crystals. The ionization of this mixture by the laser induces the desorption and transfer of protons from photo-excited matrix to analyte to form a protonated molecule. During the analysis process, proteins are ionized without fragmentation by the coordinated

M. Performance Characteristics (if/when applicable):

Performance Characteristics:

The following performance characteristics were obtained by testing routine fresh and stock



strains from patient cultures in clinical microbiology laboratories and bioMérieux laboratories in the United States and France. The strains included:

- Gram-positive bacteria
- Gram-negative bacteria (including *Brucella*)
- Yeasts
- Moulds
- *Mycobacterium*
- *Nocardia*

	VITEK® MS IDENTIFICATION					Discordant ID ³	No ID ⁴
Organism Group	Total Correct Genus ID (One Choice and Low Discrimination)	One Choice	Low Discrimination				
		Correct: Genus ID	Correct: Genus ID				
		Correct: Species ID or Group/ Complex ID					
		<i>One choice reference result</i>	<i>Multiple choice reference result</i> ¹	<i>One choice reference result</i>	<i>Multiple choice reference result</i> ²		
Gram-positive bacteria	95.8% (3594/3750) 95% CI [95.2 ; 96.5]%	89.9% (3372/3750)	1.9% (29/1494)	5.0% (188/3750)	0.3% (5/1494)	0.4% (14/3750)	3.8% (142/3750)
Gram-negative bacteria	95.2% (5788/6079) 95% CI [94.6 ; 95.7]%	88.9% (5407/6079)	0.1% (2/2543)	6.2% (379/6079)	0.0% (0/2543)	1.0% (60/6079)	3.8% (231/6079)
• Gram-negative bacteria (<i>Brucella</i> only)	91.7% (220/240) 95% CI [87.4 ; 94.8]%	91.7% (220/240)	0.0% (0/240)	0.0% (0/240) ⁵	0.0% (0/240)	0.0% (0/240)	8.3% (20/240) ⁶
Yeasts	96.8% (1316/1360) 95% CI [95.7 ; 97.6]%	95.9% (1304/1360)	0.5% (1/204)	0.8% (11/1360)	0.0% (0/204)	0.1% (2/1360)	3.1% (42/1360)
Moulds	92.7% (1398/1508) 95% CI [91.3 ; 94.0]%	91.2% (1376/1508)	N/A	1.5% (22/1508)	N/A	0.9% (13/1508)	6.4% (97/1508)
<i>Mycobacterium</i>	96.5% (777/805) 95% CI [95.0 ; 97.7]%	96.5% (777/805)	N/A	0.0% (0/805)	N/A	0.4% (3/805)	3.1% (25/805)
• <i>Mycobacterium</i> Solid	97.4% (713/732) 95% CI [96.0 ; 98.4]%	97.4% (713/732)	N/A	0.0% (0/732)	N/A	0.1% (1/732)	2.5% (18/732)
• <i>Mycobacterium</i> Liquid	87.7% (64/73) 95% CI [77.9 ; 94.2]%	87.7% (64/73)	N/A	0.0% (0/73)	N/A	2.7% (2/73)	9.6% (7/73)
<i>Nocardia</i>	97.9% (374/382) 95% CI [95.9 ; 99.1]%	89.3% (341/382)	N/A	8.6% (33/382)	N/A	0.8% (3/382)	1.3% (5/382)
Total	95.4% (13247/13884) 95% CI [95.1 ; 95.8]%	90.6% (12577/13884)	0.8% (32/4241)	4.6% (633/13884) ⁷	0.1% (5/4241) ⁷	0.7% (95/13884)	3.9% (542/13884)

1 = Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK® MS result matches one of these reference results. Only reference results to a species level were included for V2.0 and V3.0 claimed organisms, and these organisms are designated by N/A in the Multiple Choice Reference Result column in the performance tables.

2 = Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK® MS result matches the reference result at a Genus level. Only reference results to a species level were included for V2.0 and V3.0 claimed organisms, and these organisms are designated by N/A in the Multiple Choice Reference Result column in the performance tables.

3 = Includes single choice incorrect identifications and low discrimination results with >1 choice in the same genus but the genus does not match the reference genus.

4 = Includes Low Discrimination with multiple genera or No ID (Bad Spectra, Not Enough Peaks, Too Many Peaks (Bad spectrum), or No ID (Good spectrum)).

