DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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BRUKER DALTONICS, INC
MARKUS KOSTRZEWA
VICE PRESIDENT CLINICAL MASS SPECTROMETRY R&D
FAHRENHEILSTRASSE-4
BREMEN 28359
DE

March 27, 2015

Re: K142677
Trade/Device Name: MALDI Biotyper CA System
Regulation Number: 21 CFR 866.3361
Regulation Name: Mass spectrometer system for clinical use for the identification of microorganisms
Regulatory Class: II
Product Code: PEX
Dated: February 27, 2015
Received: March 2, 2015

Dear Dr. Kostrzewa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142677

Device Name

MALDI Biotyper CA System

Indications for Use *(Describe)*

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.

BACTERIA
Achromobacter xylosoxidans
Acinetobacter baumannii complex [4]
Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffii
Acinetobacter radioresistens
Acinetobacter ursingii
Actinomyces meyeri
Actinomyces neuii
Actinomyces odontolyticus
Actinomyces oris
Aerococcus urinae
Aerococcus viridans
Aeromonas salmonicida
Aeromonas sp[7]
Alcaligenes faecalis
Anaerococcus vaginalis
Bacteroides fragilis
Bacteroides ovatus group
Bacteroides thetaiotaomicron group
Bacteroides uniformis
Bacteroides vulgatus group
Bordetella group[3]
Bordetella hinzii
Brevibacterium casei
Brevundimonas diminuta group
Burkholderia cepacia complex [13]
Burkholderia gladioli
Burkholderia multivorans
Campylobacter coli
Campylobacter jejuni
Campylobacter ureolyticus
Capnocytophaga ochracea
Capnocytophaga sputigena

Chryseobacterium gleum
Chryseobacterium indologenes
Citrobacter amalonaticus complex
Citrobacter freundii complex
Citrobacter koseri
Clostridium difficile
Clostridium perfringens
Corynebacterium amycolatum
Corynebacterium aurimucosum group
Corynebacterium bovis
Corynebacterium diphtheriae
Corynebacterium glucuronolyticum
Corynebacterium jeikeium
Corynebacterium kroppenstedtii
Corynebacterium macginleyi
Corynebacterium minutissimum
Corynebacterium propinquum
Corynebacterium pseudodiphtheriticum
Corynebacterium riegelii
Corynebacterium striatum group
Corynebacterium tuberculostearicum
Corynebacterium ulcerans
Corynebacterium urealyticum
Corynebacterium xerosis
Cronobacter sakazakii group
Cupriavidus pauculus group
Delftia acidovorans group
Dermacoccus nishinomiyaensis
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia meningoseptica group
Enterobacter aerogenes
Enterobacter amnigenus
Enterobacter cloacae complex
Enterococcus avium group
Enterococcus casseliflavus
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Escherichia coli
Finegoldia magna
Fusobacterium canifelinum
Fusobacterium necrophorum
Fusobacterium nucleatum
Gardnerella vaginalis
Gemella haemolysans
Gemella sanguinis
Granulicatella adiacens
Haemophilus haemolyticus
Haemophilus influenzae
Haemophilus parahaemolyticus group
Haemophilus parainfluenzae
Hafnia alvei

Kingella kingae
Klebsiella oxytoca / Raoultella ornithinolytica
Klebsiella pneumoniae
Kocuria kristinae
Kytococcus sedentarius
Lactococcus garvieae
Lactococcus lactis
Leuconostoc mesenteroides
Macrococcus caseolyticus
Micrococcus luteus
Moraxella sg Branhamella catarrhalis
Moraxella sg Moraxella nonliquefaciens
Moraxella sg Moraxella osloensis
Morganella morganii
Myroides odoratimimus
Myroides odoratus
Oligella ureolytica
Oligella urethralis
Pantoea agglomerans
Parabacteroides distasonis
Pasteurella multocida
Pediococcus pentosaceus
Peptoniphilus harei group
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Porphyromonas gingivalis
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella melaninogenica
Propionibacterium acnes
Proteus mirabilis
Proteus vulgaris group
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa
Pseudomonas fluorescens group
Pseudomonas oryzihabitans
Pseudomonas putida group
Pseudomonas stutzeri
Rhizobium radiobacter
Rothia aeria
Rothia dentocariosa
Rothia mucilaginosa
Salmonella sp
Serratia liquefaciens
Serratia marcescens
Serratia plymuthica
Serratia rubidaea
Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus caprae

