510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K212461

B Applicant

bioMerieux, Inc.

C Proprietary and Established Names

Vitek MS Prime

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QBN	Class II	21 CFR 866.3378 - Clinical Mass Spectrometry Microorganism Identification And Differentiation System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Premarket notification for the VITEK MS PRIME.

B Measurand:

See Intended Use

C 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.

III Intended Use/Indications for Use:

A Intended Use(s):

VITEK MS PRIME 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 PRIME system is a qualitative in vitro diagnostic device indicated for use in conjuction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections.

The following organisms are claimed:

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 neuii
Actinomyces odontolyticus
Actinotignum schaalii
Aerococcus viridans
Aeromonas hydrophila
Aeromonas jandaei
Aeromonas punctata (caviae)
Aeromonas sobria
Aeromonas veronii
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 lusitaniae
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
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 cloacae
Enterobacter asburiae
Enterobacter cancerogenus
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
Hathewaya histolytica
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
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
Paraclostridium bifermentans
Parvimonas micra
Pasteurella aerogenes
Pasteurella multocida
Pediococcus acidilactici
Peptoniphilus asaccharolyticus
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Pluralibacter gergoviae
Porphyromonas asaccharolytica / uenonis
Porphyromonas gingivalis
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella loescheii
Prevotella melaninogenica
Prevotella oralis
Prevotella oris
Propionibacterium acidipropionici
Propionibacterium acnes
Propionibacterium avidum
Propionibacterium granulosum
Propionibacterium propionicum
Proteus mirabilis
Proteus penneri
Proteus vulgaris
Providencia alcalifaciens
Providencia rettgeri
Providencia rustigianii
Providencia stuartii
Pseudomonas aeruginosa
Pseudomonas alcaligenes
Pseudomonas fluorescens
Pseudomonas luteola
Pseudomonas mendocina
Pseudomonas oryzihabitans
Pseudomonas putida
Pseudomonas stutzeri
Ralstonia pickettii
Raoultella ornithinolytica
Raoultella planticola
Raoultella terrigena
Rhizobium radiobacter
Rhodotorula mucilaginosa
Rothia mucilaginosa
Saccharomyces cerevisiae
Salmonella enterica ssp *enterica*
Saprochaete capitata
Serratia ficaria
Serratia fonticola
Serratia grimesii
Serratia liquefaciens
Serratia marcescens
Serratia odorifera
Serratia plymuthica
Serratia proteamaculans
Serratia quinivorans
Serratia rubidaea
Shewanella putrefaciens
Sphingobacterium multivorum
Sphingobacterium spiritivorum
Sphingomonas paucimobilis
Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus chromogenes
Staphylococcus cohnii ssp *cohnii*
Staphylococcus cohnii ssp *urealyticus*
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus hyicus
Staphylococcus intermedius
Staphylococcus pseudintermedius
Staphylococcus kloosii
Staphylococcus lentus
Staphylococcus lugdunensis
Staphylococcus saprophyticus
Staphylococcus schleiferi
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus warneri
Staphylococcus xylosus
Stenotrophomonas maltophilia
Streptococcus agalactiae
Streptococcus alactolyticus
Streptococcus anginosus
Streptococcus canis
Streptococcus constellatus
Streptococcus cristatus
Streptococcus dysgalactiae ssp *dysgalactiae*

Streptococcus dysgalactiae ssp *equisimilis*
Streptococcus equi ssp *equi*
Streptococcus equi ssp *zooepidemicus*
Streptococcus equi ssp ruminatorum
Streptococcus equinus
Streptococcus gallolyticus ssp *gallolyticus*
Streptococcus gallolyticus ssp *pasteurianus*
Streptococcus gordonii
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 dermatis / mucoides
Trichosporon inkin

B Indication(s) for Use:
See Intended Use

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

VITEK MS PRIME System

IV Device/System Characteristics:

A Device Description:

The VITEK MS PRIME system is a benchtop 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, Knowledge Base v3.2 reference database, VITEK FLEXPREP software, and the VITEK MS PRIME instrument and associated software.

Reagent Description:

- The VITEK MS-CHCA (Alpha-cyano-4-hydroxy-cinnamic acid) is a solution that serves as a matrix which will crystalize with the microbial sample on the target slide spot. One microliter 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.
- The VITEK MS MYCOBACTERIUM/NOCARDIA KIT includes ethanol and vials with glass beads to inactivate *Mycobacterium* and *Nocardia* species by disrupting the cells. The kit also includes formic acid and acetonitrile to complete the extraction of proteins.
- The VITEK MS MOULD KIT method uses ethanol, formic acid, and acetonitrile to inactivate molds and extract their proteins.
- The *Brucella* inactivation solvent mixture contains API Suspension Medium or sterile deionized water, absolute ethanol (HPLC grade), acetonitrile (HPLC grade), and trifluoroacetic acid (TFA) (HPLC grade).

VITEK MS-DS Target Slides:

VITEK MS-DS target slides are single-use disposable slides which contain three acquisition groups of 16 sample spots. Each group includes one calibration spot.

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.

Software:

The VITEK MS PRIME 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. At a general level, the VITEK MS System / Software controls:

- The VITEK MS PRIME workflow management (which includes connection with a Preparation Station (called FLEXPREP)
- The identification computation engine (and its' interface with the VITEK MS knowledge base)
- The identification results review functionality
- Communication with the LIS/MYLA
- The prepared slides supervision
- Customer reports creation (e.g., QC reports, isolate reports, spot and usage reports) as well as the data export)
- High level system supervision (display alarms, alerts for each sub systems)

VITEK MS PRIME instrument:

The VITEK MS PRIME instrument is a MALDI-ToF mass spectrometer that is a benchtop model with a smaller footprint than the predicate VITEK MS instrument.

B Principle of Operation:

With the VITEK MS PRIME System, microorganism identification is made via matrix-assisted laser desorption/ionization (time of flight mass spectrometry (MALDI-TOF MS)) technology, which includes the three basic principles of ionization, separation, and detection. As a first step, a VITEK MS-DS Target Slide is prepared in accordance with the instructions for use.

Once the specimen (cultured from the appropriate media) is spotted to the target slide, a matrix is added for the purpose of easy sublimation and strong absorbance in the laser wavelength employed by the instrument.

The prepared slide is then loaded onto the VITEK MS PRIME instrument, where a laser targets the sample spot and pulses the isolate spot, resulting in vibrational excitation of matrix and analyte molecules. The matrix transfer protons to the analyte resulting in a positive charge. So as part of the first basic principle, the ionized molecules are then accelerated in an electromagnetic field and a grid electrode in the ionization chamber.

