September 26, 2024

Accelerate Diagnostics Inc.
℅ Jo-Ann Gonzales
Senior Director, IVD Regulatory Consulting
Precision for Medicine, Inc.
2 Bethesda Metro Center, Suite 850
Bethesda, Maryland 20814

Re: K240854
Trade/Device Name: Accelerate Arc System
Regulation Number: 21 CFR 866.3378
Regulation Name: Clinical Mass Spectrometry Microorganism Identification And Differentiation System
Regulatory Class: Class II
Product Code: QNJ
Dated: August 29, 2024
Received: August 29, 2024

Dear Jo-Ann Gonzales:

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240854

Device Name
Accelerate Arc system

Indications for Use *(Describe)*
The Accelerate Arc system is an automated sample preparation device that uses lysis and centrifugation to prepare concentrated microbial suspensions from positive blood culture samples that can be used for bacterial and yeast identification with the Bruker MALDI Biotyper CA System (MBT-CA System) with MBT-CA Sepsityper software extension. Samples are processed directly from BD BACTEC blood culture bottles identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial by Gram stain.

The Accelerate Arc system is an in vitro diagnostic device comprised of the Accelerate Arc instrument, Accelerate Arc system software, and the Accelerate Arc BC kit. The Accelerate Arc BC kit is a disposable consumable that includes reagents to concentrate and purify microbial cells from positive blood culture samples.

Microbial suspensions prepared by the Accelerate Arc system can be used to identify bacterial species and yeasts in accordance with the Bruker MBT-CA reference library.

Subculture of positive blood culture is necessary to recover organisms not identified by the Bruker MBT-CA System with MBT-CA Sepsityper software extension, species not indicated for testing with the Bruker MBT-CA System with MBT-CA Sepsityper software extension, for susceptibility testing, for epidemiologic testing, and for differentiation/recovery of organisms present in polymicrobial samples.

The Accelerate Arc system is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bloodstream infections.

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.

510(k) Summary

A. Date Prepared: September 24, 2024

B. Measurand: See Indications for Use

C. Type of Test

The Accelerate Arc™ system, comprised of the Accelerate Arc instrument (including the Accelerate Arc module, a computing system, a touchscreen monitor, and a barcode reader), Accelerate Arc system software, and Accelerate Arc BC kit for use with Bruker's MALDI Biotyper® CA System (MBT-CA System) and MBT-CA Sepsityper® software extension, is a qualitative *in vitro* diagnostic device for species identification of Gram positive and negative bacteria and yeasts in positive blood cultures from BD BACTEC™ bottles.

D. Submitter Information:

Submitted By:
Accelerate Diagnostics, Inc.
3950 South Country Club Rd, Suite 470

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E. Proprietary and Established Names:

Trade Name: Accelerate Arc™ system

Common Name: Blood culture processing device that includes associated reagents that are intended to concentrate and purify microbial cells from blood culture samples identified as positive by a continuous monitoring blood culture system with organisms subsequently identified by spectrometry.

F. Regulatory Information:

1. Classification Name: 866.3378 - Clinical mass spectrometry microorganism identification and differentiation system
2. Product Code: QNJ
3. Panel: MI (Microbiology)
4. Device Class: Class II

G. Intended Use/Indications for Use

1. Intended Use

See Indications for Use.

2. Indications for Use

The Accelerate Arc™ system is an automated sample preparation device that uses lysis and centrifugation to prepare concentrated microbial suspensions from positive blood culture samples that can be used for bacterial and yeast identification with the Bruker MALDI Biotyper® CA System (MBT-CA System) with MBT-CA Sepsityper® software extension. Samples are processed directly from BD BACTEC™ blood culture bottles identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial by Gram stain.

The Accelerate Arc system is an in vitro diagnostic device comprised of the Accelerate Arc instrument, Accelerate Arc system software, and the Accelerate Arc BC kit. The Accelerate Arc BC kit is a disposable consumable that includes reagents to concentrate and purify microbial cells from positive blood culture samples.

Microbial suspensions prepared by the Accelerate Arc system can be used to identify bacterial species and yeasts in accordance with the Bruker MBT-CA reference library.

Subculture of positive blood culture is necessary to recover organisms not identified by the Bruker MBT-CA System with MBT-CA Sepsityper software extension, species not indicated for testing with the Bruker MBT-CA System with MBT-CA Sepsityper software extension, for susceptibility testing, for epidemiologic testing, and for differentiation/recovery of organisms present in polymicrobial samples.