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

YEAST
Candida albicans
Candida boidinii
Candida dubliniensis
Candida duobushaemulonii
Candida famata
Candida glabrata
Candida guilliermondii
Candida haemulonis
Candida inconspicua
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitaniae
Candida metapsilosis
Candida norvegensis

Candida orthopsilosis
Candida parapsilosis
Candida pararugosa
Candida pelliculosa
Candida tropicalis
Candida valida
Cryptococcus gattii
Cryptococcus neoformans var grubii
Cryptococcus neoformans var neoformans
Geotrichum candidum
Geotrichum capitatum
Kloeckera apiculata
Pichia ohmeri
Saccharomyces cerevisiae
Trichosporon asahii

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Date of Summary: March 27, 2015

Product Name MBT-CA System

Sponsor
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Device Identification

Trade or Proprietary Name: MALDI Biotyper CA System
Common or Usual Name: System, mass spectrometry, maldi tof, microorganism identification, cultured isolates
Product Code: PEX
Regulation Section: 21 CFR 866.3361
Device Class: Class II
Panel: Microbiology

Substantial Equivalency

The Bruker Daltonics, Inc. MBT-CA System is substantially equivalent to the bioMérieux Vitek MS (K124067) and the Bruker Daltonics, Inc. MBT-CA System (K130831). Table 1 compares the characteristics of the MBT-CA System (New Device) and the Vitek MS (Predicate Device).

Table 1. Substantial Equivalency Table

Similarities			
Characteristic	NEW DEVICE Bruker Daltonics, Inc. MBT-CA System (TBD)	PRIMARY PREDICATE DEVICE Vitek® MS (K124067)	PREDICATE DEVICE Bruker Daltonics, Inc. MBT-CA System (K130831)
Product Codes	PEX	PEX	PEX
Intended use	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 Vitek® 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 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.	See "Differences"
Sample type	Isolated colony from any patient sample source. Acceptable media: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate agar • MacConkey Agar • Columbia CNA agar with 5% sheep blood • Brucella Agar with 5% horse blood • CDC anaerobe Agar with 5% sheep blood • CDC anaerobe 5% sheep blood Agar with phenylethyl alcohol • CDC anaerobe laked sheep blood Agar with kanamycin and vancomycin • Bacteroides bile esculin Agar with amikacin • Clostridium difficile Agar with 7% sheep blood • Sabouraud-Dextrose Agar • Brain Heart Infusion Agar • Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood • Bordet Gengou Agar with 15% sheep blood	Isolated colony from any patient sample source. Acceptable media: • Columbia blood agar with 5% sheep blood • Trypitcase soy agar with 5% sheep Blood • Chocolate polyvitex agar • Campylosel agar • MacConkey Agar • Modified Sabouraud dextrose Agar • ChromID CPS	Isolated colony from any patient sample source. Acceptable media: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate agar • MacConkey Agar
Type of Test	Automated Mass Spectrometry System	Automated Mass Spectrometry System	Automated Mass Spectrometry System

Similarities			
Characteristic	NEW DEVICE Bruker Daltonics, Inc. MBT-CA System (TBD)	PRIMARY PREDICATE DEVICE Vitek® MS (K124067)	PREDICATE DEVICE Bruker Daltonics, Inc. MBT-CA System (K130831)
Matrix	α-Cyano-4-hydroxycinnamic acid	α-Cyano-4-hydroxycinnamic acid	α-Cyano-4-hydroxycinnamic acid
Method of Testing	Bacteria & Yeast: Direct testing If after initial analysis the log(score) is reported at <2.00, organisms may be processed using the Extraction (Ext) procedure or extended Direct Transfer (eDT, 70% aqueous formic acid) procedure. If eDT procedure still yields log(score) <2.00, organism may be processed via Ext procedure.	Bacteria & Yeast: Direct testing	Bacteria: Direct testing If after initial analysis the log(score) is reported at <2.00, organisms are processed using the Extraction procedure.
Result Reporting	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.	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 groups are retained. When more than four organisms or organism groups are found, or when no match is found, the organism is considered unidentified.	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.
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