The acceleration in the electromagnetic field is the beginning of the second basic principle (i.e. the separation process that is based of the time-of-flight principle). The velocity of the molecules depends on the mass-to-charge (m/z) ratio of the analyte, with heavier molecules having a higher moment of inertia resulting in a lower velocity.

As a final step in the basic principle of MALDI-ToF technology (i.e. detection) the time of flight is measured precisely by the ions arrival at a particle detector. This speed of the ions in flight depends on their mass - 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 analyte sample mixture is generated. The recorded signal is processed and presented as a spectrum of intensity versus mass in Daltons (Da). The mass spectrum displays results as a series of peaks (spectrum) which correspond to the ionized proteins derived from the analyte sample. And for identification of an unknown organism, the resulting mass spectra are sufficiently distinctive to allow taxonomic characterization at the genus and species when compared against the VITEK MS Knowledge Base v3.2.

C Instrument Description Information:

1. Instrument Name:

   VITEK MS PRIME System

2. Specimen Identification:

   Same as K181412

3. Specimen Sampling and Handling:

   Manual process

4. Calibration:

   Escherichia coli ATCC 8739 strain is used for calibration for each test plate.

5. Quality Control:

   Per manufacturer's instructions (See Section VII(A)(6) below)

V Substantial Equivalence Information:

A Predicate Device Name(s):
Vitek MS

B Predicate 510(k) Number(s):
K181412

C Comparison with Predicate:

Item		Predicate:
Similarities		
Intended Use Same – the only difference is that for the VITEK MS PRIME the yeast and mould were simplified / combined to indicate "fungal.")	VITEK MS PRIME is a mass spectrometry system using matrix-assisted laser desorption / ionization time of flight mass spectrometry (MALDI-TOF S) for the identification of microorganisms cultured from human specimens. The VITEK MS PRIME 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 and fungal infections. (For a list of FDA Indications for Use see Section 1.5 of this 510(k))	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 PRIME 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. (For a list of FDA Indications for Use see 510(k) K181412)
Where Used	Clinical laboratories	Same
Test Methodology	Use of MALDI-TOF MS technology for microorganism identification, as a qualitative *in vitro* diagnostic device to be used in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections	Same
Analyte Tested	Microorganisms cultured from human specimens. The bacterial and fungal cultures are from solid media, or in the case of Mycobacteria may be isolated from either solid or liquid media.	Same
Preparation Reagents / Components / Set Up Methods	• CHCA Matrix • FA Reagent • VITEK MS DS Target Slides • Myco. / Nocardia Preparation Kit (and liquid media components for Mycobacteria) • Mould Preparation Kit	Same
Knowledge Base	KB v3.2	Same

Item	Device: VITEK MS PRIME	Predicate: VITEK MS (K181412)
Differences		
Instrument	1. Benchtop model – with shorter flight tube 2. Laser - neodymium-doped yttrium fluoride lasing (YFL) laser 3. Multichannel plate detector in a photomultiplier tube 4. Optics are on access for irradiation 5. Load and go approach for loading slides onto the system – system can load up to 16 slides with the option for slide prioritization.	1. Floor standing model – with longer flight tube 2. Nitrogen based 3. Multiple dynode detector 4. Optics used for irradiation are asymmetrical of deflectors 5. Maximum of four slides can be loaded onto the instrument (slides must be read in the order that they were loaded).
Accelerated ions	Cations	Cations and anions
Rastering Pattern	Continuous boustrophedon raster path across the slide spot. The "profile" for the sample is defined as an average of 50 spectra obtained by as many consecutive laser shots (this averaging is done in "real-time" by the digitizer hardware). This means that the number of shots on a given spot type does not vary. Sample spots always get 7,300 shots, which comes out to a possible 146 profiles. The final spectrum is created by averaging the resulting profiles. A "good spectrum" is any spectrum average that is greater than 30 unitary profiles.	Rastering is accomplished by firing the laser at the first raster point (five shots are made to obtain one profile). If the profile is good, then the laser will re-shoot the same spot to acquire a new profile. If there are two consecutive failed profiles, then the laser moves to the next raster point. The acquisition process stops when the target of 100 good profiles is achieved, or when all raster points have been visited. If the final total of good profiles is less than 30 then the acquisition has failed, and if more than 30 good profiles are obtained then the spectrum is OK.

VI Standards/Guidance Documents Referenced:

- **CLSI M58,** "Methods for the Identification of Cultured Microorganisms Using MALDI-TOF Mass Spectrometry, 1st edition" (26-APR-17)
- **CLSI** MMO9-A, "Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline, 2nd edition" **(14-AUG-2015)**
- **CLSI** MM18, "Interpretive Criteria for Identification of Bacteria and Fungi **by DNA** Target Sequencing; Approved Guideline, 2nd edition" **(JUL-2018)**
- **CLSI M35-A2,** "Abbreviated Identification of Bacteria and Yeast, Approved Guideline, 2nd edition" (24-NOV-2008)
- **CLSI EPO9-A3,** "Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, 3rd edition" **(30-AUG-2013)**
- **CLSI EP12-A2,** "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, 2nd edition" **(25-JAN-2008)**

- **IEC 61010** -1:2010 (Amendment **1:2016),** "Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use **-** Part **1:** General Requirements, Edition **3.1" (JAN 2017)**
- **IEC 60601-1-1-2:2014-02,** "Medical electrical equipment **-** Part 1-2: General requirements for basic safety and essential performance **-** Collateral Standard: Electromagnetic disturbances **-** Requirements and tests, 4th edition" (FEB 2014)
- **IEC 60825-1:2014** "Safety of laser products **-** Part **1:** Equipment classification, and requirements, Edition **3"** (15-MAY-2014)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

System reproducibility was determined by testing bacteria, yeasts, *Nocardia* and mould strains, as determined in the previous V2.0 and V3.0 VITEK MS studies. A total of 10 strains were included in the reproducibility set (6 routine bacteria strains, 2 yeast strains, 1 *Nocardia* strain and 1 mould strain).

Testing was conducted on three instrument systems, with one instrument at one internal testing site and two instruments at another internal testing site. Each of the organisms of the reproducibility panel were tested in duplicate (from separately prepared samples) in each of two runs on the VITEK MS PRIME, on five separate days (not necessarily consecutive), by two technologists on each instrument for a total of 60 tests per organism.

Each day of testing, samples were positioned on the target slide in sequential order by sample number by one technologist and positioned on the target slide in random order by a second technologist. The two technologists alternated the sequential and randomized order of testing on subsequent test days. Results from the Reproducibility Study are presented in Table 1. A summary of repeat testing (e.g., due to No ID, bad spectrum during acquisition) is presented in Table 2.