The Accelerate Arc system is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bloodstream infections.

1. Special conditions for use statement(s):

   Rx - For Prescription Use Only

IVD – For In Vitro Diagnostic Use Only

2. Special instrument requirements:

MALDI Biotyper® CA System with MBT-CA Sepsityper® software extension

H. Device/System Characteristics:

1. Device Description:

The Accelerate Arc system is an automated sample preparation device with associated consumables that uses lysis and centrifugation to prepare microbial suspensions from positive blood culture (PBC) samples from BD BACTEC™ bottles that have rung positive on a continuous monitoring system and confirmed to be monomicrobial by Gram stain. Suspensions containing concentrated, monomicrobial microorganisms are intended for use with the downstream mass spectrometry (MS) analyzer Bruker MALDI Biotyper® CA System with MBT-CA Sepsityper® software extension for qualitative identification and differentiation of microorganisms to aid in the early diagnosis of bacterial and yeast infections. This device is comprised of an automated sample preparation instrument (Accelerate Arc instrument), system software (Accelerate Arc system software), and sample preparation kit (Accelerate Arc BC kit).

The Accelerate Arc system was designed to standardize workflow to minimize operator error and variability. The Accelerate Arc instrument, system software and BC kit rapidly clean up and concentrate microorganisms from positive blood culture samples for downstream identification of the microorganism using the Bruker MALDI Biotyper® CA System with MBT-CA Sepsityper® software extension. The confidence score range from the MBT-CA Sepsityper® software extension is used to denote high confidence (1.8 to 3), low confidence (1.6 to 1.79), and no identification (0 to 1.59). Altogether, rapid microorganism identification direct from PBC can be achieved in about 1 ½ hours following this workflow.

The maximum system configuration of eight Accelerate Arc modules can process greater than 150 PBCs in a single day.

The Accelerate Arc™ system is comprised of:

- Accelerate Arc™ instrument
- Accelerate Arc™ system software
- Accelerate Arc™ BC kit

Samples prepared by the Accelerate Arc system are intended for use with:

- Bruker MALDI Biotyper® CA System with MBT-CA Sepsityper® software extension

2. Principle of Operation:

The Accelerate Arc BC kit contains a sample capsule and reagent cartridge. Positive blood culture (PBC) sample processing is performed on the Accelerate Arc instrument ,

which uses automated fluid handling and centrifugation in conjunction with Accelerate Arc system software to prepare PBC samples for subsequent organism identification using MALDI-ToF MS. The user loads the PBC sample into the sample capsule, scans the reagent cartridge barcode using the provided handheld barcode scanner, places the reagent cartridge and sample capsule into an Accelerate Arc module and closes the module door to start the run. The rest of the operations are automated as described below.

Single-Use Consumables

The Accelerate Arc BC kit includes a single-use, disposable capsule and reagent cartridge. The user loads the sample into the capsule and seals with the provided cap. The capsule is then inserted into the Accelerate Arc module along with the reagent cartridge. The capsule was designed for efficient sample pelleting along its equator (middle of the capsule) during centrifugation.

Centrifugation

Inline centrifugation is used to sediment microorganisms contained in liquid samples. It performs a separation in which the microorganisms are concentrated in an equatorial pellet within the capsule and the fluid component forms a subnatant. The subnatant is then removed by aspiration, dispensed to a waste well, and replaced with clean fluid. This process is repeated multiple times with fresh reagents. By these means, blood, cellular debris, and culture media matrix components are reduced from the sample.

Fluid Handling

Fluid handling is performed within the Accelerate Arc module by means of an automated pipetting system. The pipetting system uses disposable tips included in the kit to access and transfer liquid reagents in the reagent cartridge to and from the capsule.

Resuspension

Resuspension is accomplished in the Accelerate Arc module by performing lower speed spins in which the direction of rotation is repeatedly reversed. The rapid reversals of the rotor generate shear within the fluid that acts on the pellet to lift it off the capsule wall and allows its resuspension in the fresh reagent fluid dispensed by the Arc module.

I. Instrument Description Information:

1. Instrument Name:

   Accelerate Arc system (Accelerate Arc instrument, system software, and BC kit)

2. Specimen Identification:

   The user can use the Accelerate Arc instrument's barcode reader or manually enter the specimen identification and Accelerate Arc BC kit information into the system at the start of a run. This information is required before the run can proceed.