Similarities			
Characteristic	NEW DEVICE Bruker Daltonics, Inc. MBT-CA System (TBD)	PRIMARY PREDICATE DEVICE Vitek® MS (K124067)	PREDICATE DEVICE Bruker Daltonics, Inc. MBT-CA System (K130831)
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 • 48 positions reusable steel targets	See "Differences"	US IVD 48 Spot Target • 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			
Characteristic	NEW DEVICE Bruker Daltonics, Inc. MBT-CA System (TBD)	PREDICATE DEVICE Vitek® MS (K124067)	PREDICATE DEVICE Bruker Daltonics, Inc. MBT-CA System (K130831)
Culture Age	Bacteria and yeasts growth should be between 18h to 48h (+12h storage at RT) 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.	Bacteria and yeast growth should be between 24 to 72 hours.	Bacteria growth should be between 18h to 36h
Calibration	Bruker US IVD Bacterial Test Standard (BTS)	E. coli ATCC 8739	See "Similarities"
MALDI Target Plate	US IVD 48 Spot Target • 48 positions reusable steel targets	VITEK MS-DS Target Slides • 48 positions disposable plastic targets	See "Similarities"
MALDI-TOF MS instruments	Bruker microflex (benchtop)	Shimadzu AXIMA® Assurance MS (floor standing)	See "Similarities"
Database	MALDI Biotyper for Clinical Applications (MBT-CA)	VITEK® MS V2.0 Knowledge Base	See "Similarities"

Differences			
Characteristic	NEW DEVICE Bruker Daltonics, Inc. MBT-CA System (TBD)	PREDICATE DEVICE Vitek® MS (K124067)	PREDICATE DEVICE Bruker Daltonics, Inc. MBT-CA System (K130831)
Intended Use	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.	See "Similarities"	The Bruker Daltonics, Inc. MALDI Biotyper CA System is a qualitative *in vitro* 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.

These differences do not affect substantial equivalence of the MBT-CA System, Vitek® MS system and MBT-CA System (K130831). All systems are mass spectrometers using matrix-assisted laser desorption/ionization – time-of-flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens. The differences noted above do not impact the intended use and do not raise questions as to the safety and effectiveness of the test (new) device.

Intended Use

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	Cupriavidus pauculus group	Propionibacterium acnes
Acinetobacter haemolyticus	Delftia acidovorans group	Proteus mirabilis
Acinetobacter johnsonii	Dermacoccus nishinomiyaensis	Proteus vulgaris group
Acinetobacter junii	Edwardsiella tarda	Providencia rettgeri
Acinetobacter lwoffii	Eikenella corrodens	Providencia stuartii
Acinetobacter radioresistens	Elizabethkingia meningoseptica group	Pseudomonas aeruginosa
Acinetobacter ursingii	Enterobacter aerogenes	Pseudomonas fluorescens group
Acinetobacter baumannii complex [4]	Enterobacter amnigenus	Pseudomonas oryzihabitans
Actinomyces meyeri	Enterobacter cloacae complex	Pseudomonas putida group
Actinomyces neuii	Enterococcus casseliflavus	Pseudomonas stutzeri
Actinomyces odontolyticus	Enterococcus faecalis	Rhizobium radiobacter
Actinomyces oris	Enterococcus faecium	Rothia aeria
Aerococcus urinae	Enterococcus gallinarum	Rothia dentocariosa
Aerococcus viridans	Enterococcus hirae	Rothia mucilaginosa
Aeromonas salmonicida	Enterococcus avium group	Salmonella sp
Aeromonas sp[7]	Escherichia coli	Serratia liquefaciens
Alcaligenes faecalis	Finegoldia magna	Serratia marcescens
Anaerococcus vaginalis	Fusobacterium canifelinum	Serratia plymuthica
Bacteroides fragilis	Fusobacterium necrophorum	Serratia rubidaea
Bacteroides uniformis	Fusobacterium nucleatum	Staphylococcus aureus
Bacteroides ovatus group	Gardnerella vaginalis	Staphylococcus auricularis
Bacteroides thetaiotaomicron group	Gemella haemolysans	Staphylococcus capitis
Bacteroides vulgatus group	Gemella sanguinis	Staphylococcus caprae
Bordetella group[3]	Granulicatella adiacens	Staphylococcus carnosus
Bordetella hinzii	Haemophilus haemolyticus	Staphylococcus cohnii
Brevibacterium casei	Haemophilus influenzae	Staphylococcus epidermidis
Brevundimonas diminuta group	Haemophilus parainfluenzae	Staphylococcus equorum
Burkholderia gladioli	Haemophilus parahaemolyticus group	Staphylococcus felis
Burkholderia multivorans	Hafnia alvei	Staphylococcus haemolyticus
Burkholderia cepacia complex [13]	Kingella kingae	Staphylococcus hominis
Campylobacter coli	Klebsiella pneumoniae	Staphylococcus lugdunensis
Campylobacter jejuni	Klebsiella oxytoca / Raoultella ornithinolytica	Staphylococcus pasteuri
Campylobacter ureolyticus	Kocuria kristinae	Staphylococcus pettenkoferi
Capnocytophaga ochracea	Kytococcus sedentarius	Staphylococcus pseudintermedius
Capnocytophaga sputigena	Lactococcus garvieae	Staphylococcus saccharolyticus