Table 1: Reproducibility Testing Results

	Day						
Organism	**1**	**2**	**3**	**4**	**5**	**Total (%)**	**95% CI**
Enterobacter aerogenes	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Pseudomonas aeruginosa	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Staphylococcus aureus	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Streptococcus agalactiae	9/12*	12/12	12/12	12/12	12/12	57/60 (95.0%)	[86.1, 99.0]%
Klebsiella oxytoca	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%

Candida albicans	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Candida glabrata	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Escherichia coli	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Aspergillus brasiliensis	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%
Nocardia farcinica	12/12	12/12	12/12	12/12	12/12	60/60 (100.0%)	[94.0, 100.0]%

**S. agalactiae*: For three spots, No ID results were obtained for initial and repeat testing

Table 2: Reproducibility Study, Summary of Repeat Testing

Repro Species Code	N	Spot Repeat (Percent)
Enterobacter aerogenes	60	2 (3.3%)
Nocardia farcinica	60	4 (6.7%)
Pseudomonas aeruginosa	60	1 (1.7%)
Staphylococcus aureus	60	0 (0.0%)
Streptococcus agalactiae	60	17 (28.3%)
Klebsiella oxytoca	60	4 (6.7%)
Candida albicans	60	0 (0.0%)
Candida glabrata	60	0 (0.0%)
Escherichia coli	60	1 (1.7%)
Aspergillus brasiliensis	60	2 (3.3%)
Total	600	31 (5.2%)

2. Linearity:

   Not applicable, qualitative assay.

3. Analytical Specificity:

   An exclusivity study was conducted to evaluate the identifications obtained with VITEK MS PRIME when testing species that are not included in the KB V3.2. A total of 50 species were evaluated in the study, with testing in triplicate.

   A selection of representative species was made among the species tested during the previous studies done for VITEK MS KB V3.0 and KB V3.2. Those species are listed in the VITEK MS KB 3.2 user manuals as not identified and/or as cross-identified with closely related species or species from the same genus. Additional strains were also tested to ensure inclusion of representatives of each microorganism group: gram-positive bacteria, gram-negative bacteria, Mycobacterium, *Nocardia*, yeasts, and moulds.

   The selected organisms also included non-BSL3 species which are phylogenetically close to *Brucella* species and that have been reported to be misidentified as *Brucella* in the literature.

   Exclusivity testing results:

- 42 species not included in the KB V3.2 database and not included in a complex gave either No Identification results or an identification to closely related species (same genus but different species).
- 8 species not included in the KB V3.2 database but included in a complex generated a result of either No Identification or Single choice ID to the expected species/complex.
- *Brucella* cross-identification results: As expected, testing did not result in a *Brucella* identification with VITEK MS PRIME. All strains tested were identified to the proper species both with direct deposit and *Brucella* protocols.

4. Equivalency Study:

A biological equivalency study was performed to evaluate the clinically validated species that are included in the VITEK MS Knowledge Base (most recent clearance in K181412). The study consisted of testing 477 claimed species represented by 400 displayed labels on the VITEK MS PRIME system, using one well-characterized strain per species. Two species (*Coccidiodes immitis* and *Coccocidiodes posadasii*) of the 479 total claimed species in the VITEK MS Knowledge Base were not evaluated due to the lack of available strains.

The 477 microorganisms evaluated in the study include gram-positive aerobic and anaerobic bacteria, gram-negative aerobic and anaerobic bacteria (including *Brucella* species), yeasts, moulds, *Mycobacterium* species and *Nocardia* species.

Testing was conducted in triplicate for each of the 477 species, for a total of 1461 test spots evaluated:

- 467 species tested in triplicate: 1401 results
- Ten species tested in six replicates: 60 results
    - Nine *Mycobacteria*: three replicates from solid medium and three replicates from liquid medium
    - One *Cronobacter muytjensii*: six replicates

The results obtained with VITEK MS PRIME were compared to the results previously obtained with VITEK MS using KB v3.2 (predicate device). Study results demonstrated that 98.1% (1433/1461) of tests generated the expected identification (i.e., results including either correct single choice ID or low discrimination to the correct genus).

NOTE: For *Klebsiella variicola* on VITEK MS PRIME, all three replicates of the initial strain evaluated were misidentified as *K. pneumoniae*. Three additional strains of *K. variicola* were also misidentified as *K. pneumoniae*. A limitation is included in the VITEK MS PRIME 3.2 Knowledge Base User Manual indicating that *Klebsiella variicola* was misidentified as *Klebsiella pneumoniae* by VITEK MS PRIME and should not be considered as a clinically validated organism for this instrument system.

For each organism group evaluated in the Biological Equivalency Study, VITEK MS PRIME testing met the performance acceptance criteria of higher than 95% correct identification (correct single choice ID or low discrimination to the correct genus)) for each microorganism group. Results are presented in Table 3. A summary of repeat testing rates is presented in Table 4.

Table 3: Biological Equivalency Results

VITEK MS PRIME Identification / Organism Group	Total Correct Genus ID (One Choice and Low Discrimination)	One Choice Correct: Genus ID Correct: Species ID or Group/Complex ID	Low Discrimination Correct: Genus ID	Discordant ID [2]	No ID
Gram-positive bacteria	99.0% (395/399)	93.50% (373/399)	5.50% (22/399)	0% (0/399)	1.0% (4/399)
Gram-negative bacteria (including Brucella)	97.2% (624/642)	87.7% (563/642)	9.5% (61/642)	0.8% (5/642)	2.0% (13/642)
Yeasts	100% (108/108)	99.1% (107/108)	0.9% (1/108)	0% (0/108)	0% (0/108)
Moulds [1]	97.4% (152/156)	93.6% (146/156)	3.8% (6/156)	0% (0/156)	2.6% (4/156)
Mycobacterium liquid	97.62% (82/84)	97.62% (82/84)	0% (0/84)	0% (0/84)	2.38% (2/84)
Mycobacterium solid	100% (33/33)	100% (33/33)	0% (0/33)	0% (0/33)	0% (0/33)
Nocardia	100% (39/39)	100% (39/39)	0% (0/39)	0% (0/39)	0% (0/39)
Total	98.1% (1433/1461)	91.9% (1343/1461)	6.2% (90/1461)	0.3% (5/1461)	1.6% (23/1461)

[1]Two species from the 479 claimed species (*Coccidioides immitis* and *C. posadasii*) were not tested due to lack of available strains.