3. Specimen Sampling and Handling:
   Below is a summary of the procedure and is detailed in the Instructions for Use:

1. Vortex blood culture bottle for 10 sec. Vent bottle and transfer 1.7 mL ± 0.2 mL of positive blood culture media using a 3 mL syringe and 21-23g needle (or equivalent) into a labeled and uncapped Arc capsule, then cap.

   Note: PBCs must be processed up to 16 hours after positivity if kept on the blood culture instrument or up to 24 hours if kept at room temperature.

2. Select an available Arc module and scan or enter the barcode information.

3. Load the capped and labeled Arc sample capsule and Arc reagent cartridge with the adhesive sticker removed into the selected Arc module.

4. Close the Arc module door and select run sample on the user interface.

5. Upon run completion, press the Arc module button to unlock the door to dispose of the reagent cartridge.

6. Vortex the capped Arc sample capsule prior to subsequent MALDI Biotyper CA System microbial identification.

   Note: The Arc-processed PBC sample is stable for up to 8 hours refrigerated or room temperature prior to spotting on target plate.

7. Determine microbial identification of the Arc processed sample on the MBT-CA System with MBT-CA Sepsityper software extension.

   a. Add 1 µl of the Arc-processed sample to two sequential spots (DT and eDT) on a target plate and allow spots to completely dry.

   b. Add 1 µl of 70% formic acid to ONLY the second test spot (eDT).

   c. Spot the US IVD BTS onto two target plate positions following Instructions for Use for the US IVD BTS and allow spots to completely dry.

   d. Overlay each test and BTS spots with 1 µl of US IVD HCCA matrix solution and allow all spots to completely dry.

      Note: Target plates can be kept at room temperature for up to 24 hours prior to MALDI identification.

   e. Record the test spots in the Bruker software.

   f. Insert the target plate into the Bruker MBT-CA System and run through the MBT-CA Sepsityper identification process following the Bruker User Manual of MBT-CA System.

4. Calibration:

Calibration is only performed at time of installation and preventative maintenance visits by an Accelerate Diagnostics, Inc. trained field service engineer when warranted. There is no calibration required by the user for the Accelerate Arc system.

Accelerate Arc system quality checks are hardware performance checks performed throughout each run to ensure the system is functioning as expected. All quality checks must pass for successful run completion, indicating the sample has been processed to procedure specification. In the event of a quality check failure, the sample has NOT been processed per specification.

No external quality control check of kit consumables is required by the user.

5. Quality Control:

The user will follow local, state and/or federal regulations for Quality Control requirements.

J. Substantial Equivalence Information

1. Predicate Device Name: MBT Sepsityper
2. Predicate 510(k) Number: K193419
3. Comparison with Predicate:

A comparison of the features of the Accelerate Arc system and the MBT Sepsityper, predicate device, are as provided in **Table 1**.

Table 1: Substantial Equivalence Table

	Proposed Device (Accelerate Arc system, K240854)	Predicate (MBT Sepsityper, K193419)
Intended Use/Indications for Use	The Accelerate Arc™ system is an automated sample preparation device that uses lysis and centrifugation to prepare concentrated microbial suspensions from positive blood culture samples that can be used for bacterial and yeast identification with the Bruker MALDI Biotyper® CA System (MBT-CA System) with MBT-CA Sepsityper® software extension. Samples are processed directly from BD BACTEC™ blood culture bottles identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial by Gram stain. The Accelerate Arc system is an in vitro diagnostic device comprised of the Accelerate Arc instrument, Accelerate Arc system software, and the Accelerate Arc BC kit. The Accelerate Arc BC kit is a disposable consumable that includes reagents to concentrate and purify microbial cells from positive blood culture samples.	The MBT Sepsityper is a qualitative in vitro diagnostic device consisting of a MBT-CA (Sepsityper) software extension and a reagent kit (MBT Sepsityper Kit US IVD) for use in conjunction with other clinical and laboratory findings to aid in the early diagnosis of bacterial and yeast infections from positively flagged blood cultures using the MALDI Biotyper CA System. The MBT Sepsityper Kit US IVD is a disposable blood culture processing device that includes associated reagents that are intended to concentrate and purify microbial cells from blood culture samples identified as positive by a continuous monitoring blood culture system and confirmed to demonstrate the presence of a single organism as determined by Gram stain. This sample preparation manual method is performed by laboratory health professionals in a clinical diagnostic setting. Subculturing of positive blood cultures is necessary to recover organisms for identification of organisms not identified by the MBT-CA System, for susceptibility testing and for differentiation of mixed growth. Positive MBT Sepsityper results do