Chryseobacterium gleum	Lactococcus lactis	Staphylococcus saprophyticus
Chryseobacterium indologenes	Leuconostoc mesenteroides	Staphylococcus schleiferi
Citrobacter amalonaticus complex	Macrococcus caseolyticus	Staphylococcus simulans
Citrobacter koseri	Micrococcus luteus	Staphylococcus vitulinus
Citrobacter freundii complex	Moraxella sg Branhamella catarrhalis	Staphylococcus warneri
Clostridium difficile	Moraxella sg Moraxella nonliquefaciens	Stenotrophomonas maltophilia
Clostridium perfringens	Moraxella sg Moraxella osloensis	Streptococcus agalactiae
Corynebacterium amycolatum	Morganella morganii	Streptococcus anginosus
Corynebacterium bovis	Myroides odoratimimus	Streptococcus constellatus
Corynebacterium diphtheriae	Myroides odoratus	Streptococcus dysgalactiae
Corynebacterium glucuronolyticum	Oligella ureolytica	Streptococcus gallolyticus
Corynebacterium jeikeium	Oligella urethralis	Streptococcus gordonii
Corynebacterium kroppenstedtii	Pantoea agglomerans	Streptococcus intermedius
Corynebacterium macginleyi	Parabacteroides distasonis	Streptococcus lutetiensis
Corynebacterium minutissimum	Pasteurella multocida	Streptococcus mutans
Corynebacterium propinquum	Pediococcus pentosaceus	Streptococcus pneumoniae
Corynebacterium pseudodiphtheriticum	Peptoniphilus harei group	Streptococcus pyogenes
Corynebacterium riegelii	Peptostreptococcus anaerobius	Streptococcus salivarius
Corynebacterium tuberculostearicum	Plesiomonas shigelloides	Streptococcus mitis / oralis group
Corynebacterium ulcerans	Porphyromonas gingivalis	Sutterella wadsworthensis
Corynebacterium urealyticum	Prevotella bivia	Vibrio parahaemolyticus
Corynebacterium xerosis	Prevotella buccae	Vibrio vulnificus
Corynebacterium aurimucosum group	Prevotella denticola	Yersinia enterocolitica
Corynebacterium striatum group	Prevotella intermedia	Yersinia pseudotuberculosis
Cronobacter sakazakii group	Prevotella melaninogenica	

Yeast:

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

Methodology

Biochemical methods are currently the most commonly used methods for the identification of microorganisms. Organisms are tested against a range of reagents and organism identification is based on a microorganism's reaction to these reagents.