[2]There were five discordant identifications during the VITEK MS PRIME biological equivalency study. The five misidentifications included the following:

Species Tested	Species Identified
Citrobacter youngae	*Citrobacter braakii*
Serratia grimesii	*Serratia liquefaciens*
Klebsiella variicola	*Klebsiella pneumoniae*
Klebsiella variicola	*Klebsiella pneumoniae*
Klebsiella variicola	*Klebsiella pneumoniae*

Table 4: Equivalency Study, Repeat Testing Rate

Organism Classification		N	Spot Repeat (Percent)
Gram+ Bacteria	Aerobic	276	17 (6.2%)
	Anaerobic	123	9 (7.3%)
Gram- Bacteria	Aerobic	546	55 (10.1%)
	Anaerobic	96	9 (9.4%)
Yeasts	Aerobic	108	7 (6.5%)
Moulds	Moulds	156	54 (34.6%)
Myco/Nocardia	Mycobacteria	117	22 (18.8%)
	Nocardia	39	1 (2.6%)
~All~	***Total***	***1461***	***174 (11.9%)***

5. Assay Reportable Range:

   Not applicable, qualitative assay.

6. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Calibrator:

   E. coli ATCC 8739 is used as a calibrator. This organism is deposited with VITEK MS-CHCA matrix on up to three plate positions on the VITEK MS-DS target slides depending on the number of samples tested (one calibrator per acquisition group of 16 spots). The VITEK MS PRIME goes to the calibration spot in an acquisition group and performs a calibration. If the calibration passes, the instrument goes to the first spot in the acquisition group. If the calibration fails, an error is reported and VITEK MS PRIME proceeds to the next acquisition group without collecting sample spectra. After spectra have been acquired from each sample spot in an acquisition group, the calibration spot is checked again. The calibration sample should provide *E. coli* identification at 99.9% in the VITEK MS Software.

   Sample Stability on Target Slide:

   A study was conducted to evaluate the deposit stability on the slide after matrix addition The study assessed the following conditions: f:

   - Part 1: Length of time that the slide (after deposit and matrix addition) can stay in the instrument carrousel before being read (stability inside the instrument, 16 hours was selected as the worst-case testing delay that may occur when testing a full rack of 16 slides.)
   - Part 2: Length of time that the slide (after deposit and matrix addition) can be stored on the bench before the introduction into VITEK MS PRIME instrument (stability outside the instrument).

   The study covered all microorganism groups including bacteria (30 species) , yeast (5 species), moulds (6 species), *Brucella*-like species (1 strain), *Nocardia* (2 species for Part 1, 16 additional *Nocardia* strains for Part 2) and *Mycobacterium* (6 species). Testing was conducted in duplicate for each strain initially (T0, without testing delays) as well as at T72, T72+8.5 hours, and T72+16 hours.

   The acceptance criteria for the study included a minimum overall 90% correct identification for all tests performed for each microorganism group.

   The results from Part 1 of the study showed that fresh deposits were stable inside the instrument up to 16 hours for all groups of microorganisms: bacteria, yeast, *Brucella*-like species, moulds, *Nocardia* species and *Mycobacterium* species. Stability was validated for *Mycobacterium* species using both liquid and solid media.

   The results from Part 2 of the study demonstrated deposit stability outside the instrument when combined with 16 hours inside the instrument for the following:

   - Up to 72h for bacteria, yeast, *Brucella*-like species and *Mycobacterium* species from liquid and solid media.
   - Up to 48h for moulds and *Nocardia* species.

Controls:

The following Positive Quality Control organisms are recommended in the VITEK MS PRIME User Manual.

Organism Type	Quality Control Strain	Expected Results
Bacteria	*Klebsiella* (*Enterobacter*) *aerogenes* ATCC 13048	*Klebsiella aerogenes*
Yeast	*Candida glabrata* ATCC MYA-2950	*Candida glabrata*
Mycobacteria	*Mycoicibacterium smegmatis* ATCC 19420	*Mycoicibacteriuum smegmatis*
Nocardia	*Nocardia farcinica* ATCC 3308	*Nocardi*a farcinica
Moulds	*Aspergillus brasiliensis* ATCC 16404	*Aspergillus brasiliensis*
Brucella	*Brucella melitensis* ATCC 23456	*Brucella* spp.
Negative Control	Reagent Alone (Bacteria - CHCA; Yeast-FA and CHCA; Mould, Mycobacteria and Nocardia – FA, acetonitrile and CHCA	No ID

During the validation studies conducted for the VITEK MS PRIME, five of the above recommend positive control organisms were used for quality control testing. *Brucella meletensis* was not tested in the study. Negative control testing included testing of reagents, as applicable depending on the microorganism group being evaluated at the time of testing. During validation studies, applicable quality control organisms were tested by VITEK MS PRIME each day a bacterium, yeast or mould was tested as well as with each new batch of VITEK MS-CHCA or VITEK MS-DS target slides.

During the Clinical Study, Challenge and Reproducibility studies, quality control testing was conducted at each clinical study site. Quality Control testing results are presented in Table 5. The overall repeat rate was 1.5%.

Table 5: Quality Control Testing Results, Clinical, Challenge and Reproducibility Studies.

QC Species	N	Correct One Choice (or No ID for Negative Control)	Percent Correct
Aspergillus brasiliensis	81	80	98.8%
Candida glabrata	61	61	100%
Klebsiella (Enterobacter) aerogenes	77	76	98.7%
Mycobacterium smegmatis	45	42	93.3%
Nocardia farcinica	63	61	96.8%
Negative control (reagents alone)	130	130	100%

7. Detection Limit:

   A limit of detection (LoD) study with the VITEK MS PRIME was conducted to verify the detection limit was at least equivalent to the LoD established on the VITEK MS, which is 10^5 CFU/spot (1 µL) for bacteria and 10^4 CFU/spot (1 µL) for yeast.

   Five species, representative of the main groups of microorganisms including gram-negative, gram-positive, fastidious bacteria and yeast, were tested to assess the LoD of the VITEK MS PRIME.

   The limits of detection obtained in this study with VITEK MS PRIME were evaluated at 10^5 CFU/spot (1µ) for bacteria and 10^4 CFU/spot (1µ) for yeast. The LoD values obtained with the VITEK MS PRIME are comparable to those obtained with the VITEK MS. The acceptance criteria were met.

8. Assay Cut-Off:

   See K181412 - Both VITEK MS and VITEK MS PRIME systems use the same analysis algorithms and Knowledge Base.

9. VITEK MS PRIME Automatic Reshoot:

   The VITEK MS PRIME offers the user the option to configure automatic reshoot(s) on sample spots. When the spectra acquisition does not meet the quality criteria, the system will automatically reshoot the spot. The maximum number of acquisitions per sample is three - one original shot plus two repeat shots.

   A study was conducted to test conditions of organism spotting that could lead to automatic reshoot of the sample. The study also included evaluation of the biological impact of reshooting on the negative controls such as occurrence of false positive results.

   The following test conditions that could lead to automatic reshoot of the sample (i.e., conditions that would generate bad quality spectra) were evaluated:

   - Sample deposits made without CHCA matrix
   - Testing of negative reagent spots (no organism added)

- Simulation of incorrect deposits (thick deposit with too much material, thin deposit with too little material)

The results of the study demonstrated the reshoot process functioned as expected meeting the acceptance criteria in all test case challenges. No discordant or false positive results were observed following a reshoot.