5 = On occasions the VITEK® MS result for *Brucella* spp will report as a low discrimination result of *Brucella* spp/*Brucella* spp, even though it is a single choice correct identification of *Brucella* spp. This will be corrected in a future software release.

6 = Of the 240 *Brucella* spp strains tested in the clinical trial, 20 (8.3%) resulted in No ID. Samples suspected of *Brucella* should be handled accordingly.

7 = Of the 707 low discrimination same genus results, 689 (97.5%) had the correct species present and 18 (2.5%) did not have the correct species present.

Clinical studies:

The objective of the clinical trial is to evaluate the percent agreement of the VITEK® MS to identify microorganisms in a clinical setting as compared to the reference method [DNA sequencing analysis and supplemental testing when necessary, or previously well characterized strains (ATCC or equivalent)]. Samples were sequenced by the appropriate reference laboratory, and if needed,



additional analysis was performed internally to obtain a reference identification (GenBank, dendrogram analysis). Organisms tested during the clinical trial included aerobic and anaerobic gram positive and gram negative bacteria, including *Brucella*, and yeasts.

The VITEK® MS KB v3.2.0 clinical trial consisted of quality control and clinical testing of bacteria (other than *Brucella*) and yeasts at one external clinical trial site and one internal site. For *Brucella*, clinical trial testing consisted of quality control, reproducibility, challenge and clinical testing at one external clinical trial site. Prior to initiation of the clinical trial, a proficiency panel was tested by all participating technologists at the external sites to ensure adequate training.

A total of 4,241 test results are included in the performance data.

Performance was determined by comparing the VITEK® MS identification to a one choice or multiple choice (more than one species) reference identification.

The VITEK® MS v3 / KB v3.2.0 release demonstrated high performance at 98.8% (4189/4241) agreement for clinical isolates tested, with a very low number of discordant (0.3%) and no identification (0.9%) results obtained. When excluding No ID results, performance improves to 99.7% (4189/4201) agreement with the same low discordant rate of 0.3%.

Overall performance for all organisms tested from all sites combined:

VITEK MS KB 3.2 Overall Performance for All Sites Combined												
			VITEK MS IDENTIFICATION									
Organism Classification		N	Number of Unique Isolates	Total Correct GENUS ID (One Choice and Low Discrim.)	One Choice				Low Discrimination Correct: Genus ID	Discordant ID	No ID	
					Correct: Species ID or Group/Complex ID							
				One choice reference result	Multiple choice reference result ¹		One choice reference result	Multiple choice reference result ²				
Gram + Bacteria	Aerobic	801	281	99.4% (796/801)	86.1% (690/801)	0.5% (4/801)		12.1% (97/801)	0.6% (5/801)		0.0% (0/801)	0.6% (5/801)
	Anaerobic	693	295	99.3% (689/693)	95.5% (662/693)	3.6% (25/693)		0.1% (1/693)	0.0% (0/693)		0.0% (0/693)	0.7% (5/693)
	Total	1494	496	99.3% (1484/1494)	90.5% (1352/1494)	1.9% (29/1494)		6.6% (98/1494)	0.3% (5/1494)		0.0% (0/1494)	0.7% (10/1494)
Gram - Bacteria	Aerobic	2119	570	98.2% (2080/2119)	92.5% (1960/2119)	0.1% (2/2119)		5.6% (118/2119)	0.0% (0/2119)		0.6% (12/2119)	1.3% (27/2119)
	Anaerobic	424	72	99.5% (422/424)	99.3% (421/424)	0.0% (0/424)		0.2% (1/424)	0.0% (0/424)		0.0% (0/424)	0.5% (2/424)
	Total	2543	642	98.4% (2502/2543)	93.6% (2381/2543)	0.1% (2/2543)		4.7% (119/2543)	0.0% (0/2543)		0.5% (12/2543)	1.1% (29/2543)
Yeasts	Total	204	44	99.5% (203/204)	99.0% (202/204)	0.5% (1/204)		0.0% (0/204)	0.0% (0/204)		0.0% (0/204)	0.5% (1/204)
	Grand Total	4241	1122	98.8% (4189/4241)	92.8% (3935/4241)	0.8% (32/4241)		5.1% (217/4241)	0.1% (5/4241)		0.3% (12/4241)	0.9% (40/4241)

¹Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results

²Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level

98.8% (4189/4241) agreement, 95% CI [98.3%, 99.0%], was obtained for all clinical bacteria and yeast isolates tested (correct one choice identification plus a low discrimination correct genus result) from all sites combined, with 12 (0.3%) misidentifications and 40 (0.9%) No ID results.

