

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM**

A. 510(k) Number: K142677

B. Purpose for Submission:

To add the following additional organism identification claims to the already cleared device K130831.

Bacteria	
Acinetobacter haemolyticus	Clostridium perfringens
Acinetobacter johnsonii	Corynebacterium amycolatum
Acinetobacter junii	Corynebacterium aurimucosum group
Actinomyces meyeri	Corynebacterium bovis
Actinomyces neuii	Corynebacterium diphtheriae
Actinomyces odontolyticus	Corynebacterium glucuronolyticum
Actinomyces oris	Corynebacterium jeikeium
Aerococcus urinae	Corynebacterium kroppenstedtii
Aerococcus viridans	Corynebacterium macginleyi
Aeromonas salmonicida	Corynebacterium minutissimum
Anaerococcus vaginalis	Corynebacterium propinquum
Bacteroides fragilis	Corynebacterium pseudodiphtheriticum
Bacteroides ovatus group	Corynebacterium riegelii
Bacteroides thetaiotaomicron group	Corynebacterium striatum group
Bacteroides uniformis	Corynebacterium tuberculostearicum
Bacteroides vulgatus group	Corynebacterium ulcerans
Bordetella group[3]	Corynebacterium urealyticum
Bordetella hinzii	Corynebacterium xerosis
Brevibacterium casei	Cronobacter sakazakii group
Brevundimonas diminuta group	Cupriavidus pauculus group
Campylobacter coli	Delftia acidovorans group
Campylobacter jejuni	Dermacoccus nishinomiyaensis
Campylobacter ureolyticus	Edwardsiella tarda
Capnocytophaga ochracea	Elizabethkingia meningoseptica group
Capnocytophaga sputigena	Enterobacter amnigenus
Chryseobacterium gleum	Enterococcus avium group
Chryseobacterium indologenes	Enterococcus casseliflavus
Clostridium difficile	Enterococcus faecalis

Bacteria	
Enterococcus faecium	Rothia aeria
Enterococcus gallinarum	Rothia dentocariosa
Enterococcus hirae	Rothia mucilaginosa
Finegoldia magna	Serratia plymuthica
Fusobacterium canifelinum	Serratia rubidaea
Fusobacterium necrophorum	Staphylococcus aureus
Fusobacterium nucleatum	Staphylococcus auricularis
Gardnerella vaginalis	Staphylococcus capitis
Gemella haemolysans	Staphylococcus caprae
Gemella sanguinis	Staphylococcus carnosus
Granulicatella adiacens	Staphylococcus cohnii
Haemophilus haemolyticus	Staphylococcus epidermidis
Haemophilus influenzae	Staphylococcus equorum
Haemophilus parahaemolyticus group	Staphylococcus felis
Kingella kingae	Staphylococcus haemolyticus
Kocuria kristinae	Staphylococcus hominis
Kytococcus sedentarius	Staphylococcus lugdunensis
Lactococcus garvieae	Staphylococcus pasteurii
Lactococcus lactis	Staphylococcus pettenkoferi
Leuconostoc mesenteroides	Staphylococcus pseudintermedius
Macrococcus caseolyticus	Staphylococcus saccharolyticus
Micrococcus luteus	Staphylococcus saprophyticus
Moraxella sg Moraxella nonliquefaciens	Staphylococcus schleiferi
Myroides odoratimimus	Staphylococcus simulans
Myroides odoratus	Staphylococcus vitulinus
Oligella ureolytica	Staphylococcus warneri
Oligella urethralis	Streptococcus agalactiae
Parabacteroides distasonis	Streptococcus anginosus
Pediococcus pentosaceus	Streptococcus constellatus
Peptoniphilus harei group	Streptococcus dysgalactiae
Peptostreptococcus anaerobius	Streptococcus gallolyticus
Plesiomonas shigelloides	Streptococcus gordonii
Porphyromonas gingivalis	Streptococcus intermedius
Prevotella bivia	Streptococcus lutetiensis
Prevotella buccae	Streptococcus mitis/oralis group
Prevotella denticola	Streptococcus mutans
Prevotella intermedia	Streptococcus pneumoniae
Prevotella melaninogenica	Streptococcus pyogenes
Propionibacterium acnes	Streptococcus salivarius
Pseudomonas oryzae	Sutterella wadsworthensis
Pseudomonas stutzeri	Vibrio parahaemolyticus
Rhizobium radiobacter	Vibrio vulnificus

YEASTS	
Candida albicans	Candida orthopsilosis
Candida boidinii	Candida parapsilosis
Candida dubliniensis	Candida pararugosa
Candida duobushaemulonii	Candida pelliculosa
Candida famata	Candida tropicalis
Candida glabrata	Candida valida
Candida guilliermondii	Cryptococcus gattii
Candida haemulonis	Cryptococcus neoformans var grubii
Candida inconspicua	Cryptococcus neoformans var neoformans
Candida kefyr	Geotrichum candidum
Candida krusei	Geotrichum capitatum
Candida lambica	Kloeckera apiculata
Candida lipolytica	Pichia ohmeri
Candida lusitanae	Saccharomyces cerevisiae
Candida metapsilosis	Trichosporon asahii
Candida norvegensis	

C. Measurand: See Intended Use

D. Type of Test:

The MALDI Biotyper CA System 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:

Bruker Daltonics, Inc.

F. Proprietary and Established Names:

Trade Name: MALDI Biotyper CA System

Common Name: MBT-CA System

G. Regulatory Information:

1. Regulation section: 21 CFR 866.3361
2. Classification: Class II (special controls)

3. Product code: PEX
4. Panel: Microbiology (83)

H. Intended Use:

1. Intended use(s):

The Bruker Daltonics, Inc. MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ionization – time-of-flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens.

The MALDI Biotyper CA 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 yeast infections.

The following organisms are claimed:

Bacteria	
Achromobacter xylosoxidans	Burkholderia gladioli
Acinetobacter haemolyticus	Burkholderia multivorans
Acinetobacter johnsonii	Burkholderia cepacia complex [13]
Acinetobacter junii	Campylobacter coli
Acinetobacter lwoffii	Campylobacter jejuni
Acinetobacter radioresistens	Campylobacter ureolyticus
Acinetobacter ursingii	Capnocytophaga ochracea
Acinetobacter baumannii complex [4]	Capnocytophaga sputigena
Actinomyces meyeri	Chryseobacterium gleum
Actinomyces neuii	Chryseobacterium indologenes
Actinomyces odontolyticus	Citrobacter amalonaticus complex
Actinomyces oris	Citrobacter koseri
Aerococcus urinae	Citrobacter freundii complex
Aerococcus viridans	Clostridium difficile
Aeromonas salmonicida	Clostridium perfringens
Aeromonas sp[7]	Corynebacterium amycolatum
Alcaligenes faecalis	Corynebacterium aurimucosum group
Anaerococcus vaginalis	Corynebacterium bovis
Bacteroides fragilis	Corynebacterium diphtheriae
Bacteroides ovatus group	Corynebacterium glucuronolyticum
Bacteroides uniformis	Corynebacterium jeikeium
Bacteroides thetaiotaomicron group	Corynebacterium kroppenstedtii
Bacteroides vulgatus group	Corynebacterium macginleyi
Bordetella group[3]	Corynebacterium minutissimum
Bordetella hinzii	Corynebacterium propinquum
Brevibacterium casei	Corynebacterium pseudodiphtheriticum
Brevundimonas diminuta group	Corynebacterium riegelii

Bacteria	
Corynebacterium tuberculostearicum	Macrococcus caseolyticus
Corynebacterium ulcerans	Micrococcus luteus
Corynebacterium urealyticum	Moraxella sg Branhamella catarrhalis
Corynebacterium xerosis	Moraxella sg Moraxella nonliquefaciens
Corynebacterium striatum group	Moraxella sg Moraxella osloensis
Cronobacter sakazakii group	Morganella morganii
Cupriavidus pauculus group	Myroides odoratimimus
Delftia acidovorans group	Myroides odoratus
Dermacoccus nishinomiyaensis	Oligella ureolytica
Edwardsiella tarda	Oligella urethralis
Eikenella corrodens	Pantoea agglomerans
Elizabethkingia meningoseptica group	Parabacteroides distasonis
Enterobacter aerogenes	Pasteurella multocida
Enterobacter amnigenus	Pediococcus pentosaceus
Enterobacter cloacae complex	Peptoniphilus harei group
Enterococcus casseliflavus	Peptostreptococcus anaerobius
Enterococcus faecalis	Plesiomonas shigelloides
Enterococcus faecium	Porphyromonas gingivalis
Enterococcus gallinarum	Prevotella bivia
Enterococcus hirae	Prevotella buccae
Enterococcus avium group	Prevotella denticola
Escherichia coli	Prevotella intermedia
Finegoldia magna	Prevotella melaninogenica
Fusobacterium canifelinum	Propionibacterium acnes
Fusobacterium necrophorum	Proteus mirabilis
Fusobacterium nucleatum	Proteus vulgaris group
Gardnerella vaginalis	Providencia rettgeri
Gemella haemolysans	Providencia stuartii
Gemella sanguinis	Pseudomonas aeruginosa
Granulicatella adiacens	Pseudomonas fluorescens group
Haemophilus haemolyticus	Pseudomonas oryzihabitans
Haemophilus influenzae	Pseudomonas putida group
Haemophilus parainfluenzae	Pseudomonas stutzeri
Haemophilus parahaemolyticus group	Rhizobium radiobacter
Hafnia alvei	Rothia aeria
Kingella kingae	Rothia dentocariosa
Klebsiella pneumoniae	Rothia mucilaginosa
Klebsiella oxytoca/ Raoultella ornithinolytica	Salmonella sp
Kocuria kristinae	Serratia liquefaciens
Kytococcus sedentarius	Serratia marcescens
Lactococcus lactis	Serratia plymuthica
Lactococcus garvieae	Serratia rubidaea
Leuconostoc mesenteroides	Staphylococcus aureus