10. Carry-Over:

See DEN130013

11. Impact of Mixed Cultures:

Though the intended use of the VITEK MS PRIME is to identify pure cultures, it is possible that mixed cultures may inadvertently be tested by a laboratory technologist. This study assessed the impact of mixed cultures on the identification of bacteria, yeast, moulds, mycobacteria and Nocardia when tested on the VITEK MS PRIME. A minimum of four replicates were evaluated for each organism mixture.

Four representative bacterial species (*K. aerogenes, P. aeruginosa*, *S. aureus* and *C. jeikeium*) and one yeast (*Candida glabrata*) were evaluated in the study. Testing included suspension mixtures with two organisms (one species at a high positive concentration mixed with another species at a moderate positive concentration). For 10 different organism/concentration mixtures (60 total tests) VITEK MS PRIME testing reported the following:

- Correct Identification for only one of the organisms in the mixture (58 tests)
- Low discrimination with both organisms listed (1 test)
- No Identification (1 tests).

Five representative mould species (*Aspergillus brasiliensis*, *Penicillium chrysogenum*, *Pseudallescheria boydii, Lecythophora hoffamanni*, *Epidemophyton floccosum*) were evaluated in the study. Testing included suspension mixtures with two different mould species (high positive/low positive). For eight different organism/concentration mixtures (32 total tests), VITEK MS PRIME testing resulted in the following:

- Correct Identification for only one of the organisms in the mixture (20)
- Low Discrimination with both organisms listed (12)

From solid media, nine Mycobacteria, including rapid-growers and slow-growers (*M. smegmatis*, *M. intracellulare*, *M. abscessus*, *M. fortuitum*, *M. chelonae*, *M. tuberculosis*, *M. scrofulaceum*, *M. kansasii*, *M. fortuitum*) and three *Nocardia* species (*N. farcinica, N. asteroides, N. brasiliensis*) were evaluated in the study. Testing included suspension mixtures (derived from solid media growth) of two different species (high positive/moderate positive). For 18 different organism/concentration mixtures (72 total tests), VITEK MS PRIME testing resulted in the following:

- Correct Identification for only one of the organisms in the mixture (60)
- Low Discrimination with both organisms listed (9)
- No Identification (3)

For liquid media, five Mycobacterium spp., two bacterial species and one yeast were evaluated in the study. Testing included suspension mixtures (derived from liquid media growth) of two different species (high positive/moderate positive). For the six different organism/concentration mixtures (24 total tests), VITEK MS PRIME testing resulted in correct identification for only one of the organisms in each mixture evaluated.

In summary, no misidentification results occurred for the mixed cultures evaluated. All mixed cultures were identified as either correct single choice ID of one of the two species in the test mixture, low discrimination listing the two organisms, or No ID.

For the majority of organism mixtures that generated single choice ID the high-positive organism is identified. Results from the study demonstrate that VITEK MS PRIME algorithm cannot consistently identify both organisms present in a sample. Therefore, as stated in the VITEK PRIME User Manual, users should test pure cultures.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Performance: (Refer also to DEN1300013/K124067/K162950/K181412 for additional clinical validation for the VITEK MS Knowledge Base using the predicate device, VITEK MS)

   The objective of the clinical study was to evaluate the performance of the VITEK MS PRIME for identification of representative microorganisms in a clinical setting as compared to the reference method (DNA sequencing analysis and other methods as necessary, i.e., genotypic and/or phenotypic testing and/or dendrogram analysis). Organisms evaluated in the study included well-characterized aerobic and anaerobic gram-positive and gram-negative bacteria, *Mycobacteria*, *Nocardia*, yeasts, and moulds that were previously tested on the VITEK MS (predicate device) during previous clinical or internal studies. Testing was conducted at two testing sites (internal Biomerieux sites), with one instrument used at one internal testing site and two other instruments used at a second internal testing site. The study was conducted in two parts 1) Challenge Testing and 2) Clinical Isolate Testing. Repeat testing was conducted according to VITEK MS PRIME User Manual instructions (e.g., for initial No ID, Low Discrimination results, or poor spectra quality).

   Clinical Study, Challenge Testing:

   The VITEK MS PRIME challenge set consisted of 100 well-characterized species (clinical isolates) selected from challenge organisms, including less common and rare species, that were evaluated in previous VITEK MS clinical studies. Challenge isolates were tested once each with the VITEK MS PRIME system. All organism identities were blinded to the operator, and testing was conducted across three instruments at two testing sites. The performance observed in the study was 94.0% (94/100) correct single choice ID. The other

6/100 strains generated results of low discrimination to the correct genus. Results from Challenge testing are summarized by organism group in Table 6 and stratified by species in Table 7. Table 8 includes a summary of repeat testing that was conducted (e..g., for initial No ID results)

Table 6: Clinical Study, Challenge Testing Results

VITEK MS IDENTIFICATION						
Organism Classification		**N**	**Number of Unique Isolates**	**Total Correct GENUS ID (One Choice and Low Discrim.)**	**One Choice Correct: Genus ID Correct: Species ID or Group/Complex ID**	**Low Discrimination Correct: Genus ID**
Gram + Bacteria	Aerobic	16	16	100.0% (16/16)	93.8% (15/16)	6.3% (1/16)
	Anaerobic	8	8	100.0% (8/8)	100.0% (8/8)	0.0% (0/8)
	Total	*24*	*24*	*100.0% (24/24)*	*95.8% (23/24)*	*4.2% (1/24)*
Gram - Bacteria	Aerobic	34	34	100.0% (34/34)	85.3% (29/34)	14.7% (5/34)
	Anaerobic	2	2	100.0% (2/2)	100.0% (2/2)	0.0% (0/2)
	Total	*36*	*36*	*100.0% (36/36)*	*86.1% (31/36)*	*13.9% (5/36)*
Yeasts	*Total*	*12*	*12*	*100.0% (12/12)*	*100.0% (12/12)*	*0.0% (0/12)*
Moulds	*Total*	*12*	*12*	*100.0% (12/12)*	*100.0% (12/12)*	*0.0% (0/12)*
Myco/Nocardia	Mycobacteria	8	8	100.0% (8/8)	100.0% (8/8)	0.0% (0/8)
	Nocardia	8	8	100.0% (8/8)	100.0% (8/8)	0.0% (0/8)
	Total	*16*	*16*	*100.0% (16/16)*	*100.0% (16/16)*	*0.0% (0/16)*
~All~	***Total***	***100***	***100***	***100.0% (100/100)***	***94.0% (94/100)***	***6.0% (6/100)***