	Proposed Device (Accelerate Arc system, K240854)	Predicate (MBT Sepsityper, K193419)
	Microbial suspensions prepared by the Accelerate Arc system can be used to identify bacterial species and yeasts in accordance with the Bruker MBT-CA reference library. Subculture of positive blood culture is necessary to recover organisms not identified by the Bruker MBT-CA System with MBT-CA Sepsityper software extension, species not indicated for testing with the Bruker MBT-CA System with MBT-CA Sepsityper software extension, for susceptibility testing, for epidemiologic testing, and for differentiation/recovery of organisms present in polymicrobial samples. The Accelerate Arc system is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bloodstream infections.	not rule out co-infection with organisms that may not be detected by the MBT-CA System. Results of the MBT Sepsityper should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Results of the MBT Sepsityper should be correlated with Gram stain results and used in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and yeast bloodstream infections. See MBT Sepsityper FDA decision summary (K193419) for organisms recovered from positive blood culture bottles that are suitable for identification using the MBT Sepsityper.
Classification	Class II	Same
Product Code	QNJ	Same
Regulation	21 CFR 866.3378 - Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates	Same
Type of Test	Sample processing device for use with mass spectrometry system	Mass spectrometry system
Matrix	α-Cyano-4-hydroxycinnamic acid	Same
Matching Algorithm	Arc-prepared samples are tested with the MBT-CA System with MBT-CA Sepsityper software extension matching algorithm	Calculates matches by comparing a new spectrum against each single reference entry of a reference database.
Sample Type	Positive blood cultures	Same
Sample Volume	1.7ml +/- 0.2ml	1ml
Test Sample/Validated Blood Culture Bottles	The following positively flagged BD BACTEC™ blood culture bottles: • BD BACTEC™ Standard - Aerobic / Anaerobic • BD BACTEC™ PLUS - Aerobic / Anaerobic • BD BACTEC™ - Lytic Anaerobic • BD BACTEC™ - BD Peds Plus™ • BD BACTEC™ - Myco/F Lytic	Bottles of the BD BACTEC™ (Becton Dickinson) System: • BD BACTEC™ Standard - Aerobic / Anaerobic • BD BACTEC™ PLUS - Aerobic / Anaerobic • BD BACTEC™ - Lytic Anaerobic • BD BACTEC™ - BD Peds Plus™ • BD BACTEC™ - Myco/F Lytic • BD BACTEC™ - Mycosis IC Bottles without charcoal of the BacT/ALERT® (bioMérieux) System: • BacT/ALERT® SA Standard Aerobic • BacT/ALERT® SN Standard Anaerobic • BacT/ALERT® FA Plus

	Proposed Device (Accelerate Arc system, K240854)	Predicate (MBT Sepsityper, K193419)
		• BacT/ALERT® FN Plus • BacT/ALERT® PF Plus Bottles of the VersaTREK® (Thermo Scientific) System: • VersaTREK® REDOX 1 • VersaTREK® REDOX 2
Sample Preparation Instrument	Accelerate Arc instrument	None
Sample Preparation Instrument Software	Accelerate Arc system software	N/A
Sample Preparation Kit	Accelerate Arc BC kit	MBT Sepsityper Kit US IVD
MALDI-ToF MS Instrument	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	MALDI Biotyper® (MBT) CA System
MALDI-ToF MS Instrument Software	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	MBT-CA System software with reference library and the MBT-CA (Sepsityper) software extension
Reference Library	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	MALDI Biotyper® (MBT) CA System
Analyzed Mass Range	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	4,000 – 15,000 m/z (Sepsityper samples)
Mix Culture Hint	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	Yes
MALDI Target Plate	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	US IVD 48 Spot Target (48 positions reusable steel targets) MBT Biotarget 96 US IVD (96 positions disposable targets)
Calibration and Quality Control	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	Bruker US IVD Bacterial Test Standard (BTS)
MALDI Workflow	The approved DT and eDT MBT-CA System Workflow (same as predicate) plus the Accelerate Arc system and Accelerate Arc BC kit Workflow	The approved MBT-CA Workflow plus the MALDI Sepsityper Workflows [Rapid Sepsityper DT (RS_DT), Rapid Sepsityper eDT (RS_eDT) and Full Sepsityper (Ext)]
log(score) Values	Intended for use with the Bruker MBT-CA System with MBT-CA Sepsityper software extension	MBT Sepsityper Samples: • High Confidence ID: 1.80 - 3.00; • Low Confidence ID: 1.60 - 1.79; • No Organism ID Possible: 0.00 - 1.59

K. Standards/Guidance Documents Referenced

None.