Bacteria	
Staphylococcus auricularis	Stenotrophomonas maltophilia
Staphylococcus capitis	Streptococcus agalactiae
Staphylococcus caprae	Streptococcus anginosus
Staphylococcus carnosus	Streptococcus constellatus
Staphylococcus cohnii	Streptococcus dysgalactiae
Staphylococcus epidermidis	Streptococcus gallolyticus
Staphylococcus equorum	Streptococcus gordonii
Staphylococcus felis	Streptococcus intermedius
Staphylococcus haemolyticus	Streptococcus lutetiensis
Staphylococcus hominis	Streptococcus mitis / oralis group
Staphylococcus lugdunensis	Streptococcus mutans
Staphylococcus pasteurii	Streptococcus pneumoniae
Staphylococcus pettenkoferi	Streptococcus pyogenes
Staphylococcus pseudintermedius	Streptococcus salivarius
Staphylococcus saccharolyticus	Sutterella wadsworthensis
Staphylococcus saprophyticus	Vibrio parahaemolyticus
Staphylococcus schleiferi	Vibrio vulnificus
Staphylococcus simulans	Yersinia enterocolitica
Staphylococcus vitulinus	Yersinia pseudotuberculosis
Staphylococcus warneri	

YEASTS	
Candida albicans	Candida orthopsilosis
Candida boidinii	Candida parapsilosis
Candida dubliniensis	Candida pararugosa
Candida duobushaemulonii	Candida pelliculosa
Candida famata	Candida tropicalis
Candida glabrata	Candida valida
Candida guilliermondii	Cryptococcus gattii
Candida haemulonii	Cryptococcus neoformans var grubii
Candida inconspicua	Cryptococcus neoformans var neoformans
Candida kefyr	Geotrichum candidum
Candida krusei	Geotrichum capitatum
Candida lambica	Kloeckera apiculata
Candida lipolytica	Pichia ohmeri
Candida lusitanae	Saccharomyces cerevisiae
Candida metapsilosis	Trichosporon asahii
Candida norvegensis	

2. Indication(s) for use: Same as intended use.
3. Special conditions for use statement(s):

The MALDI Biotyper CA System is for prescription use only in accordance with 21 CFR 801.109.

4. Special instrument requirements:

Mass Spectrometer: microflex LT/SH mass spectrometer

Target Plates: US IVD 48 Spot Target

Reagents:

- US IVD Bacterial Test Standard (BTS)
- US IVD HCCA portioned (α -Cyano-4-hydroxycinnamic acid)

Database: MALDI Biotyper for Clinical Applications (MBT-CA)

Software:

- MBT-CA System Software Package:
 - MBT-CA System client software displaying the user interface
 - MBT-CA System Server
 - MBT-CA System DB Server
- flexControl Software Package
 - GTPS firmware
 - flexControl acquisition software

Honeywell (Hyperion 1300g) Barcode Reader (optional)

I. Device Description:

The MBT-CA System consists of the microflex LT/SH mass spectrometer, reference library, kit reagents (US IVD HCCA, US IVD Bacterial Test Standard), US IVD 48 Spot Target slides, and software. The MALDI Biotyper CA System with closed safety covers is a Class 1 Laser product. With the safety cover opened it becomes a Class 4 Laser product. The laser is a 337 nm fixed focus, nitrogen laser. The MALDI Biotyper CA System also referred to as the MBT-CA System.

The reference library, MALDI Biotyper for Clinical Applications, includes type strains, clinical strains and culture collection strains. The MALDI Biotyper CA System reference library was established by analyzing the type strain from each claimed species combined with 5 to 38 additional strains from the same species provided by clinical laboratories or different commercial strain collections for a total of 1492 strains. Library mass spectra used for matching contain up to 70 peaks. The MALDI Biotyper for Clinical Applications is also referred to as the MBT-CA.

US IVD HCCA portioned (α -Cyano-4-hydroxycinnamic acid) is a solution that is used when processing test organisms for identification on the MALDI Biotyper CA System. US IVD HCCA is reconstituted in accordance with instructions provided using recommended solvent. 1.0 μ L of the matrix is added to the spot with the sample and allowed to dry.

US IVD Bacterial Test Standard (BTS) is an in-vitro-diagnostic product used for quality

control and validation of the microflex LT/SH mass spectrometers. US IVD BTS contains a manufactured extract of *Escherichia coli* DH5 alpha that demonstrates a characteristic peptide and protein profile mass spectrum, when tested on the MALDI Biotyper CA System. US IVD BTS is spiked with two additional proteins that extend the upper boundary of the mass range of the US IVD BTS. The overall mass range covered by US IVD BTS is 3.6 to 17 kDa.

US IVD 48 Spot Target plates are reusable steel plates which have been developed for the preparation and identification of test organisms using the MALDI Biotyper CA System. The target allows for the identification of 48 test organisms. The target has five cross-joint positions which should be used for US IVD BTS control. Target plate cleaning is performed after each run.

MALDI Biotyper CA System client software displays a user-interface which guides the user through the MALDI Biotyper CA System workflow. The MALDI Biotyper CA System client also interfaces to the flexControl software for automated acquisition of mass spectra on the microflex LT/SH instrument.

The MALDI Biotyper CA System server communicates with the MALDI Biotyper CA System client and the MBT-DB server. It performs preprocessing on acquired spectra, and matches peaks lists against the Main Spectrum (reference pattern, (MSP)) for matching and calculates the score value (log (score)). The MBT-DB server stores all information for the MALDI Biotyper CA System. The MBT-DB maintains spectra data (creation information and mass/intensity lists), project data (results of defined and executed runs), method data (parameter lists for spectra preprocessing and identification), user management data, reference patterns and other peak lists plus additional maintenance data.

GTPS firmware communicates with the flexControl PC software, controls and monitors the vacuum, moves the sample carrier and performs the docking of the target plate, controls and monitors high voltages in the ion source, generates trigger signals, and monitors instrument status.

The flexControl acquisition software communicates with the MALDI Biotyper CA System client, loads automatic run jobs, communicates with the GTPS firmware, communicates with the laser in the microflex LT/SH instrument, sets the acquisition parameters in the digitizer and reads the acquired data from the digitizer, performs automated data acquisition, evaluates acquired spectra, adjusts the laser power during automatic data acquisition, performs a re-calibration of the time-of-flight to mass transformation, stored acquired spectra on disk and performs source cleaning. The flexControl software does not display a user interface.

The optional Honeywell (Hyperion 1300g) Barcode Reader USB cable is connected to the MALDI Biotyper CA System computer. The barcode reader scans the unique ten-digit target ID which appears in the Target ID box on the target plate. After the target ID has been entered, the a new Run page opens and the ten-digit target ID appears as the Plate Id and is appended to the Run name. Sample identifications are entered into the computer corresponding to the target plate position for that run.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bruker Daltonics, Inc MBT-CA System, VITEK® MS

2. Predicate 510(k) number(s):

K124067, K130831

3. Comparison with predicate:

Similarities			
Item	Device	Predicate	Predicate Bruker Daltonics, Inc MBT-CA System (K130831)
Product Code	PEX	PEX	PEX
Intended Use	<p>The Bruker Daltonics, Inc. MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ionization – time-of-flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens.</p> <p>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 yeast infections.</p>	<p>The VitekR MS is a mass spectrometer system using matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) for the identification of microorganisms cultured from human specimen. 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 and yeast infections.</p>	See “Differences”
Sample type	<p>Isolated colony from any patient sample source.</p> <p>Acceptable media:</p> <ul style="list-style-type: none"> • Columbia blood agar with 5% sheep blood (Gram negative aerobic bacteria) • Trypticase soy agar with 5% sheep Blood (Gram negative aerobic bacteria, Gram-aerobic positive bacteria, yeasts) • Chocolate agar (Gram-negative aerobic bacteria, Gram positive aerobic bacteria) • MacConkey Agar (Gram-negative aerobic bacteria) • Columbia CNA agar with 5% sheep blood (Gram positive aerobic bacteria) 	<p>Isolated colony from any patient sample source.</p> <p>Acceptable media:</p> <ul style="list-style-type: none"> • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate polyvitex agar • Campyloset agar • MacConkey Agar • Modified Sabouraud dextrose Agar • ChromID CPS 	<p>Isolated colony from any patient sample source.</p> <p>Acceptable media:</p> <ul style="list-style-type: none"> • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate agar • MacConkey Agar