The MBT-CA System uses a different methodology for organism identification based on unique protein patterns of the microorganisms obtained from mass spectrometry. The test organism's spectrum (a pattern of mass peaks) is compared with a reference spectra library (database). Using biostatistical 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 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.

Some MBT-CA identifications displayed are non-clinically validated organisms. In the interest of public health, these organisms are displayed but are grayed out in the MBT-CA report as a means of directing the required additional laboratory testing. These results are not reported; identifications must be confirmed using alternate laboratory methods. Results for non-clinically validated organisms cannot be transmitted from the MBT-CA to the laboratory information system.

Organisms to be identified with the MBT-CA System should be isolated for purity on appropriate isolation media.

Direct Transfer (DT): An individual colony from a subculture plate is transferred to a selected position on an US IVD 48 Spot Target plate (target) and overlaid with US IVD HCCA portioned (matrix). The standard solvent (50% acetonitrile / 47.5% H_2O / 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 MBT-CA System. If after initial analysis the log(score) is reported as <2.00, organisms can be processed using the extended Direct Transfer (eDT) procedure or the Extraction (Ext) procedure and analysis repeated. If eDT is employed and log(score) is reported as <2.00, reanalysis via the Extraction procedure may be used.

extended Direct Transfer (eDT):
If DT analysis yields a (log(score) <2.00) result, an individual colony from a subculture plate may be transferred to a selected position on a target and overlaid with 70% aqueous formic acid solution. The target is air-dried and then matrix is overlaid. When dried matrix crystallizes, the inoculated target is ready to be analyzed on the MBT-CA System. If a high confidence result is not achieved (log(score) is reported at <2.00), organisms can be processed using the Extraction procedure and analysis repeated.

Extraction procedure (Ext): If after initial analysis and eDT procedure the log(score) is reported at <2.00, organisms are processed using the Extraction procedure and analysis repeated. For this purpose, isolated colonies from the subculture plate are extracted in accordance with MBT-CA System user manual. Afterwards they are transferred to the target and treated as described above.

MALDI-TOF Analysis:
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. A laser in the MALDI- TOF mass spectrometer irradiates the matrix sample composite, causing evaporation and release of positively charged intact proteins and peptides ("soft" ionization technique). These ions are electrostatically accelerated over a short distance and arrive in the flight tube at a mass-dependent speed. 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 MBT-CA Software. The spectrum of the unknown organism is first transformed into a peak list. Using a biostatistical algorithm, this peak list is compared to the reference peak lists of organisms 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.

The log(score) ranges, defined in the MBT-CA System, are indicative of 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, etc.

Performance Data

Precision/Repeatability:

Validation of the whole MALDI Biotyper CA System was performed on six (6) working days with two (2) runs/day following manufacturer's instructions for use. Ten (10) test organisms were tested in triplicate via Direct Transfer (DT) and extended Direct Transfer (eDT) in each run. If a replicate yielded a log(score) <2.00, the test organism was repeated in triplicate via Extraction. The study also tested multiple sources of system variability including two (2) test operators, two

(2) microflex LT/SH instruments and two (2) target plates. Overall results from the precision/repeatability study are presented below.

Table 2: Overall Precision per Test Organism

Test organism	# samples measured	# samples ≥2.0 ID (DT)	# samples ≥2.0 ID (eDT)	# samples ≥2.0 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%)**

Based upon the data presented, the study confirms repeatability and precision of the MALDI Biotyper CA System independent from:

- System Operators
- microflex LT/SH instruments
- Target plates

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 was not feasible for the Direct Transfer procedure].

Turbidity measurements of stock suspensions containing microbial material were performed at a wavelength of 600 nm. To determine the amount of cfu/µL 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). 10 µL from the final diluted test-suspensions were transferred to TSA isolation media plates and incubated for 18-24h at (37±2)°C for Gram-positive bacteria and at (29±2)°C for yeasts, respectively. To account for random errors, the determination of each suspension's concentration in cfu/µL containing microbial material was done in triplicate. All suspensions were tested in replicates of eight (8) via each testing methodology (DT, eDT, Ext). Study results concluded that the estimated dynamic range for the Direct, extended Direct and Extraction procedure are as follows:

	DT		eDT		EXT	
Test Organism	Lower limit [cfu/µL]	Upper limit [cfu/µL]	Lower limit [cfu/µL]	Upper limit [cfu/µL]	Lower limit [cfu/µL]	Upper limit [cfu/µL]
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
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

Media and Colony Stability

With the inclusion of Gram-negative microaerophilic, Gram-negative anaerobic, Gram-positive aerobic and anaerobic and yeast organisms, a study on the following media was conducted to confirm acceptability of the recommended agar and the stability of the colony for up to 12 hours at room temperature after initial plate incubation prior to analysis.