L. Test Principle

Organisms to be identified with the Bruker MALDI Biotyper CA System (MBT-CA System) and MBT-CA Sepsityper software extension are processed beforehand using the Accelerate Arc system with positive blood culture samples. Users are instructed to test the Arc processed sample on the Bruker MBT-CA System with MBT-CA Sepsityper software extension using both the direct transfer (DT) and extended direct transfer (eDT) techniques following the steps described in the Bruker MALDI Biotyper CA System User Manual to operate the MBT-CA System and MBT-CA Sepsityper identification process to report results.

M. Performance Characteristics

1. Analytical Performance

   a. *Precision/Reproducibility:*

   This study used 10 different organisms commonly found in PBC samples, tested in replicates of 3 across 3 non-consecutive days at a total of 3 sites. Isolates were contrived in blood culture bottles containing whole blood from healthy donors, incubated on the BD BACTEC™ continuous blood culture monitoring system until positive, and then PBC samples run with the Accelerate Arc system. Three Accelerate Arc instruments, and three different Accelerate Arc BC kit lots were used for each group of triplicate replicates tested per organism on each day. Two operators executed testing on alternate days. Overall, 96% of all samples tested produced a High or Low confidence ID result and no incorrect identifications were observed using the DT PLUS eDT workflow (see **Table 2**).

Table 2: Reproducibility of the Accelerate Arc system

Site	DT PLUS eDT Result	Operator 1	Operator 2	All Operators
1	High	97.9%	81.0%	90.0%
	Low	0.0%	11.9%	5.6%
	No ID	2.1%	7.1%	4.4%
2	High	83.3%	92.9%	87.8%
	Low	6.3%	2.4%	4.4%
	No ID	10.4%	4.8%	7.8%
3	High	100%	95.2%	97.8%
	Low	0.0%	4.8%	2.2%
	No ID	0.0%	0.0%	0.0%
All Sites	High	93.8%	89.7%	91.9%
	Low	2.1%	6.3%	4.1%
	No ID	4.2%	4.0%	4.1%

b. *Detection limit:*

Five representative microbial species (*Staphylococcus aureus*, *Streptococcus agalactiae*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Candida tropicalis*) were used to contrive PBCs using fresh donor blood incubated in the BD BACTEC™ continuous blood culture monitoring system until positive. Ten replicate samples per species were run immediately after flagging positive (at positivity) using the Accelerate Arc system. Successful reporting of accurate ID results would demonstrate that the limit of detection for samples prepared by the Accelerate Arc system was equal to at least the concentration of organisms found in a PBC sample at positivity. (**Table 3**) One of the *Staphylococcus aureus* replicate tests initially produced a no ID result but subsequently produced an accurate High Confidence ID result upon re-spotting of the same Arc-processed sample with DT and eDT workflow and re-analysis with the MBT-CA System with MBT-CA Sepsityper software extension.

Additionally, PBC samples removed at positivity were 1:10 diluted into a negative blood culture sample containing no organisms to produce a contrived sample containing a lower concentration of microorganisms. This sample dilution and preparation was performed using samples from the same five representative microbial species and a second set of 10 replicate samples per species was run using the Accelerate Arc system. The resulting samples were prepared for ID testing to demonstrate that no inaccurate ID results would be reported.

For PBCs containing bacterial organisms there is sufficient biological material at positivity for successful identification using the Accelerate Arc system followed by DT and eDT workflow and MBT-CA System with MBT-CA Sepsityper software extension analysis. For blood cultures containing yeast organisms, ID was successful after incubation of the PBC for approximately one hour (**Table 3**). For samples diluted 1:10, a lower concentration of microorganisms in test samples does not produce any false identifications.

Table 3: Results for Undiluted Samples. Number of High or Low confidence ID results or No ID (no identification) results for all replicate tests performed for undiluted samples. Results for bacterial organisms are shown for samples tested at positivity. i.e. 0 hour TPP (time post positive). Result for yeast shown for samples tested at 1 hour TPP.