Overall performance for all organisms tested from all sites combined excluding No ID results:

VITEK MS KB 3.2 Overall Performance for All Sites Combined - Excluding No ID Results										
Organism Classification		N	Number of Unique Isolates	VITEK MS IDENTIFICATION						Discordant ID
				Total Correct GENUS ID (One Choice and Low Discrim.)	One Choice Correct: Genus ID		Low Discrimination Correct: Genus ID			
					Correct: Species ID or Group/Complex ID					
					One choice reference result	Multiple choice reference result ¹	One choice reference result	Multiple choice reference result ²		
Gram + Bacteria	Aerobic	796	278	100.0% (796/796)	86.7% (690/796)	0.5% (4/796)	12.2% (97/796)	0.6% (5/796)	0.0% (0/796)	
	Anaerobic	688	203	100.0% (688/688)	96.2% (662/688)	3.6% (25/688)	0.1% (1/688)	0.0% (0/688)	0.0% (0/688)	
	Total	1484	481	100.0% (1484/1484)	91.1% (1352/1484)	2.0% (29/1484)	6.6% (98/1484)	0.3% (5/1484)	0.0% (0/1484)	
Gram - Bacteria	Aerobic	2092	561	99.4% (2080/2092)	93.7% (1960/2092)	0.1% (2/2092)	5.6% (118/2092)	0.0% (0/2092)	0.6% (12/2092)	
	Anaerobic	422	70	100.0% (422/422)	99.8% (421/422)	0.0% (0/422)	0.2% (1/422)	0.0% (0/422)	0.0% (0/422)	
	Total	2514	631	99.5% (2502/2514)	94.7% (2381/2514)	0.1% (2/2514)	4.7% (119/2514)	0.0% (0/2514)	0.5% (12/2514)	
Yeasts	Total	203	43	100.0% (203/203)	99.5% (202/203)	0.5% (1/203)	0.0% (0/203)	0.0% (0/203)	0.0% (0/203)	
~All~	Grand Total	4201	1155	99.2% (4189/4201)	93.7% (3935/4201)	0.8% (32/4201)	5.2% (217/4201)	0.1% (6/4201)	0.3% (12/4201)	

¹Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results

²Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level

99.7% (4189/4201) agreement, 95% CI [99.5%, 99.8%], was obtained for all clinical bacteria and yeast isolates tested (correct one choice identification plus a low discrimination correct genus result) from all sites combined when excluding No ID results, with 12 (0.3%) misidentifications.

Overall performance of *Brucella* organisms tested at ATCC:

VITEK MS KB 3.2 Overall Performance for ATCC										
VITEK MS IDENTIFICATION Site: ATCC										
Organism Classification		N	Number of Unique Isolates	Total Correct GENUS ID (One Choice and Low Discrim.)	One Choice Correct: Genus ID		Low Discrimination Correct: Genus ID		Discordant ID	No ID
					Correct: Species ID or Group/Complex ID					
					One choice reference result	Multiple choice reference result ¹	One choice reference result	Multiple choice reference result ²		
Brucella	Total	240	60	91.7% (220/240)	91.7% (220/240)	0.0% (0/240)	0.0% (0/240)	0.0% (0/240)	0.0% (0/240)	8.3% (20/240)

¹Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results

²Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level

Note: On occasions the VITEK MS result for *Brucella* spp will report as a low discrimination result of *Brucella* spp / *Brucella* spp, even though it is a single choice correct identification of *Brucella* spp. This will be corrected in a future software release.



91.7% (220/240) agreement, 95% CI [87.4%, 94.8%], was obtained for all *Brucella* isolates tested at ATCC, with 20 (8.3%) No ID results and no misidentifications.

Overall performance of *Brucella* organisms tested at ATCC excluding No ID results:

VITEK MS KB 3.2 Overall Performance for ATCC - Excluding No ID Results									
VITEK MS IDENTIFICATION Site: ATCC									
Organism Classification	N	Number of Unique Isolates	Total Correct GENUS ID (One Choice and Low Discrim.)	One Choice Correct: Genus ID		Low Discrimination Correct: Genus ID		Discordant ID	
				Correct: Species ID or Group/Complex ID					
				One choice reference result	Multiple choice reference result ¹	One choice reference result	Multiple choice reference result ²		
Brucella	Total	220	45	100.0% (220/220)	100.0% (220/220)	0.0% (0/220)	0.0% (0/220)	0.0% (0/220)	

Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results.

Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level.

Note: On occasion the VITEK MS result for Brucella spp will report as a low discrimination result of Brucella spp / Brucella spp, even though it is a single choice correct identification of Brucella spp. This will be corrected in a future software release.

100% (220/220) agreement, 95% CI [98.3%, 100.0%], was obtained for all *Brucella* isolates tested at ATCC when excluding No ID results, with no misidentifications.

Overall performance of *Brucella* reproducibility testing:

VITEK MS KB 3.2 REPRODUCIBILITY

Sample	Organism	Day					Total (%)	95% CI
		1	2	3	4	5		
R1	Brucella abortus	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
R2	Brucella melitensis	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
R3	Brucella suis	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
All	All	36/36	36/36	36/36	36/36	36/36	180/180 (100.0%)	[98.0, 100.0]%

NOTE: Reproducibility results display the *Brucella* species tested (*Brucella abortus*, *Brucella melitensis* and *Brucella suis*). However, the VITEK MS will only provide a genus level identification of *Brucella* spp in Myla.

100% agreement was obtained with the *Brucella* reproducibility strains tested at ATCC.

Overall performance of *Brucella* challenge testing:

VITEK MS KB3.2 BRUCELLA CHALLENGE										
Organism Classification		N	Number of Unique Isolates	Total Correct GENUS ID (One Choice and Low Discrim.)	VITEK MS IDENTIFICATION				Discordant ID	No ID
					One Choice Correct: Genus ID		Low Discrimination Correct: Genus ID			
					Correct: Species ID or Group/Complex ID					
				One choice reference result	Multiple choice reference result ¹	One choice reference result	Multiple choice reference result ²			
Brucella spp	Total	15	45	64.4% (29/45)	64.4% (29/45)	0.0% (0/45)	0.0% (0/45)	0.0% (0/45)	35.6% (16/45)	

Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results.
¹Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level.
²Note: On occasion the VITEK MS result for Brucella spp will report as a low discrimination result of Brucella spp / Brucella spp, even though it is a single choice correct identification of Brucella spp. This will be corrected in a future software release.

VITEK MS KB3.2 BRUCELLA CHALLENGE EXCLUDING NO ID RESULTS									
Organism Classification	N	Number of	Total Correct GENUS ID	VITEK MS IDENTIFICATION				Discordant ID	
				One choice	Multiple choice reference result	One choice	Multiple choice reference result ¹		
Brucella spp	Total	12	29	100.0% (29/29)	100.0% (29/29)	0.0% (0/29)	0.0% (0/29)	0.0% (0/29)	

Reference ID represents multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches one of these reference results
¹Reference ID represents correct Genus with multiple related species that cannot be resolved by sequencing rDNA and the VITEK MS result matches the reference result at a Genus level
²Note: On occasion the VITEK MS result for Brucella spp will report as a low discrimination result of Brucella spp / Brucella spp, even though it is a single choice correct identification of Brucella spp. This will be corrected in a future software release

64.4% (29/45) agreement was obtained for the 15 *Brucella* challenge strains tested at ATCC in triplicate, with 16 (35.6%) No ID results and no misidentifications. 100% (29/29) agreement was obtained when excluding No ID results.

Overall performance of quality control testing:

VITEK MS KB 3.2 QUALITY CONTROL				
Organism Identification	Correct ID/Total (%) Per Site			
	ATCC	CCF	LBM	All Sites Combined
* <i>Brucella melitensis</i>	48/48 (100.0%)			48/48 (100.0%)
<i>Candida glabrata</i>		27/27 (100.0%)	24/24 (100.0%)	51/51 (100.0%)
<i>Enterobacter aerogenes</i>		47/47 (100.0%)	47/47 (100.0%)	94/94 (100.0%)
Negative Control	51/51 (100.0%)	48/48 (100.0%)	49/49 (100.0%)	148/148 (100.0%)

* Quality control result displays as *Brucella melitensis*. However, the VITEK MS will only provide a genus level identification of *Brucella* spp in Myla.



100% agreement was obtained with the all quality control strains tested at all sites.

N. Instrument Name:

VITEK[®] MS