Table 7: Clinical Study, Challenge Testing, Results By Species

VITEK MS Result	Ref/Gold Std	Interpretation
Staphylococcus xylosus	*Staphylococcus xylosus*	Correct One Choice
Streptococcus intermedius	*Streptococcus intermedius*	Correct One Choice
Streptococcus sobrinus	*Streptococcus sobrinus*	Correct One Choice
Cedecea davisae	*Cedecea davisae*	Correct One Choice
Chryseobacterium gleum	*Chryseobacterium gleum*	Correct One Choice
Cedecea lapagei	*Cedecea lapagei*	Correct One Choice
Burkholderia gladioli	*Burkholderia gladioli*	Correct One Choice

Elizabethkingia meningoseptica	*Elizabethkingia meningoseptica*	Correct One Choice
Kluyvera intermedia	*Kluyvera intermedia*	Correct One Choice
Providencia alcalifaciens	*Providencia alcalifaciens*	Correct One Choice
Yersinia frederiksenii	*Yersinia frederiksenii*	Correct One Choice
Leclercia adecarboxylata	*Leclercia adecarboxylata*	Correct One Choice
Serratia plymuthica	*Serratia plymuthica*	Correct One Choice
Acinetobacter junii	*Acinetobacter junii*	Correct One Choice
Pseudomonas luteola	*Pseudomonas luteola*	Correct One Choice
Pseudomonas mendocina	*Pseudomonas mendocina*	Correct One Choice
Delftia acidovorans	*Delftia acidovorans*	Correct One Choice
Ochrobactrum anthropi	*Ochrobactrum anthropi*	Correct One Choice
Sphingomonas paucimobilis	*Sphingomonas paucimobilis*	Correct One Choice
Yersinia kristensenii; Yersinia enterocolitica	***Yersinia kristensenii***	**Low Discrim, Correct Genus**
Yersinia pseudotuberculosis; Yersinia similis	*Yersinia pseudotuberculosis*	Low Discrim, Correct Genus
Acinetobacter haemolyticus	*Acinetobacter haemolyticus*	Correct One Choice
Alcaligenes faecalis ssp faecalis	*Alcaligenes faecalis ssp faecalis*	Correct One Choice
Bordetella bronchiseptica	*Bordetella bronchiseptica*	Correct One Choice
Citrobacter amalonaticus	*Citrobacter amalonaticus*	Correct One Choice
Citrobacter farmeri	*Citrobacter farmeri*	Correct One Choice
Citrobacter youngae	*Citrobacter youngae*	Correct One Choice
Enterobacter asburiae; Enterobacter cloacae	***Enterobacter asburiae***	**Low Discrim, Correct Genus**
Pluralibacter gergoviae	*Pluralibacter gergoviae*	Correct One Choice
Escherichia hermannii	*Escherichia hermannii*	Correct One Choice
Pantoea agglomerans	*Pantoea agglomerans*	Correct One Choice
Pasteurella aerogenes	*Pasteurella aerogenes*	Correct One Choice
Pseudomonas putida	*Pseudomonas putida*	Correct One Choice
Ralstonia pickettii	*Ralstonia pickettii*	Correct One Choice
Raoultella ornithinolytica; Raoultella planticola	***Raoultella planticola***	**Low Discrim, Correct Genus**
Aeromonas sobria; Aeromonas veronii; Aeromonas salmonicida/bestiarum	***Aeromonas sobria***	**Low Discrim, Correct Genus**
Lactococcus lactis	*Lactococcus lactis ssp lactis*	Correct One Choice
Aerococcus viridans	*Aerococcus viridans*	Correct One Choice
Streptococcus parasanguinis	*Streptococcus parasanguinis*	Correct One Choice
Streptococcus uberis	*Streptococcus uberis*	Correct One Choice
Nocardia abscessus	*Nocardia abscessus*	Correct One Choice
Nocardia asteroides	*Nocardia asteroides*	Correct One Choice
Nocardia paucivorans	*Nocardia paucivorans*	Correct One Choice
Nocardia pseudobrasiliensis	*Nocardia pseudobrasiliensis*	Correct One Choice
Nocardia transvalensis	*Nocardia transvalensis*	Correct One Choice
Nocardia wallacei	*Nocardia wallacei*	Correct One Choice

Nocardia otitidiscaviarum	*Nocardia otitidiscaviarum*	Correct One Choice
Candida rugosa	*Candida rugosa*	Correct One Choice
Trichosporon inkin	*Trichosporon inkin*	Correct One Choice
Malassezia pachydermatis	*Malassezia pachydermatis*	Correct One Choice
Candida zeylanoides	*Candida zeylanoides*	Correct One Choice
Candida intermedia	*Candida intermedia*	Correct One Choice
Candida lipolytica	*Candida lipolytica*	Correct One Choice
Penicillium chrysogenum	*Penicillium chrysogenum*	Correct One Choice
Candida famata	*Candida famata*	Correct One Choice
Candida lambica	*Candida lambica*	Correct One Choice
Candida norvegensis	*Candida norvegensis*	Correct One Choice
Candida utilis	*Candida utilis*	Correct One Choice
Kodamaea ohmeri	*Kodamaea ohmeri*	Correct One Choice
Trichosporon dermatis/mucoides	*Trichosporon mucoides*	Correct One Choice
Peptostreptococcus anaerobius	*Peptostreptococcus anaerobius*	Correct One Choice
Paraclostridium bifermentans	*Paraclostridium bifermentans*	Correct One Choice
Bacteroides uniformis	*Bacteroides uniformis*	Correct One Choice
Fusobacterium necrophorum	*Fusobacterium necrophorum*	Correct One Choice
Hathewaya histolytica	*Hathewaya histolytica*	Correct One Choice
Clostridium ramosum	*Clostridium ramosum*	Correct One Choice
Clostridium cadaveris	*Clostridium cadaveris*	Correct One Choice
Clostridium tertium	*Clostridium tertium*	Correct One Choice
Parvimonas micra	*Parvimonas micra*	Correct One Choice
Clostridium baratii	*Clostridium baratii*	Correct One Choice
Mycobacterium simiae	*Mycobacterium simiae*	Correct One Choice
Pseudallescheria boydii	*Pseudallescheria boydii*	Correct One Choice
Alternaria alternata	*Alternaria alternata*	Correct One Choice
Aspergillus sydowii	*Aspergillus sydowii*	Correct One Choice
Exophiala xenobiotica	*Exophiala xenobiotica*	Correct One Choice
Lecythophora hoffmannii	*Lecythophora hoffmannii*	Correct One Choice
Purpureocillium lilacinum	*Purpureocillium lilacinum*	Correct One Choice
Scedosporium prolificans	*Scedosporium prolificans*	Correct One Choice
Lichtheimia corymbifera	*Lichtheimia corymbifera*	Correct One Choice
Aspergillus calidoustus/ustus	*Aspergillus calidoustus*	Correct One Choice
Aspergillus lentulus	*Aspergillus lentulus*	Correct One Choice
Mycobacterium chelonae	*Mycobacterium chelonae*	Correct One Choice
Mycobacterium immunogenum	*Mycobacterium immunogenum*	Correct One Choice
Mycobacterium marinum	*Mycobacterium marinum*	Correct One Choice
Mycobacterium mucogenicum	*Mycobacterium mucogenicum*	Correct One Choice
Mycobacterium scrofulaceum	*Mycobacterium scrofulaceum*	Correct One Choice
Mycobacterium smegmatis	*Mycobacterium smegmatis*	Correct One Choice
Citrobacter braakii	*Citrobacter braakii*	Correct One Choice
Aspergillus nidulans	*Aspergillus nidulans*	Correct One Choice
Nocardia veterana	*Nocardia veterana*	Correct One Choice
Mycobacterium malmoense	*Mycobacterium malmoense*	Correct One Choice