Similarities

Item	Device	Predicate	Predicate Bruker Daltonics, Inc MBT-CA System (K130831)
	Bruker Daltonics, Inc MBT-CA System (K142677)	VITEK MS (K124067)	
	<ul style="list-style-type: none"> • Brucella Agar with 5% horse blood (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) • 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 bacteria) • Bacteroides bile esculin Agar with amikacin (<i>Bacteroides</i> species) • Clostridium difficile Agar with 7% sheep blood (<i>Clostridium difficile</i>) • Sabouraud-Dextrose Agar (Yeasts) • Brain Heart Infusion Agar (Yeasts) • Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood (<i>Campylobacter</i> species) • Bordet Gengou Agar with 15% sheep blood (<i>Bordetella</i> species) 		
Type of Test	Automated Mass Spectrometry System	Automated Mass Spectrometry System	Automated Mass Spectrometry System
Matrix	alpha-cyano-4-hydroxy-cinnamic acid	alpha-cyano-4-hydroxy-cinnamic acid	alpha-cyano-4-hydroxy-cinnamic acid
Method of Testing	<p>Bacteria & Yeast: Direct testing</p> <ul style="list-style-type: none"> • 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. 	<p>Bacteria: Direct testing</p> <p>Yeast: Direct with VITEK MS-FA</p>	<p>Bacteria: Direct testing</p> <p>If after initial analysis the log (score) is reported at < 2.00, organisms are processed using the extraction procedure.</p>
Result Reporting	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.	A single identification is displayed, with a confidence value from 60.0 to 99.9, when one significant organism or organism group is retained. "Low-discrimination" identifications are displayed when more than one but not more than four significant organisms or organism	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

Similarities			
Item	Device	Predicate	Predicate
	Bruker Daltonics, Inc MBT-CA System (K142677)	VITEK MS (K124067)	Bruker Daltonics, Inc MBT-CA System (K130831)
		groups are retained. When more than four organisms or organism groups are found, or when no match is found, the organism is considered unidentified.	between 1.70 and <2.00.
Matching Algorithm	Calculates matches by comparing a new spectrum against each single reference entry of a reference database.	Uses a proprietary process called "mass binning." In this process, the spectrum between 3,000 and 17,000 Daltons are divided into 1300 pre-defined intervals called "bins". Next, an algorithm based on supervised machine learning known as the "Advanced Spectrum Classifier", is used to determine how informative each bin was in differentiating that species from all other species in the database.	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	2,000 - 20,000 m/z
Calibration	Bruker US IVD Bacterial Test Standard (BTS)	See "Differences"	Bruker US IVD Bacterial Test Standard (BTS)
MALDI Target Plate	US IVD 48 Spot Target with 48 positions reusable steel targets	See "Differences"	US IVD 48 Spot Target with 48 positions reusable steel targets
MALDI-TOF MS Instruments	Bruker microflex (benchtop)	See "Differences"	Bruker microflex (benchtop)
Database	MALDI Biotyper for Clinical Applications (MBT-CA)	See "Differences"	MALDI Biotyper for Clinical Applications (MBT-CA)

Differences			
Item	Device	Predicate	Predicate
	Bruker Daltonics, Inc MBT-CA System (K142677)	VITEK MS (K124067)	Bruker Daltonics, Inc MBT-CA System (K130831)
Culture Age	Bacteria and yeasts growth should be between 18h to 48h (+12h storage at RT) <u>Specific</u> requirements: • <i>Bordetella</i> : Incubation on BG agar should not be longer than 24h (+12h storage at RT).	Bacteria and yeast growth should be between 24 to 72 hours.	Bacteria growth should be between 18h to 36h

Differences			
Item	Device	Predicate	Predicate Bruker Daltonics, Inc MBT-CA System (K130831)
	<ul style="list-style-type: none"> • <i>Campylobacter</i>: Incubation can be prolonged to 72h (+12h storage at RT). • <i>Streptococcus pneumoniae</i>: Incubation should not be longer than 24h (+12h storage at RT) due to possible autolysis. 	VITEK MS (K124067)	
Calibration	Bruker US IVD Bacterial Test Standard (BTS)	E. coli ATCC 8739	See “Similarities”
MALDI Target Plate	US IVD 48 Spot Target with 48 positions reusable steel targets	VITEK MS-DS Target Slides _ 48 positions disposable plastic targets	See “Similarities”
MALDI-TOF MS Instrument	Bruker microflex (benchtop)	Shimadzu AXIMAR Assurance MS (floor standing)	See “Similarities”
Database	MALDI Biotyper for Clinical Applications (MBT-CA)	VITEKR MS V2.0 Knowledge Base	See “Similarities”
Intended Use	<p>The Bruker Daltonics, Inc. MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ionization – time-of-flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens.</p> <p>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 yeast infections.</p>	See “Similarities”	<p>The Bruker Daltonics, Inc MALDI Biotyper CA System is a qualitative <i>in vitro</i> diagnostic mass spectrometer system for the identification of Gram-negative bacterial colonies cultured from human specimens using matrix-assisted laser desorption/ ionization - time of flight (MALDI-TOF) mass spectrometry technology. The MALDI Biotyper CA System is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of Gram-negative bacterial infections.</p>

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

	Standards No.	Recognition No.(FDA)	Standards Title	Date
1	CLSI MM-18A	7-192	Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline, 1 st Edition	4/28/2008

L. Test Principle:

Organisms to be identified with the MALDI Biotyper CA System are isolated using the appropriate isolation media. Users are instructed to first test the organism using the direct transfer technique; if results are less than <2.0 log(score), users are then directed to perform extraction procedure.

Direct Transfer (DT): An individual colony from an overnight subculture plate is transferred to a selected position on an US IVD 48 Spot Target (target). The target is air dried and US IVD HCCA portioned (matrix) is added. The standard solvent (50% acetonitrile / 47.5% H₂O / 2.5% trifluoroacetic acid) in the matrix solution extracts proteins (mainly ribosomal proteins, which are present in high concentration) from the microorganisms. When dried matrix crystallizes, the inoculated target is ready to be analyzed on the MALDI Biotyper CA System.

extended Direct Transfer (eDT): An isolated colony of bacteria or yeast is transferred as a thin film directly onto a sample position on a cleaned target. The sample spot is overlaid with 1 μ L 70% aqueous formic acid directly on the target plate and allowed to dry at room temperature. Afterwards the spots are overlaid with US IVD HCCA portioned (matrix) and allowed to dry. When dried matrix crystallizes, the inoculated target is ready to be analyzed on the MALDI Biotyper CA System.

Extraction Procedure (Ext): For this purpose, isolated colonies from the overnight subculture plate are extracted using an ethanol/formic acid procedure. Afterwards they are transferred to the target plate and allowed to dry. Afterwards the spots are overlaid with US IVD HCCA portioned (matrix) and allowed to dry. When dried matrix crystallizes, the inoculated target is ready to be analyzed on the MALDI Biotyper CA System.

Samples are analyzed using MALDI (matrix-assisted laser desorption/ionization) TOF (time-of-flight) mass spectrometry. The matrix transfers protons onto the extracted proteins and absorbs UV light. After complete drying, the mixture is exposed to laser pulses, resulting in energy transfer from the matrix causing evaporation and release of positively charged intact proteins and peptides ("soft" ionization technique). The ionized molecules are accelerated by electrical potentials through a flight tube to the mass spectrometer, with separation of the particles determined by their mass/charge ratio (m/z). As different proteins/peptides have different masses, ions arrive at the detector at different times (time of flight). The system measures the time (in the nanosecond range) between pulsed acceleration and the corresponding detector signal, the speed is converted into an exact molecular mass. The mass-to-charge ratio of an ion is proportional to the square of its drift time. Highly abundant microbial proteins (mainly ribosomal proteins) result in a mass spectrum with characteristic mass and intensity distribution. It is species-specific for many bacteria and is interpreted as a molecular fingerprint to identify the test organism. Data acquisition is controlled with MALDI Biotyper CA System Software. The spectrum of the unknown organism is first transformed into a peak list. This peak list is compared to the reference peak list of each organism found in the reference library (database) and a log(score) is generated. A higher log(score) indicates a higher degree of similarity to the organism in the reference library. Organism identification is reported with high confidence if the log(score) is ≥ 2.00 . An organism identification is reported with low confidence if the log(score) is between 1.70 and <2.00 .

If different specimen identifications are obtained via different sample preparation techniques (DT v. eDT v. Ext), testing should be repeated from a new colony from the same isolation plate (assuming plate is <12 hours old). If after repeat, concordance is still not obtained, additional testing using traditional laboratory methods and clinical presentation is recommended for final organism identification.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision/repeatability study for Gram negative bacteria was successfully performed and reported in 510(k) K130831. The precision study was conducted for six (6) days with two (2) runs each day, two (2) operators, two (2) microflex LT/SH instrument and two (2) target plates.

Table: Overall Precision per Test Organism: High Confidence ID (≥ 2.0)

Test organism	# samples measured	# samples >2.00 ID (DT)	# samples >2.00 ID (eDT)	# samples >2.00 ID (DT/eDT+Ext)
Brevibacterium casei	36	36 (100%)	36 (100%)	36 (100%)
Enterococcus faecalis	36	34 (94%)	36 (100%)	36 (100%)
Micrococcus luteus	36	21 (58%)	36 (100%)	36 (100%)
Staphylococcus aureus	36	36 (100%)	36 (100%)	36 (100%)
Staphylococcus epidermidis	36	36 (100%)	36 (100%)	36 (100%)
Streptococcus agalactiae	36	34 (94%)	36 (100%)	36 (100%)
Candida albicans	36	18 (50%)	30 (83%)	36 (100%)
Candida parapsilosis	36	6 (17%)	32 (89%)	36 (100%)
Candida tropicalis	36	34 (94%)	35 (97%)	36 (100%)
Saccharomyces cerevisiae	36	20 (56%)	27 (75%)	36 (100%)

The reproducibility study for Gram-positive aerobic bacteria, Gram-negative microaerophilic bacteria, Gram-positive anaerobic bacteria, Gram-negative anaerobic bacteria and yeast organisms was performed at three different clinical study sites. The study was conducted for five (5) days with two (2) runs (two (2) operators) each day per testing site with at least four (4) target plates/each clinical study site and a total of four (4) microflex LT/SH instruments.