- 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)

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 study results confirmed the acceptability of all culture media tested with the following parameters:

- Bacteria and yeasts growth should be between 18h to 48h (+12h storage at room temperature (RT)).

Specific requirements:

- *Bordetella*: Incubation on BG agar should not be longer than 24h (+12h storage at RT).
- *Campylobacter*: Incubation on CAMPY BAP 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.

Organism Stability Prior to MBT-CA Analysis

This study was conducted to assess Gram-positive and yeast isolate stability on the target plate prior to matrix overlay via Direct Transfer (DT), extended Direct transfer (eDT) and Extraction (Ext) procedure. Two (2) Gram-positive organisms were inoculated eight times and overlaid with matrix at five (5) different time points. Five (5) yeasts organisms were inoculated eight times and overlaid with matrix at (4) different time points. Extracts of Gram-positive bacteria and yeasts were stored at room temperature and inoculated eight times and overlaid with matrix at five (5) different time points. All testing was performed in duplicate.

The study results confirmed that Gram-positive bacteria and yeast organisms are stable on the target plate for up to 60 minutes and 30 minutes respectively prior to matrix addition. Extracts of Gram-positive bacteria and yeasts are stable at room temperature for up to 24 hours and 4 hours respectively.

Sample Stability Overlaid with Matrix

This study was conducted to assess test organism stability overlaid with matrix after inoculation on the target plate. For this study, six (6) organisms were tested (three (3) Gram-positive and three (3) yeast organisms). All organisms were subcultured and aging experiments were conducted at two (2) temperatures and two (2) different relative humidity conditions to stress the plate. Plates were inoculated with the test organism via DT, eDT and Ext procedure. Plates were then read immediately (0h) and then incubated at each test condition and analyzed at three (3) additional time points (4 hours, 8 hours and 24 hours).

The study results confirmed that organisms overlaid with matrix on the target plate are stable for up to 24 hours when stored at room temperature.

Reproducibility:

The reproducibility study for Gram-positive aerobic bacteria, Gram-negative microaerophilic bacteria, Gram-positive anaerobic bacteria, Gram-negative anaerobic bacteria and yeast organisms was carried out to confirm day-to-day reproducibility and precision of the MALDI Biotyper CA System at different clinical study sites. The study was conducted for five (5) days with two (2) runs (two (2) operators) each day per clinical site. The sources of variability tested were:

* Two (2) operators/each clinical study site
* Three (3) clinical study sites
* At least four (4) target plates/each clinical study site
* Four (4) microflex LT/SH instruments

Ten (10) well-characterized organisms were chosen for this study and tested in duplicate via Direct Transfer and extended Direct Transfer procedure in accordance with product instructions. When the DT and/or eDT log(score) was <2.00, per product instructions, the test organism was tested following Extraction procedure in duplicate.

Table 3: Overall Reproducibility Panel Testing per Test Organism using ≥2.0 MBT-CA log(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%)**
TOTAL		**467/600 (78%)**	**479/600 (80%)**	**561/600 (94%)**

94% of test organisms were correctly identified with a log(score) ≥2.00 result. In addition, no isolates were falsely identified. Thus, data confirm reproducibility and precision of the whole MALDI Biotyper CA System independent from:

- Clinical Site
- System operator
- microflex LT/SH instrument
- Target plate

Challenge Panel:

A panel of 55 organisms (24 Gram-positive aerobic bacteria, 1 Gram-negative microaerophilic bacterium, 4 Gram-negative anaerobic bacteria, 6 Gram-positive anaerobic bacteria, 20 yeasts) was tested at four (4) study sites. Fifty-three (53) of the organisms included in the panel were selected from stored organisms tested during the clinical study. Two (2) were selected from strain collections. 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 procedure in accordance with product instructions. If DT and/or eDT result yielded a log(score) <2.00, the organism was retested using the Extraction procedure.