Staphylococcus lentus	*Staphylococcus lentus*	Correct One Choice
Staphylococcus sciuri	*Staphylococcus sciuri*	Correct One Choice
Staphylococcus hyicus	*Staphylococcus hyicus*	Correct One Choice
Staphylococcus schleiferi	*Staphylococcus schleiferi*	Correct One Choice
Staphylococcus auricularis	*Staphylococcus auricularis*	Correct One Choice
Staphylococcus cohnii ssp cohnii	*Staphylococcus cohnii ssp cohnii*	Correct One Choice
Staphylococcus chromogenes	*Staphylococcus chromogenes*	Correct One Choice
Enterococcus hirae	*Enterococcus hirae*	Correct One Choice
Staphylococcus intermedius; Staphylococcus pseudintermedius	***Staphylococcus pseudintermedius***	**Low Discrim, Correct Genus**

Table 8: Challenge Testing, Repeat Rate

Organism Classification		N	Spot Repeat (Percent)
Gram+ Bacteria	Aerobic	16	0 (0.0%)
	Anaerobic	8	0 (0.0%)
Gram- Bacteria	Aerobic	34	0 (0.0%)
	Anaerobic	2	0 (0.0%)
Yeasts	Aerobic	12	1 (8.3%)
Moulds	Moulds	12	1 (8.3%)
Myco/Nocardia	Mycobacteria	8	1 (12.5%)
	Nocardia	8	0 (0.0%)
~All~	***Grand Total***	***100***	***3 (3.0%)***

Clinical Study, Clinical Isolates (Different species than were included in Challenge testing)

The organisms selected for the second portion of the clinical study were well-characterized strains previously tested on the VITEK MS system at clinical trial sites and/or during internal studies. The organism set included up to five strains for each of 100 common and/or clinically relevant species/groups/complexes from all organism groups combined. Testing was conducted using three instrument systems at two internal testing sites (one instrument used at one internal testing site and two instruments used at the second internal testing site). Of the 500 isolates tested in the study, 491 were unique clinical isolates and nine were clones of clinical isolates. The numbers of species and strains evaluated for each organism group are presented in Table 9.

Table 9: Organism Groups: Numbers of Species and Strains Tested

Organism Group	# of Species	# of Strains/Organism Group
Aerobic Gram Positive Bacteria	25	125
Anaerobic Gram Positive Bacteria	4	20
Aerobic Gram Negative Bacteria	27	135
Anaerobic Gram Negative Bacteria	5	25
Mycobacterium	8	40
Nocardia	4	20
Moulds	10	50
Yeasts	17	85
Total	**100**	**500**

VITEK MS PRIME identification results were compared to the reference identification result and the rate of correct identification and corresponding exact 95% confidence interval was calculated for each of the organisms tested, as well as overall. The study demonstrated 98.4% (492/500) agreement, 95% CI [96.8%, 99.3%], for all clinical bacteria, moulds, and yeast isolates tested (correct single choice ID or low discrimination correct genus) from all sites combined, with 2 (0.4%) misidentifications and 6 (1.2%) No ID results. Results by organism group are presented in Table 10. Results stratified by species are presented in Table 11.

Table 10: Clinical Study, Performance by Organism Group

			VITEK MS IDENTIFICATION						
Organism Classification		**Unique Isolates**	**Total Correct GENUS ID (One Choice and Low Discrim.)**	**One Choice Correct: Genus ID Correct: Species ID or Group/Complex ID**		**Low Discrimination Correct: Genus ID**		**Discordant ID**	**No ID**
				One choice reference result	**Multiple choice reference result[1]**	**One choice reference result**	**Multiple choice reference result[1]**		
Gram + Bacteria	Aero	125	99.2% (124/125)	92.0% (115/125)	0.0% (0/125)	7.2% (9/125)	0.0% (0/125)	0.8% (1/125)	0.0% (0/125)
	Anaero	20	100.0% (20/20)	100.0% (20/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)
	Total	*145*	*99.3% (144/145)*	*93.1% (135/145)*	*0.0% (0/145)*	*6.2% (9/145)*	*0.0% (0/145)*	*0.7% (1/145)*	*0.0% (0/145)*
Gram - Bacteria	Aero	135	98.5% (133/135)	94.8% (128/135)	0.0% (0/135)	3.7% (5/135)	0.0% (0/135)	0.0% (0/135)	1.5% (2/135)
	Anaero	25	100.0% (25/25)	100.0% (25/25)	0.0% (0/25)	0.0% (0/25)	0.0% (0/25)	0.0% (0/25)	0.0% (0/25)
	Total	*160*	*98.8% (158/160)*	*95.6% (153/160)*	*0.0% (0/160)*	*3.1% (5/160)*	*0.0% (0/160)*	*0.0% (0/160)*	*1.3% (2/160)*
Yeasts	*Total*	*85*	*95.3% (81/85)*	*95.3% (81/85)*	*0.0% (0/85)*	*0.0% (0/85)*	*0.0% (0/85)*	*0.0% (0/85)*	*4.7% (4/85)*
Moulds	*Total*	*42*	*98.0% (49/50)*	*76.0% (38/50)*	*20.0% (10/50)*	*2.0% (1/50)*	*0.0% (0/50)*	*2.0% (1/50)*	*0.0% (0/50)*
Myco/Nocardia	Mycobacteria	39	100.0% (40/40)	100.0% (40/40)	0.0% (0/40)	0.0% (0/40)	0.0% (0/40)	0.0% (0/40)	0.0% (0/40)
	Nocardia	20	100.0% (20/20)	100.0% (20/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)
	Total	*59*	*100.0% (60/60)*	*100.0% (60/60)*	*0.0% (0/60)*	*0.0% (0/60)*	*0.0% (0/60)*	*0.0% (0/60)*	*0.0% (0/60)*
~All~	***Grand Total***	***491***	***98.4% (492/500)***	***93.4% (467/500)***	***2.0% (10/500)***	***3.0% (15/500)***	***0.0% (0/500)***	***0.4% (2/500)***	***1.2% (6/500)***

[1] Multiple choice reference result indicates when the reference identification method identifies the genus but does not distinguish between two or more species. VITEK MS PRIME results for 10 mould isolates were concordant with one of the species included in the multiple-choice reference ID.