For all study processes described above, the following ten (10) blinded reproducibility test organisms were tested:

- | | |
|----------------------------|------------------------------------|
| Enterococcus faecalis | Clostridium perfringens |
| Staphylococcus epidermidis | Propionbacterium acnes |
| Streptococcus agalactiae | Candida albicans |
| Bacteroides fragilis | Saccharomyces cerevisiae |
| Fusobacterium necrophorum | Cryptococcus neoformans var grubii |

All organisms were tested via Direct Transfer (DT) and extended Direct Transfer (eDT) methods in duplicate (each method/each test organism) across two instrument runs (one by each operator) for five (5) testing days (each clinical study site) in accordance with product instructions for use. If DT and/or eDT results log(score) were <2.0, the test organism was tested via the Extraction technique (Ext) in duplicate in accordance with product instructions.

During the course of the five (5) day Reproducibility Panel testing, a total of forty (40) MALDI Biotyper identifications (20 ID's for DT and 20 ID's for eDT technique) for each test-organism at each clinical site were carried out [each organism x 2 replicates x 2 operators x 5 days].

Table: Overall Reproducibility Panel Testing per Test Organism using ≥ 2.0 MBT-CA scores

Blinded Test Organism	Reproducibility Panel	≥ 2.0 ID (DT)	≥ 2.0 ID (eDT)	≥ 2.0 ID (DT+eDT+Ext)
Enterococcus faecalis	REPRO-1	60/60 (100%)	60/60 (100%)	60/60 (100%)
Staphylococcus epidermidis	REPRO-2	58/60 (97%)	59/60 (98%)	60/60 (100%)
Streptococcus agalactiae	REPRO-3	58/60 (97%)	55/60 (92%)	60/60 (100%)
Bacteroides fragilis	REPRO-4	60/60 (100%)	60/60 (100%)	60/60 (100%)
Fusobacterium necrophorum	REPRO-5	56/60 (93%)	53/60 (88%)	58/60 (97%)
Clostridium perfringens	REPRO-6	53/60 (88%)	58/60 (97%)	59/60 (98%)
Propionibacterium acnes	REPRO-7	53/60 (88%)	49/60 (82%)	60/60 (100%)
Candida albicans	REPRO-8	33/60 (55%)	41/60 (68%)	60/60 (100%)
Saccharomyces cerevisiae	REPRO-9	5/60 (8%)	0/60 (0%)	31/60 (52%)
Cryptococcus neoformans var grubii	REPRO-10	31/60 (52%)	44/60 (73%)	53/60 (88%)

In total, 60 MALDI Biotyper CA identifications of each test-organism for each of DT and eDT methods were performed. All reproducibility isolates passed established acceptance criteria and no isolates were falsely identified.

The reproducibility study for aerobic Gram-negative bacteria was previously reported in 510(k) K130831.

b. *Linearity/assay reportable range:*

Not applicable, qualitative assay.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

US IVD BTS is used for mass spectrum calibration and optimization as well as a performance control for the identification of microorganisms with the MALDI Biotyper CA System. US IVD BTS contains a manufactured extract of *Escherichia coli* DH5 alpha that demonstrates a characteristic peptide and protein profile mass spectrum, when tested on the MALDI Biotyper CA System. US IVD BTS is spiked with two additional proteins that extend the upper boundary of the mass range of the US IVD BTS. The overall mass range covered by US IVD BTS is 3.6 to 17 kDa. Two US IVD BTS control positions on a US IVD 48 Spot Target are selected and inoculated with US IVD BTS solution. The US IVD BTS solution is allowed to dry at room temperature and then overlaid with reconstituted US IVD HCCA portioned solution. If US IVD BTS does not meet all required performance specifications, the test run will be invalid. If US IVD BTS is not inoculated onto a target prior to processing, the test run will be invalid.

Controls:

The external control organism testing is outlined below:

- Gram-Negative (aerobic/anaerobic) Test Organism: Run one (1) of the Gram-Negative QC organisms via whatever testing methodology is included on the target plate (i.e., DT, eDT or Ext)
- The Haemophilus Quality control organism should be tested only if the site is testing an organism suspected to be a Haemophilus.
- Gram-Positive (aerobic/anaerobic) Test Organism: Run one (1) of the Gram-Positive QC organisms via whatever testing methodology is included on the target plate (i.e., DT, eDT or Ext)
- Yeast Test Organism: Run one (1) of the Gram-Positive QC organisms via whatever testing methodology is included on the target plate (i.e., DT, eDT or Ext).

The following external quality control test organisms were included in the clinical trial:

For Gram-negative bacteria:

- *Enterobacter cloacae*: ATCC: 13047 = DSM 30054
- *Klebsiella pneumoniae*: ATCC: 13883 = DSM 30104
- *Proteus vulgaris*: ATCC: 29905 = DSM 13387
- *Pseudomonas aeruginosa*: ATCC: 10145 = DSM 50071
- *Escherichia coli*: ATCC: 25922 = DSM 1103

For Haemophilus samples:

- Haemophilus influenzae: ATCC: 49766 = DSM 11970 (for Chocolate Agar)

For Gram positive bacteria:

- Enterococcus faecalis: ATCC: 17433T = DSM 20478T
- Enterococcus faecium: ATCC: 19434T = DSM 20477T
- Staphylococcus aureus: ATCC: 12600T = DSM 20231T

If the QC organism is not correctly identified or yields a log(score) <2.00, the run was considered invalid. All isolates and QC organisms were re-spotted using a new target plate and testing repeated.

Of the 795 Quality Control runs conducted during the course of the method comparison study, there were forty (40) instances where a Quality Control organism failed to yield an expected result. As a result, all isolates included in that plate run for the appropriate methodology were repeated using a fresh QC organism transfer. The overall plate repeat rate was 5.0% (40/795). All repeat testing of QC organisms provided valid results.

d. Limit of Detection/Dynamic Range:

The Limit of Detection study was conducted to estimate the dynamic range (in terms of sample amount) of Gram-positive bacteria and yeasts to be identified on the MALDI Biotyper CA System. Six (6) frequently occurring clinically relevant test organisms [three (3) Gram-positive and three (3) yeast] were chosen for this study. [NOTE: Due to the nature of yeast organisms, dynamic range studies using known yeast concentration were not feasible for the Direct Transfer procedure].

Turbidity measurements of stock suspensions containing microbial material were performed at a wavelength of 600 nm. To verify the concentration of the organisms in the dilutions, the stock suspensions of each test-organism were diluted in a series of 1:10 dilutions resulting in a final dilution of 10^7 (Gram-positive bacteria) and 10^6 (yeasts). To account for random errors, the determination of each suspension's concentration in CFU/ μ L containing microbial material was done in triplicate. All suspensions were tested in replicates of eight (8) via each testing methodology (Direct (DT), extended Direct (eDT) and Extraction (EXT)).

Table: Organism Dynamic range for the Direct, extended Direct and Extraction procedures

Test Organism	DT		eDT		EXT	
	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]
Enterococcus faecalis	1.2×10^6	6.0×10^7	3.6×10^6	1.8×10^8	3.6×10^6	1.8×10^8
Enterococcus faecium	4.5×10^7	4.5×10^7	2.1×10^6	1.1×10^8	2.1×10^6	1.1×10^8

Test Organism	DT		eDT		EXT	
	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]	Lower limit [CFU/ μ L]	Upper limit [CFU/ μ L]
Staphylococcus aureus	3.5×10^5	1.8×10^8	4.1×10^4	2.1×10^8	4.1×10^5	2.1×10^8
Candida albicans	N/A	N/A	2.0×10^5	2.0×10^6	2.0×10^6	1.0×10^7
Candida parapsilosis	N/A	N/A	2.5×10^5	2.5×10^6	2.5×10^6	1.3×10^7
Saccharomyces cerevisiae	N/A	N/A	1.5×10^5	1.5×10^6	1.5×10^5	7.5×10^6

When testing at the extremes of the defined dynamic range for all organisms tested, no incorrect MALDI Biotyper CA identifications were reported. Results at the extremes were reported as “No Peaks” or “No Identification” (i.e., no false results were reported.)

e. Analytical specificity:

To confirm specificity, all organism spectra in the MBT-CA database (179 bacteria/group/complex claims with 5-74 strains per each organism/group/complex and 31 yeasts with 5-14 strains per each organism for a total of 2020 spectra) and MBT-non-clinically validated databases (930 microorganisms (1-16 strains each) for a total of 1999 spectra) were cross-checked *in silico* against each other. If an indication for the possibility of cross-matching patterns was found, the organism was included in the matching hint table found in the package labelling.

f. Assay cut-off:

Using statistical analysis, a probability ranking of the organism identification is generated. The probability ranking is represented as a log (score) between 0.00 and 3.00.