Table 4: 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	TOTAL ≥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%)
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.

93% of test organisms were correctly identified with a log(score) ≥2.00 result applying MBT-CA workflow. Testing of the challenge panel confirms intra laboratory performance of the MALDI Biotyper CA System.

Method Comparison:

To demonstrate performance of the MALDI Biotyper CA (MBT-CA) System, a method comparison study was performed at six (6) US clinical test sites and in-house laboratory. 4,395 (generating 4,399 data points) fresh and stored organisms were tested on the MALDI Biotyper CA System in accordance to manufacturer's instructions for use. All organisms included in the study were sub-cultured for purity. Testing on the MBT-CA System was done from a fresh isolated colony. Due to the rarity of some organisms, replicates of these rarer species were tested by multiple testing sites to generate additional data to support performance of the MBT-CA System. Results from the 3,802 replicate testing results were analyzed separately from the method comparison isolates.

All organisms included in the study were also sub-cultured on to an agar slant or appropriate media for isolation and shipped to the study interim reference laboratory. The interim reference laboratory stored all organisms included in the study and sent all organisms to the sequencing reference laboratory for sequencing and protein sequencing when requested.

The following Gram-negative, Gram-positive and yeast isolates are included in the reference library (please refer to K130831 for previously claimed Gram-negative organisms)

Table 5: Claimed Organisms

Organisms
Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Actinomyces meyeri
Actinomyces neuii
Actinomyces odontolyticus
Actinomyces oris
Aerococcus urinae
Aerococcus viridans
Aeromonas salmonicida
Anaerococcus vaginalis
Bacteroides fragilis
***Bacteroides ovatus* group**
***Bacteroides thetaiotaomicron* group**
Bacteroides uniformis
***Bacteroides vulgatus* group**
***Bordetella* group[3]**
Bordetella hinzii
Brevibacterium casei
***Brevundimonas diminuta* group**
Campylobacter coli
Campylobacter jejuni
Campylobacter ureolyticus
Candida albicans
Candida boidinii
Candida dubliniensis
Candida duobushaemulonii
Candida famata
Candida glabrata

Organisms
Candida guilliermondii
Candida haemulonis
Candida inconspicua
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitaniae
Candida metapsilosis
Candida norvegensis
Candida orthopsilosis
Candida parapsilosis
Candida pararugosa
Candida pelliculosa
Candida tropicalis
Candida valida
Capnocytophaga ochracea
Capnocytophaga sputigena
Chryseobacterium gleum
Chryseobacterium indologenes
Clostridium difficile
Clostridium perfringens
Corynebacterium amycolatum
***Corynebacterium aurimucosum* group**
Corynebacterium bovis
Corynebacterium diphtheriae
Corynebacterium glucuronolyticum
Corynebacterium jeikeium
Corynebacterium kroppenstedtii

Organisms
Corynebacterium macginleyi
Corynebacterium minutissimum
Corynebacterium propinquum
Corynebacterium pseudodiphtheriticum
Corynebacterium riegelii
Corynebacterium striatum group
Corynebacterium tuberculostearicum
Corynebacterium ulcerans
Corynebacterium urealyticum
Corynebacterium xerosis
Cronobacter sakazakii group
Cryptococcus gattii
Cryptococcus neoformans var grubii
Cryptococcus neoformans var neoformans
Cupriavidus pauculus group
Delftia acidovorans group
Dermacoccus nishinomiyaensis
Edwardsiella tarda
Elizabethkingia meningoseptica group
Enterobacter amnigenus
Enterococcus avium group
Enterococcus casseliflavus
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Finegoldia magna
Fusobacterium canifelinum
Fusobacterium necrophorum
Fusobacterium nucleatum
Gardnerella vaginalis
Gemella haemolysans
Gemella sanguinis
Geotrichum candidum
Geotrichum capitatum
Granulicatella adiacens
Haemophilus haemolyticus
Haemophilus influenzae
Haemophilus parahaemolyticus group
Kingella kingae
Kloeckera apiculata
Kocuria kristinae