Table 11: Clinical Study, Performance By Species

Species	N	# Unique Strains	Total Correct GENUS ID (One Choice and Low Discrim.)	One Choice Correct: Genus ID Correct: Species ID or Group/Complex ID		Low Discrimination Correct: Genus ID		Discordant ID	No ID
				One choice reference result	Multiple choice reference result[1]	One choice reference result	Multiple choice reference result[1]		
Clostridium difficile	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Clostridium perfringens	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Clostridium septicum	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus avium	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus casseliflavus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus durans	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus faecalis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus faecium	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterococcus gallinarum	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Listeria monocytogenes	**5**	**5**	**80.0% (4/5)**	**60.0% (3/5)**	**0.0% (0/5)**	**20.0% (1/5)**	**0.0% (0/5)**	**20.0% (1/5)**	**0.0% (0/5)**
Micrococcus luteus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Propionibacterium acnes	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus aureus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus capitis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus epidermidis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus haemolyticus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus hominis ssp hominis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus lugdunensis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus saprophyticus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus simulans	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Staphylococcus warneri	5	5	100.0% (5/5)	80.0% (4/5)	0.0% (0/5)	20.0% (1/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus agalactiae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus anginosus	5	5	100.0% (5/5)	60.0% (3/5)	0.0% (0/5)	40.0% (2/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus constellatus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus dysgalactiae ssp dysgalactiae	1	1	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)

Streptococcus dysgalactiae ssp equisimilis	4	4	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
Streptococcus mitis	1	1	100.0% (1/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
Streptococcus oralis	4	4	100.0% (4/4)	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
Streptococcus pneumoniae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus pyogenes	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Streptococcus sanguinis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Acinetobacter baumannii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Acinetobacter lwoffii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Aeromonas hydrophila	5	5	100.0% (5/5)	80.0% (4/5)	0.0% (0/5)	20.0% (1/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Bacteroides fragilis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Bacteroides ovatus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Bacteroides thetaiotaomicron	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Bacteroides vulgatus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Burkholderia cenocepacia	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Burkholderia multivorans	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Campylobacter jejuni	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Citrobacter freundii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Citrobacter koseri	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Elizabethkingia anophelis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterobacter aerogenes	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Enterobacter cloacae	**5**	**5**	**60.0% (3/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**60.0% (3/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**40.0% (2/5)**
Escherichia coli	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Haemophilus influenzae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Haemophilus parainfluenzae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Klebsiella oxytoca	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Klebsiella pneumoniae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Legionella pneumophila	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Moraxella (Branhamella) catarrhalis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Morganella morganii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Neisseria gonorrhoeae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)

Prevotella bivia	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Proteus mirabilis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Providencia rettgeri	5	5	100.0% (5/5)	80.0% (4/5)	0.0% (0/5)	20.0% (1/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Providencia stuartii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Pseudomonas aeruginosa	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Serratia marcescens	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Serratia odorifera	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Stenotrophomonas maltophilia	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida albicans	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida auris	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida dubliniensis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida glabrata	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida guilliermondii	**5**	**5**	**80.0% (4/5)**	**80.0% (4/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**20.0% (1/5)**
Candida inconspicua	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida kefyr	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida krusei	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida lusitaniae	**5**	**5**	**40.0% (2/5)**	**40.0% (2/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**0.0% (0/5)**	**60.0% (3/5)**
Candida parapsilosis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida pelliculosa	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Candida tropicalis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Cryptococcus neoformans	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Rhodotorula mucilaginosa	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Saccharomyces cerevisiae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Saprochaete capitata	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Trichosporon asahii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Aspergillus flavus/oryzae	5	5	100.0% (5/5)	0.0% (0/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Aspergillus fumigatus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Aspergillus niger complex	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Aspergillus terreus complex	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Blastomyces dermatitidis	5	3	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Coccidioides immitis/posadasii	5	4	100.0% (5/5)	0.0% (0/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)

Histoplasma capsulatum	5	2	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Scedosporium apiospermum	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Trichophyton interdigitale	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Trichophyton rubrum	**5**	**3**	**80.0% (4/5)**	**60.0% (3/5)**	**0.0% (0/5)**	**20.0% (1/5)**	**0.0% (0/5)**	**20.0% (1/5)**	**0.0% (0/5)**
Mycobacterium abscessus	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium avium	5	4	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium gordonae	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium houstonense	3	3	100.0% (3/3)	100.0% (3/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Mycobacterium intracellulare	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium kansasii	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium lentiflavum	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Mycobacterium peregrinum	1	1	100.0% (1/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
Mycobacterium porcinum	1	1	100.0% (1/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
Mycobacterium tuberculosis complex	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Nocardia brasiliensis	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Nocardia cyriacigeorgica	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Nocardia farcinica	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
Nocardia nova	5	5	100.0% (5/5)	100.0% (5/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)
~All~	***500***	***491***	***98.4% (492/500)***	***93.4% (467/500)***	***2.0% (10/500)***	***3.0% (15/500)***	***0.0% (0/500)***	***0.4% (2/500)***	***1.2% (6/500)***

[1]Multiple choice reference result indicates when the reference identification method identifies the genus but does not distinguish between two or more species.

Table 12 includes a summary of repeat testing that was conducted during the Clinical Study:

Table 12: Clinical Study Isolates, Summary of repeat testing

Organism Classification		N	Spot Repeat (Percent)	New Extract (Percent)
Gram+ Bacteria	Aerobic	125	3 (2.4%)	0 (0.0%)
	Anaerobic	20	0 (0.0%)	0 (0.0%)
Gram- Bacteria	Aerobic	135	7 (5.2%)	0 (0.0%)
	Anaerobic	25	3 (12.0%)	0 (0.0%)
Yeasts	Aerobic	85	6 (7.1%)	0 (0.0%)
Moulds	Moulds	50	3 (6.0%)	2 (4.0%)
Myco/Nocardia	Mycobacteria	40	10 (25.0%)	4 (10.0%)
	Nocardia	20	0 (0.0%)	0 (0.0%)
~All~	***Total***	***500***	***32 (6.4%)***	***6 (1.2%)***

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

See K181412

F Other Supportive Instrument Performance Characteristics Data:

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.