Organism identification (direct or extracted) is reported with high confidence if the log(score) is ≥ 2.00 . If a direct transfer organism identification log(score) is < 2.00 ; the user is instructed to follow and extraction procedure (eDT or EXT).

After extraction:

- If the organism identification log(score) is between 1.7 and < 2.0 , the identification is reported as low confidence.
- If the organism identification log(score) is < 1.7 , it is reported as ‘No Identification’.

Some MBT-CA identifications results are non-clinically validated organisms and are displayed in the MBT-CA report in the interest of public health as a means of directing the required additional laboratory testing. Non-clinically validated organism results are created from reference patterns which have not been clinically validated. ‘No Identification’ is reported based on the validated reference pattern (MSP) library if a result from the non-clinically validated reference pattern (MSP) library was found

to yield a higher log(score) value. The non-clinically validated result is added as a comment (grey in square brackets) below the 'No Identification' result. Identification of non-clinically validated organisms must be performed with an alternate laboratory method. Results for non-clinically validated organisms cannot be transmitted from the MBT-CA to the laboratory information system.

The log(score) value ranges defined in the MALDI Biotyper CA System reflect the probability of organism identification. Results should be reviewed by a trained microbiologist and final organism identification should be based on all relevant information available. This information includes, but is not limited to, Gram staining, colony morphology, growth characteristics, sample matrix, or other factors that might impact organism identification.

g. Stability studies (reagent/target plates):

US IVD Bacterial Test Standard (BTS) - see K130831

HCCA portioned (Matrix) Stability - see K130831

Target plate stability - see K130831

h. Carry-Over and Cross Contamination: See K130831

i. Influence of Agar Media

Testing was conducted using three (3) Gram-positive bacteria, three (3) yeasts, five (5) anaerobic bacteria, two (2) Campylobacter and three (3) Bordetella species at varying incubation time points in replicates of eight (8). After initial testing, isolates were further tested at room temperature after twelve (12) hours post-incubation.

The following media were tested:

- Chocolate Agar (CHOC)
- Columbia CNA agar with 5% sheep blood (CNA)
- Brucella Agar with 5% horse blood (BRU)
- CDC anaerobe Agar with 5% sheep blood (CDC)
- CDC anaerobe 5% sheep blood Agar with phenylethyl alcohol (CDC/PEA)
- CDC anaerobe laked sheep blood Agar with kanamycin and vancomycin (CDC/LKV)
- Bacteroides bile esculin Agar with amikacin (BBE)
- Clostridium difficile Agar with 7% sheep blood (CDA)
- Trypticase Soy Agar with 5% sheep blood (TSA)
- Sabouraud-Dextrose Agar (SDA)
- Brain-Heart Infusion Agar (BHI)
- Campylobacter Agar with 5 Antimicrobics and 10% sheep blood (CAMPY BAP)
- Bordet Gengou Agar with 15% sheep blood (BGA)
- Columbia Blood Agar with 5% sheep blood (CBA)

Study results demonstrate for measurement in the MALDI Biotyper CA System, isolates must be tested from a fresh culture - 18-48 hours incubation - or 12 hours post incubation at room temperature (total 60 hours). Specific requirements:

- Bordetella: Incubation on BG agar should not be longer than 24h (+12h storage at RT).
- Campylobacter: Incubation can be prolonged to 72h (+12h storage at RT).
- Streptococcus pneumoniae: Incubation should not be longer than 24h (+12h storage at RT) due to possible autolysis.

The following media were previously validated and reported in 510(k) K130831:

- Trypticase Soy Agar with 5% sheep blood (TSA)
- Columbia Blood Agar with 5% sheep blood (CBA)
- MacConkey Agar (MAC)
- Chocolate Agar (Choc)

j. Organism Stability prior to MALDI Biotyper CA System Analysis

The organism stability study for Gram-negative bacteria prior to MALDI Biotyper CA analysis was previously validated and reported in 510(k) K130831.

Gram-positive samples are stable on the target plate using both Direct Transfer and Extraction procedure for up to 60 minutes prior to matrix addition. In addition, the study confirmed that extracts are stable for up to 24 hours when stored at room temperature. The study and subsequent results confirm that yeast samples are stable on the target plate via Direct Transfer, extended Direct Transfer and Extraction method for up to 30 minutes prior to matrix addition. In addition, the study confirmed that extracts are stable for up to 4 hours when stored at room temperature.

k. Validation of extended Direct Transfer Technique

This study served to validate the extended Direct Transfer technique (eDT) for Gram-negative bacteria, Gram-positive bacteria and yeasts. Stability of directly transferred test organisms on the target plate in combination with delayed 70% aqueous formic acid addition and/or delayed matrix addition at ambient temperature (23 ± 2)°C prior to MALDI Biotyper CA analysis were performed. To validate extended Direct Transfer technique prior to MALDI Biotyper CA analysis, the following Gram-negative, Gram-positive and yeast organisms were cultured on Trypticase Soy Agar (TSA) and tested:

Test Organism	DSM Strain
Escherichia coli	1103
Pseudomonas aeruginosa	50071
Proteus vulgaris	13387
Enterococcus faecalis	20478 ^T
Enterococcus faecium	20477 ^T

Staphylococcus aureus	20231 ¹
Candida albicans	1665
Candida parapsilosis	5784 ¹
Saccharomyces cerevisiae	70449 ¹

The study results confirmed sample stability and MALDI Biotyper CA identification for the following settings:

- Directly transferred microbial material on MALDI target plates in combination with a delay of up to 2 h for 70% aqueous formic acid addition at $(23 \pm 2)^{\circ}\text{C}$.
- Extended Direct Transfer method in combination with a delay of up to 2 h for HCCA matrix addition at $(23 \pm 2)^{\circ}\text{C}$.
- Delayed (up to 2 h) extended Direct Transfer method in combination with delayed (up to 2 h) HCCA matrix addition at $(23 \pm 2)^{\circ}\text{C}$.

l. Sample Stability Overlaid with Matrix

The sample stability study on target plates for Gram-negative bacteria was previously validated and reported in 510(k) K130831.

To test the stability of test organisms in matrix after inoculation of the target the following Gram-positive bacteria and yeasts were selected and tested:

Test Organism	DSM Strain
Enterococcus faecalis	20478 ¹
Enterococcus faecium	20477 ¹
Staphylococcus aureus	20231 ¹
Candida albicans	1665
Candida parapsilosis	5784 ¹
Saccharomyces cerevisiae	70449 ¹

All study results confirmed that inoculated test organisms once overlaid with matrix are stable for up to 24 hours at room temperature ($20 - 25^{\circ}\text{C}$).

m. Other supportive Instrument Performance Characteristics

Mixed Culture: See K130831

Viability Study: Viability studies with organisms mixed with matrix on the target plate were not performed. The user is advised to consider all samples, microbial cultures and inoculated products as infectious. Aseptic techniques and usual precautions for handling organisms should be observed throughout the MALDI Biotyper CA System workflow according to "CLSI M29-A, Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Current revision". For additional handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH -Latest edition".

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable. Refer to the Clinical Studies section of this document.

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Proficiency/Familiarity

Prior to a site starting the clinical study, new sites (i.e., sites that did not participate in K130831) were trained on the MBT-CA System. All sites (including those previously involved in the K130831 study) will test a panel of organisms using "Direct Transfer procedure" (DT), "extended Direct Transfer procedure" (eDT), and Extraction (EXT) procedure. All operators responsible for testing during the study will participate in an initial five day proficiency testing period. Samples tested included a panel of Gram-positive quality control organisms. Samples tested also included Gram-negative quality control organisms for operators that did not participate in the proficiency testing for K130831 (i.e., new sites).

Challenge Panel

A panel of 55 organisms (24 Gram-positive aerobic bacteria, one (1) Gram-negative microaerophilic bacterium, four Gram-negative anaerobic bacteria, six (6) Gram-positive anaerobic bacteria, 20 yeasts) was tested at four (4) study sites. The study reference laboratory, prepared the panel. Organism identifications were blinded to test sites. Each site tested the challenge panel member via direct transfer and extended direct transfer method in accordance with product instructions. If DT and/or eDT result yielded a log(score) <2.00, the organism was retested using the Extraction method. No incorrect identifications occurred. A total 93% of test organisms were correctly identified with a log(score) ≥ 2 result applying the MBT-CA workflow.

Table: Challenge Panel Study Summary

Test procedure	Site A ≥2.0 ID	Site B ≥2.0 ID	Site C ≥2.0 ID	Site D ≥2.0 ID	Sites A - D ≥2.0 ID
DT method	46/55 (84%)	47/55 (85%)	35/55 (64%)*	36/55 (65%)	164/220 (75%)
eDT method	47/55 (85%)	50/55 (91%)	44/55 (80%)*	43/55 (78%)	184/220 (84%)
Ext method	54/55 (98%)	53/55 (96%)	49/55 (89%)	37/55 (67%)	193/220 (88%)
Overall MBT-CA workflow	54/55 (98%)	55/55 (100%)	49/55 (89%)	46/55 (84%)	204/220 (93%)

* One sample was incorrectly identified due to a mixed culture.