Organisms
Kytococcus sedentarius
Lactococcus garvieae
Lactococcus lactis
Leuconostoc mesenteroides
Macrococcus caseolyticus
Micrococcus luteus
Moraxella sg Moraxella nonliquefaciens
Myroides odoratimimus
Myroides odoratus
Oligella ureolytica
Oligella urethralis
Parabacteroides distasonis
Pediococcus pentosaceus
Peptoniphilus harei group
Peptostreptococcus anaerobius
Pichia ohmeri
Plesiomonas shigelloides
Porphyromonas gingivalis
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella melaninogenica
Propionibacterium acnes
Pseudomonas oryzihabitans
Pseudomonas stutzeri
Rhizobium radiobacter
Rothia aeria
Rothia dentocariosa
Rothia mucilaginosa
Saccharomyces cerevisiae
Serratia plymuthica
Serratia rubidaea
Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus caprae
Staphylococcus carnosus
Staphylococcus cohnii
Staphylococcus epidermidis
Staphylococcus equorum
Staphylococcus felis

Organisms
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus lugdunensis
Staphylococcus pasteuri
Staphylococcus pettenkoferi
Staphylococcus pseudintermedius
Staphylococcus saccharolyticus
Staphylococcus saprophyticus
Staphylococcus schleiferi
Staphylococcus simulans
Staphylococcus vitulinus
Staphylococcus warneri
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus constellatus
Streptococcus dysgalactiae
Streptococcus gallolyticus

Organisms
Streptococcus gordonii
Streptococcus intermedius
Streptococcus lutetiensis
***Streptococcus mitis / oralis* group**
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus salivarius
Sutterella wadsworthensis
Trichosporon asahii
Vibrio parahaemolyticus
Vibrio vulnificus

Tables 6 - 8 below show the overall isolate performance.

Table 6: Overall Isolate Performance - claim 2

Overall Performance - claim 2				
MBT-CA RESULT	REFERENCE ALGORITHM			
	high resolution species	*low resolution species / genus*	*Negative*	*Total*
Organism ID ≥ 2.0 (High Confidence)	3817	392	18	4227
Organism ID (≥1.7; <2.0) (Low Confidence)	107	13	9	129
- INCORRECT MBT-CA ID (≥1.7) *- NO ID (<1.7)*	42	1	n/a	43
Total	3966	406	27	4399

Positive		*Negative*
high resolution	*high & low resolution*	
96.27%	99.02%	n/a

Table 7: Overall Bacteria Performance

Overall Performance BACTERIA				
MBT-CA RESULT	REFERENCE ALGORITHM			
	high resolution species	*low resolution species / genus*	*Negative*	*Total*
Organism ID ≥ 2.0 (High Confidence)	3079	389	17	3485
Organism ID (≥1.7; <2.0) (Low Confidence)	52	12	9	73
- INCORRECT MBT-CA ID (≥1.7) *- NO ID (<1.7)*	25	1	n/a	26
Total	3156	402	26	3584

Positive		***Negative***
high resolution	*high & low resolution*	
97.47%	**99.27%**	n/a

Table 8: Overall Yeast Performance

Overall Performance YEAST				
MBT-CA RESULT	REFERENCE ALGORITHM			
	high resolution species	*low resolution species / genus*	*Negative*	*Total*
Organism ID ≥ 2.0 (High Confidence)	738	3	1	742
Organism ID (≥1.7; <2.0) (Low Confidence)	55	1	0	56
- INCORRECT MBT-CA ID (≥1.7) *- NO ID (<1.7)*	17	0	0	17
Total	810	4	1	815

Positive		***Negative***
high resolution	*high & low resolution*	
91.03%	97.91%	0.00%

Statement of Safety and Efficacy

The data presented clearly demonstrate the safety and efficacy of the Bruker Daltonics, Inc. MBT-CA System as compared to the reference algorithm, when the instructions for use are followed.