Prospective Clinical Study:

Testing was performed at seven clinical sites using Direct Transfer (DT) and extended Direct Transfer (eDT) of an organism to the target plate. If the MALDI Biotyper CA System identification of the test organism did not result in a bacteria or yeast identification with DT log(score) value of ≥ 2.00 , repeat testing was performed using the extraction procedure. Approximately 29% of all clinical results required extraction.

The reference algorithm used in the clinical study was a composite of nucleic acid sequencing using the cutoff values for percent identity scores and sequence analysis (i.e., review of ambiguous bases, review of first 100 GenBank results) as set forth in “CLSI MM18-A Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing”, protein sequencing, and biochemical testing. Due to similarities in sequence and other biochemical characteristics, some organisms in the MBT-CA claimed organism list could not be uniquely identified using the reference algorithm. In these cases the reference algorithm was indicated as low resolution and a hint for the unresolved species was listed in the Matching Hint Table found in the package insert.

The following tables summarize MALDI Biotyper CA System results for the prospective clinical study.

Table: Overall Performance of MBT-CA for All Organisms*

	REFERENCE ALGORITHM			Total
	High Resolution Species	Low Resolution Species/Genus	Negative	
Organism ID ≥ 2.0 (High Confidence)	3817	392	18 ^{1,2}	4227
Organism ID (≥ 1.7 ; < 2.0) (Low Confidence)	107	13	9 ^{3,4}	129
Incorrect MBT-CA ID (≥ 1.7) No ID (< 1.7)	42 ⁵	1 ⁵	0	43
Total	3966	406	27	4399

*See Table below for organisms corresponding to footnotes

1. MBT-CA Organism ID ≥ 2.0 ; Correct genus ID - Incorrect species ID (13 isolates); Reference Method reported a different organism.
2. MBT-CA Organism ID ≥ 2.0 ; Incorrect Genus (5 isolates); Reference Method reported a different organism.
3. MBT-CA Organism ID (≥ 1.7 - < 2.0); Correct genus ID - Incorrect species ID (8 isolates); Reference Method reported a different organism.
4. MBT-CA Organism ID (≥ 1.7 - < 2.0); Incorrect Genus (1 isolates); Reference Method reported a different organism
5. MBT-CA Incorrect Organism ID ≥ 1.7 ; no ID < 1.7 (43 isolates); Reference Method reported a species from the included in the MBT-CA Reference Library.

FOOTNOTE	MBT-CA RESULT	REFERENCE ALGORITHM
1	Acinetobacter haemolyticus	A.gyllenbergii
	Acinetobacter johnsonii	A.lwoffii
	Acinetobacter junii	A.venetianus
	Chryseobacterium gleum	C.bernardetii
	Chryseobacterium gleum	C.bernardetii
	Chryseobacterium gleum	C.indologenes
	Rhizobium radiobacter	R.nepotum
	Rhizobium radiobacter	R.massiliae
	Rhizobium radiobacter	O.anthropi
	S.pneumoniae	S.mitis / oralis
	S.pneumoniae	S.mitis / oralis
	Staphylococcus haemolyticus	S.intermedius
	Streptococcus dysgalactiae	S.canis
2	Bacteroides thetaiotaomicron	P.distasonis
	Campylobacter coli	Shigella dysenteriae
	Candida dubliniensis	Lactobacillus casei
	Prevotella buccae	Slackia exigua
	Staphylococcus epidermidis	Actinomyces neuii
3	Chryseobacterium indologenes	C.gleum
	Enterobacter amnigenus	E.asburiae
	Enterococcus hirae	E.durans
	Peptoniphilus harei	P.timonensis
	Streptococcus dysgalactiae	S.equi
	Streptococcus gordonii	S.lactarius
	Streptococcus gordonii	S.rubneri
	Streptococcus gordonii	S.parasanguinis

FOOTNOTE	MBT-CA RESULT	REFERENCE ALGORITHM
4	Staphylococcus haemolyticus	Nosocomiicoccus ampullae
5	Corynebacterium aurimucosum	C.aurimucosum
	Corynebacterium aurimucosum	C.aurimucosum
	Corynebacterium aurimucosum	C.singulare
	Finegoldia magna	F.magna
	Kytococcus sedentarius	K.sedentarius
	Parabacteroides distasonis	P.distasonis
	Propionibacterium acnes	P.acnes
	Staphylococcus hominis	S.hominis
	Staphylococcus simulans	S.simulans
	Staphylococcus simulans	S.simulans
	Actinomyces odontolyticus	A.odontolyticus
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Aerococcus viridans	A.urinaeequi
	Corynebacterium aurimucosum	C.singulare
	Staphylococcus carnosus	S.carnosus
	Candida boidinii	C.boidinii
	Candida dubliniensis	C.dubliniensis
	Candida dubliniensis	C.dubliniensis
	Candida guilliermondii	Meyerozyma caribbica
	Candida guilliermondii	Meyerozyma caribbica
	Candida guilliermondii	Meyerozyma caribbica
	Candida guilliermondii	Meyerozyma caribbica
	Candida guilliermondii	Meyerozyma caribbica
	Candida lambica	Pichia fermentans
	Candida lambica	Pichia fermentans
	Candida metapsilosis	C.metapsilosis
	Candida tropicalis	C.tropicalis
	Candida tropicalis	C.tropicalis
	Cryptococcus neoformans var grubii	C.neoformans
	Cryptococcus neoformans var grubii	C.neoformans
	Geotrichum capitatum	Geotrichum capitatum
	Saccharomyces cerevisiae	S.cerevisiae
	Actinomyces neuui	S. epidermidis
Streptococcus pneumoniae	S. mitis / oralis group	
Streptococcus pneumoniae	S. mitis / oralis group	

Performance table(s) abbreviation key:

- # Isolates (MM) – number of isolates used for multiple measurement testing (total multiple measurements performed);
- Reference Algorithm (HIGH) - Reference Algorithm High Resolution
- Reference Algorithm (LOW) - Reference Low Resolution

Table: Overall Performance of MBT-CA for Organism Groups

	Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
	MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
All	3079	389	52	12	10	5	5	3	5	0	1	0	22	1
Bacteria	85.9%	10.9%	1.5%	0.3%	0.3%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.6%	0.0%
All Yeast	738	3	55	1	0	0	0	0	1	0	0	0	17	0
	90.6%	0.4%	6.7%	0.1%	0.0%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	2.1%	0.0%
Anaerobes	482	34	5	1	0	0	1	0	3	0	0	0	4	0
	90.8%	6.4%	0.9%	0.2%	0.0%	0.0%	0.2%	0.0%	0.6%	0.0%	0.0%	0.0%	0.8%	0.0%
Gram-Negatives	607	160	6	7	6	3	2	0	1	0	0	0	0	0
	76.6%	20.2%	0.8%	0.7%	0.8%	0.4%	0.3%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%
Gram-Positives	1990	195	41	4	4	2	2	3	1	0	1	0	18	1
	88.0%	8.6%	1.8%	0.2%	0.2%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	80.0%	0.0%

Individual organism (measurand) performance is provided in the tables below. Due to the low prevalence of some organisms, multiple measurements (replicates) of clinical study isolates were tested by multiple testing sites to generate additional data to support performance of the MBT-CA System. The number of clinical isolates used for replicate testing and the number of replicates performed for that set of clinical isolates are listed in a column adjacent to the prospective study performance results of all clinical isolates (i.e., clinical isolates without replicate testing) for each organism claim. Results from the 3,802 replicate testing results were reviewed separately from the method comparison isolates; multiple measurements were used as supplementary data to support all claims.

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA <1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Acinetobacter haemolyticus	7(65)	11	2	0	0	1	0	0	0	0	0	0	0	0	0
		78.6%	14.3%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Acinetobacter johnsonii	9(25)	34	0	0	0	1	0	0	0	0	0	0	0	0	0
		97.1%	0.0%	0.0%	0.0%	2.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Acinetobacter junii	11(32)	39	4	0	1	1	0	0	0	0	0	0	0	0	0
		86.7%	8.9%	0.0%	2.2%	2.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Actinomyces meyerii	3(33)	3	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Actinomyces neuui	10(29)	26	0	0	0	0	0	0	0	1	0	0	0	0	0
		96.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Actinomyces odontolyticus	8(56)	18	0	0	0	0	0	0	0	0	0	0	0	0	1
		94.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.3%
Actinomyces oris	5(30)	10	6	0	0	0	0	0	0	0	0	0	0	0	0
		62.5%	37.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Aerococcus urinae	0	51	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Aerococcus viridans	2(8)	10	0	12	0	0	0	0	0	0	0	0	0	0	10
		31.3%	0.0%	37.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	31.3%
Aeromonas salmonicida	9(54)	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Anaerococcus vaginalis	12(42)	10	4	0	0	0	0	0	0	0	0	0	0	0	0
		71.4%	28.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bacteroides fragilis	1(1)	44	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bacteroides ovatus group	12(12)	14	18	0	0	0	0	0	0	0	0	0	0	0	0
		43.8%	56.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bacteroides thetaiotaomicron group	0	29	0	0	0	0	0	0	0	1	0	0	0	0	0
		96.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.3%	0.0%	0.0%	0.0%	0.0%	0.0%
Bacteroides uniformis	11(37)	13	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bacteroides vulgatus group	14(21)	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bordetella group[3]	8(69)	0	19	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bordetella hinzii	2(20)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Brevibacterium casei	7(20)	11	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Brevundimonas diminuta group	8(48)	0	29	0	2	0	0	0	0	0	0	0	0	0	0
		0.0%	93.5%	0.0%	6.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Campylobacter coli	9(21)	11	0	0	0	0	0	0	0	1	0	0	0	0	0
		91.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	8.3%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Campylobacter jejuni	2(20)	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Campylobacter ureolyticus	1(7)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Capnocytophaga ochracea	4(40)	2	2	0	0	0	0	0	0	0	0	0	0	0	0
		50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Capnocytophaga sputigena	4(36)	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chryseobacterium gleum	2(30)	10	0	0	0	2	1	0	0	0	0	0	0	0	0
		76.9%	0.0%	0.0%	0.0%	15.4%	7.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chryseobacterium indologenes	5(55)	15	0	1	0	0	0	1	0	0	0	0	0	0	0
		88.2%	0.0%	5.9%	0.0%	0.0%	0.0%	5.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Clostridium difficile	3(9)	26	1	0	0	0	0	0	0	0	0	0	0	0	0
		96.3%	3.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Clostridium perfringens	0	34	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium amycolatum	3(5)	5	35	0	0	0	0	0	0	0	0	0	0	0	0
		12.5%	87.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium aurimucosum group	13(23)	24	0	1	0	0	0	0	0	0	0	0	0	3	1
		82.8%	0.0%	3.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.3%	3.4%
Corynebacterium bovis	7(33)	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium diphtheriae	2(21)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium glucuronolyticum	3(33)	3	1	0	0	0	0	0	0	0	0	0	0	0	0
		75.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium jeikeium	6(41)	30	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium kroppenstedtii	3(30)	5	0	2	0	0	0	0	0	0	0	0	0	0	0
		71.4%	0.0%	28.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium macginleyi	3(30)	4	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium minutissimum	2(30)	1	1	1	0	0	0	0	0	0	0	0	0	0	0
		33.3%	33.3%	33.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium propinquum	11(29)	31	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium pseudodiphtheriticum	11(24)	25	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium riegelii	1(15)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium striatum group	2(2)	43	4	1	0	0	0	0	0	0	0	0	0	0	0
		89.6%	8.3%	2.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium tuberculostearicum	5(26)	9	0	2	0	0	0	0	0	0	0	0	0	0	0
		81.8%	0.0%	18.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Corynebacterium ulcerans	1(11)	0	3	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium urealyticum	3(23)	10	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Corynebacterium xerosis	1(15)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cronobacter sakazakii group	15(43)	37	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cupriavidus pauculus group	2(36)	10	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Delftia acidovorans group	12(35)	40	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dermacoccus nishinomiyaensis	3(35)	4	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edwardsiella tarda	4(45)	3	12	0	1	0	0	0	0	0	0	0	0	0	0
		18.8%	75.0%	0.0%	6.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Elizabethkingia meningoseptica group	3(46)	20	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterobacter amnigenus	5(53)	12	4	0	0	0	0	1	0	0	0	0	0	0	0
		70.6%	23.5%	0.0%	0.0%	0.0%	0.0%	5.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus avium group	0	53	0	2	0	0	0	0	0	0	0	0	0	0	0
		96.4%	0.0%	3.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus casseliflavus	11(11)	48	0	1	0	0	0	0	0	0	0	0	0	0	0
		98.0%	0.0%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus faecalis	0	60	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus faecium	0	58	1	0	0	0	0	0	0	0	0	0	0	0	0
		98.3%	1.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus gallinarum	0	30	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterococcus hirae	5(10)	17	0	0	0	0	0	0	1	0	0	0	0	0	0
		94.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Finegoldia magna	0	38	0	2	0	0	0	0	0	0	0	0	0	1	0
		92.7%	0.0%	4.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.4%	0.0%
Fusobacterium canifelinum	3(23)	0	3	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fusobacterium necrophorum	3(29)	3	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fusobacterium nucleatum	3(32)	4	0	2	1	0	0	0	0	0	0	0	0	0	0
		57.1%	0.0%	28.6%	14.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Gardnerella vaginalis	4(40)	5	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Gemella haemolysans	3(30)	8	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Gemella sanguinis	3(30)	3	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Granulicatella adiacens	2(25)	17	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Haemophilus haemolyticus	7(28)	21	9	1	0	0	0	0	0	0	0	0	0	0	0
		67.7%	29.0%	3.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Haemophilus influenzae	0	66	8	0	0	0	0	0	0	0	0	0	0	0	0
		89.2%	10.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Haemophilus parahaemolyticus group	7(32)	16	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Kingella kingae	11(54)	14	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Kocuria kristinae	3(24)	13	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Kytococcus sedentarius	2(20)	2	0	0	0	0	0	0	0	0	0	0	0	1	0
		66.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%
Lactococcus garvieae	5(19)	16	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Lactococcus lactis	2(20)	11	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Leuconostoc mesenteroides	3(30)	0	7	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Macrococcus caseolyticus	4(37)	10	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Micrococcus luteus	0	52	0	0	1	0	0	0	0	0	0	0	0	0	0
		98.1%	0.0%	0.0%	1.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Moraxella _sg_Moraxella nonliquefaciens	12(58)	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Myroides odoratimimus	6(40)	1	21	0	0	0	0	0	0	0	0	0	0	0	0
		4.5%	95.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Myroides odoratus	3(38)	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Oligella ureolytica	3(41)	7	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Oligella urethralis	11(54)	26	0	3	0	0	0	0	0	0	0	0	0	0	0
		89.7%	0.0%	10.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Parabacteroides distasonis	9(42)	10	2	0	0	0	0	0	0	0	0	0	0	0	0
		76.9%	15.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.7%
Pediococcus pentosceus	3(30)	5	0	1	0	0	0	0	0	0	0	0	0	0	0
		83.3%	0.0%	16.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Peptoniphilus harei group	0	31	0	0	0	0	0	1	0	0	0	0	0	0	0
		96.9%	0.0%	0.0%	0.0%	0.0%	0.0%	3.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Peptostreptococcus anaerobius	17(45)	20	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plesiomonas shigelloides	15(41)	28	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Porphyromonas gingivalis	1(11)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Prevotella bivia	7(7)	24	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Prevotella buccae	3(35)	3	0	0	0	0	0	0	0	1	0	0	0	0	0
		75.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Prevotella denticoa	2(23)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Prevotella intermedia	2(26)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Prevotella melaninogenica	2(20)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Propionibacterium acnes	0	52	0	1	0	0	0	0	0	0	0	0	0	1	0
		96.3%	0.0%	1.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.9%	0.0%
Pseudomonas oryzae	19(43)	0	36	0	2	0	0	0	0	0	0	0	0	0	0
		0.0%	94.7%	0.0%	5.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pseudomonas stutzeri	8(26)	43	6	0	0	0	0	0	0	0	0	0	0	0	0
		87.8%	12.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rhizobium radiobacter	7(40)	27	0	1	0	1	2	0	0	0	0	0	0	0	0
		87.1%	0.0%	3.2%	0.0%	3.2%	6.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rothia aeria	4(42)	3	1	0	0	0	0	0	0	0	0	0	0	0	0
		75.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rothia dentocariosa	9(18)	12	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Rothia mucilaginosa	0	37	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Serratia plymuthica	3(30)	3	6	0	1	0	0	0	0	0	0	0	0	0	0
		30.0%	60.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Serratia rubidaea	4(63)	10	2	0	0	0	0	0	0	0	0	0	0	0	0
		83.3%	16.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus aureus	0	61	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus auricularis	17(17)	25	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus capitis	0	49	1	1	0	0	0	0	0	0	0	0	0	0	0
		96.1%	2.0%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus caprae	5(5)	50	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus camosus	3(29)	0	7	0	0	0	0	0	0	0	0	0	0	0	1
		0.0%	87.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12.5%
Staphylococcus cohnii	5(10)	42	0	1	0	0	0	0	0	0	0	0	0	0	0
		97.7%	0.0%	2.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus epidermidis	0	67	0	0	1	0	0	0	0	1	0	0	0	0	0
		97.1%	0.0%	0.0%	1.4%	0.0%	0.0%	0.0%	0.0%	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus equorum	4(35)	11	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus felis	3(30)	4	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus haemolyticus	0	49	0	4	0	0	1	0	0	0	0	1	0	0	0
		89.1%	0.0%	7.3%	0.0%	0.0%	1.8%	0.0%	0.0%	0.0%	0.0%	1.8%	0.0%	0.0%	0.0%
Staphylococcus hominis	0	57	0	0	1	0	0	0	0	0	0	0	0	1	0
		96.6%	0.0%	0.0%	1.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.7%	0.0%
Staphylococcus lugdunensis	0	57	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus pasteurii	5(10)	24	0	2	0	0	0	0	0	0	0	0	0	0	0
		92.3%	0.0%	7.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus pettenkoferi	0	56	0	1	0	0	0	0	0	0	0	0	0	0	0
		98.2%	0.0%	1.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus pseudintermedius	0	0	59	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus saccharolyticus	1(10)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Organism	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Staphylococcus saprophyticus	0	0	59	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus schleiferi	0	29	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus simulans	0	46	0	1	0	0	0	0	0	0	0	0	0	2	0
		0.0%	100.0%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.1%	0.0%
Staphylococcus vitulinus	3(30)	0	10	0	0	0	0	0	0	0	0	0	0	0	0
		0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Staphylococcus warneri	0	55	0	2	0	0	0	0	0	0	0	0	0	0	0
		96.5%	0.0%	3.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus agalactiae	0	63	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus anginosus	0	68	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus constellatus	2(8)	40	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus dysgalactiae	0	58	0	0	0	1	0	1	0	0	0	0	0	0	0
		96.7%	0.0%	0.0%	0.0%	1.7%	0.0%	1.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus gallolyticus	1(4)	34	0	1	0	0	0	0	0	0	0	0	0	0	0
		97.1%	0.0%	2.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus gordonii	6(16)	27	0	0	0	0	0	1	2	0	0	0	0	0	0
		90.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.3%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus intermedius	6(14)	42	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus lutetiensis	2(22)	18	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus mitis / oralis group	1 isolate S. mitis (9)	61	6	3	1	2	0	0	0	0	0	0	0	0	0
		83.6%	8.2%	4.1%	1.4%	2.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus mutans	2(16)	25	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus pneumoniae	0	30	0	0	0	1	1	0	0	0	0	0	0	0	0
		93.8%	0.0%	0.0%	0.0%	3.1%	3.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus pyogenes	0	56	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Streptococcus salivarius	3(28)	59	0	2	0	0	0	0	0	0	0	0	0	0	0
		96.7%	0.0%	3.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Sutterella wadsworthensis	2(26)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vibrio parahaemolyticus	2(16)	20	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vibrio vulnificus	3(27)	13	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Yeast	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Candida albicans	0	49	0	1	0	0	0	0	0	0	0	0	0	0	0
		98.0%	0.0%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida boidinii	8(36)	7	0	0	0	0	0	0	0	0	0	0	0	1	0
		87.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12.5%	0.0%
Candida dubliniensis	5(13)	34	0	5	0	0	0	0	0	1	0	0	0	2	0
		81.00%	0.0%	11.9%	0.0%	0.0%	0.0%	0.0%	0.0%	2.4%	0.0%	0.0%	0.0%	4.8%	0.0%
Candida duobushaemulonii	4(42)	5	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida famata	11(28)	10	0	1	0	0	0	0	0	0	0	0	0	0	0
		90.9%	0.0%	9.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida glabrata	1(1)	43	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida guilliermondii	18(29)	30	0	1	0	0	0	0	0	0	0	0	0	5	0
		83.3%	0.0%	2.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.9%	0.0%
Candida haemulonii	7(35)	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida inconspicua	3(29)	4	3	0	1	0	0	0	0	0	0	0	0	0	0
		50.0%	37.5%	0.0%	12.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida kefyr	13(13)	38	0	3	0	0	0	0	0	0	0	0	0	0	0
		92.7%	0.0%	7.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida krusei	4(8)	67	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida lambica	10(40)	12	0	1	0	0	0	0	0	0	0	0	0	2	0
		80.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%
Candida lipolytica	11(11)	22	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida lusitanae	6(6)	50	0	2	0	0	0	0	0	0	0	0	0	0	0
		96.2%	0.0%	3.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida metapsilosis	3(22)	2	0	3	0	0	0	0	0	0	0	0	0	1	0
		33.3%	0.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	16.7%	0.0%
Candida norvegensis	13(23)	19	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida orthopsilosis	9(34)	19	0	1	0	0	0	0	0	0	0	0	0	0	0
		95.0%	0.0%	5.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida parapsilosis	0	58	0	5	0	0	0	0	0	0	0	0	0	0	0
		92.1%	0.0%	7.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table: Organism Performance		Correct: Genus ID Correct: Species ID or Group / Complex ID				Correct: Genus ID Incorrect: Species ID or Group / Complex ID				Incorrect: Genus ID				No ID	
		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA ≥2.0		MBT-CA ≥1.7 - <2.0		MBT-CA < 1.7	
Yeast	# Isolates (MM)	Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm		Reference algorithm	
		High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low
Candida pararugosa	3(35)	3	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida pelliculosa	9(24)	12	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Candida tropicalis	11(24)	56	0	2	0	0	0	0	0	0	0	0	0	2	0
		93.3%	0.0%	3.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.3%	0.0%
Candida valida	9(35)	8	0	1	0	0	0	0	0	0	0	0	0	0	0
		88.9%	0.0%	11.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cryptococcus gattii	11(22)	14	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cryptococcus neoformans var grubii	4(10)	38	0	11	0	0	0	0	0	0	0	0	0	2	0
		74.5%	0.0%	21.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.9%	0.0%
Cryptococcus neoformans var neoformans	4(34)	8	0	2	0	0	0	0	0	0	0	0	0	0	0
		80.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Geotrichum candidum	3(33)	7	0	1	0	0	0	0	0	0	0	0	0	0	0
		87.5%	0.0%	12.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Geotrichum capitatum	10(20)	20	0	1	0	0	0	0	0	0	0	0	0	1	0
		90.9%	0.0%	4.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.5%	0.0%
Kloeckera apiculata	9(27)	9	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pichia ohmeri	10(27)	6	0	4	0	0	0	0	0	0	0	0	0	0	0
		60.0%	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Saccharomyces cerevisiae	0	53	0	10	0	0	0	0	0	0	0	0	0	1	0
		82.8%	0.0%	15.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.6%	0.0%
Trichosporon asahii	6(18)	26	0	0	0	0	0	0	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

b. *Clinical specificity*: See clinical sensitivity results

c. *Other clinical supportive data*:

Organism identification (direct or extracted) is reported with high confidence if the log(score) is ≥ 2.00 . If a direct transfer organism identification log (score) is < 2.00 ; the user is instructed to follow and extraction procedure (eDT or EXT). Performance by testing method is summarized below.

Table: Overall identification results by testing method (includes isolates and replicate testing) for bacteria and yeasts.

METHOD	SCORE	BACTERIA	YEAST
DT Alone	≥ 2.0	5824 (86.8%)	731 (48.9%)
	$\geq 1.7 - < 2.0$	547 (8.2%)	224 (15.0%)
	< 1.7	337 (5.0%)	539 (36.1%)
	Total	6708	1494
DT with eDT	≥ 2.0	6309 (94.7%)	1193 (81.6%)
	$\geq 1.7 - < 2.0$	245 (3.7%)	168 (11.5%)
	< 1.7	105 (1.6%)	101 (6.9%)
	Total	6659	1462
DT with EXT	≥ 2.0	6491 (97.0%)	1220 (83.4%)
	$\geq 1.7 - < 2.0$	160 (2.4%)	156 (10.7%)
	< 1.7	39 (0.6%)	87 (5.9%)
	Total	6690	1463

4. Clinical cut-off:
See Assay cut-off
5. Expected values/Reference range:
See Assay cut-off

N. Instrument Name: MBT CA System

O. System Descriptions: Also see K130831

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes or No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

The user manually enters the specimen identification information into the MALDI Biotyper CA System. The user first defines active sample positions (see section 4.2.1 of User Manual) and US IVD BTS control positions (see section 4.2.2 of User Manual). The defined sample positions are required to have a user entered and valid sample identifier in the Id column along with an optional description. All inoculated positions must contain a valid ID before the run can proceed. After all sample positions have been input, at least two US IVD BTS control positions must be defined. It is recommended that the cross-joint positions on the target are used as quality control positions.

Alternatively, the user can use an optional Honeywell (Hyperion 1300g) Barcode Reader USB cable is connected to the MALDI Biotyper CA System computer. The barcode reader scans the unique ten-digit target ID which appears in the Target ID box on the target plate. After the target ID has been entered, the a new Run page opens and the ten-digit target ID appears as the Plate Id and is appended to the Run name. Sample identifications are entered into the computer corresponding to the target plate position for that run.

4. Specimen Sampling and Handling:

After incubation of bacteria on recommended isolation media for 18–24 h at (37°C ±2°C), colonies are stable for up to 12 h when held at room temperature. See Section M.1.i. above.

Using a sterile colony transfer device, smear isolated colonies of bacteria as a thin film directly onto a sample position on a cleaned target. Inoculating an appropriate amount of the test organism onto the target is important. Excessive or insufficient amounts of inoculum may impact organism identification. The User Manual visually illustrates suitable and unsuitable inoculum amounts of organism on target.

Each of the sample positions and US IVD BTS control positions are overlaid with 1 µL US IVD HCCA portioned solution. Use a new pipette tip to add matrix to each inoculated sample position. Dry the inoculated plate at room temperature. The inoculated MALDI target plate is now ready for use. For stability see Sections M.1.j and M.1.k above.

If the MALDI BIOTYPER CA System identification of the test organism does not result in a bacterial identification with a log(score) value of ≥ 2.0 , repeat testing using the extraction procedure in Section 3.6 of the User Manual. Briefly, the extraction of a sample from an isolated colony consists of multiple washing cycles of ethanol and water

followed by addition of formic acid and acetonitrile followed by a centrifugation step. After centrifugation, a sample of the supernatant is applied to the target plate, dried and loaded into the MALDI Biotyper CA System for analysis.

5. Calibration: See K130831
6. Quality Control: See Section M.1.c above.

P. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10, 21 CFR 801.109, and special controls of regulation 21 CFR 866. 3361.

Q. Conclusion:

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