PBC Sample		Identification Result		
Organism	**TPP**	**High**	**Low**	**No ID**
Staphylococcus aureus	0 h	8	1	1*
Streptococcus agalactiae	0 h	10	0	0
Klebsiella pneumoniae	0 h	10	0	0
Pseudomonas aeruginosa	0 h	10	0	0
Candida tropicalis	1 h	9	1	0

*Indicates test conditions that produced an accurate High Confidence ID result upon re-spotting

c. *Sample stability:*

Four representative microbial species, specifically: *Klebsiella pneumonia*, *Staphylococcus aureus, Candida tropicalis*, and *Haemophilus influenzae*, were used to contrive positive blood cultures using fresh donor blood incubated in the BD BACTEC™ continuous blood culture monitoring system until positive. All positive blood cultures samples processed with the Accelerate Arc system were prepared for ID on the MBT-CA System with MBT-CA Sepsityper software extension using DT and eDT workflows.

Post-Positive sample stability was tested using blood culture samples incubated for extended periods of time after flagging positive: 16 hours inside the blood culture incubation system or 24 hours outside the blood culture incubation system at ambient temperature. Testing at all extended incubation conditions produced reportable and accurate results, therefore positive blood cultures can remain in the incubator up to 16 hours or be stored at ambient temperature up to 24 hours prior to Accelerate Arc system processing (**Table 4**). In one instance, one replicate test for *Haemophilus influenzae* testing at the 17.5 h condition initially produced a no ID result but subsequently produced an accurate High Confidence ID result upon re-spotting of the same Arc-processed sample with DT and eDT workflow and re-analysis with the MBT-CA System with MBT-CA Sepsityper software extension.

Table 4: Results for Post-Positive Sample Stability testing. Incubation Temperature and Incubation Time indicate conditions used for testing. Each row indicates a specific Incubation Time condition in hours and "N/A" is indicated whenever testing was performed at positivity (i.e., zero-hour time point). The results under the microbial species headers show the number of replicate tests for each condition that produced either high confidence (H = ≥ 1.80 log score), low confidence (L = 1.60-1.79 log score), or no ID (No = < 1.60 log score). In all cases, each reportable ID, high or low confidence, produced the correct species level ID expected for each of the organisms tested.

Incubation Temperature	Incubation Time (hours)	*Staphylococcus aureus* (H | L | No)	*Klebsiella pneumoniae* (H | L | No)	*Candida tropicalis* (H | L | No)	*Haemophilus influenzae* (H | L | No)
N/A	0	3 | 0 | 0	3 | 0 | 0	2 | 0 | 1	3 | 0 | 0
Incubator	8	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Incubator	16	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0	3 | 0 | 0
Incubator	17.5	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	0 | 2 | 1*
Ambient	12	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0	3 | 0 | 0
Ambient	24	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0
Ambient	26.5	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0

*Indicates test conditions that produced an accurate High Confidence ID result upon re-spotting

Post-Processing sample stability was tested using samples stored for extended periods of time after Accelerate Arc™ system processing: 8 hours storage at 2 - 8 °C (refrigerated) and at ambient temperature. *Haemophilus influenzae* testing produced few instances of unsuccessful ID, but testing at extended incubation conditions generally produced reportable and accurate results for all organisms, therefore positive blood cultures processed using the Accelerate Arc system can be stored refrigerated or at ambient temperature up to 8 hours prior to application of sample to the MBT-CA System target plate and addition of matrix according to the MBT Sepsityper User Manual.

Post-Matrix sample stability was tested using samples stored for extended periods of time after addition of matrix (HCCA) to analyte spots on the MALDI-ToF target plate for 24 hours stored at ambient temperature Testing at all extended incubation conditions produced reportable and accurate results, therefore the MALDI target plate can be stored at ambient temperature up to 24 hours prior to MBT-CA System with MBT-CA Sepsityper software extension ID analysis of positive blood cultures processed using the Accelerate Arc system.

d. *Blood Culture Bottle Type Compatibility:*

Five representative microbial species (*Staphylococcus aureus*, *Streptococcus agalactiae*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Candida tropicalis*) were used to contrive PBCs using fresh donor blood incubated in the BD BACTEC continuous blood culture monitoring system until positive. Seven different BD BACTEC blood culture media bottle types (PLUS Aerobic and Standard Aerobic, PLUS Anaerobic and Standard Anaerobic, PEDS PLUS, Lytic/Anaerobic, and Myco/F Lytic) were used to contrive samples in triplicate and positive blood cultures were processed using the Accelerate Arc system followed by ID using the DT and eDT workflows and MBT-CA System with MBT-CA Sepsityper software extension analysis.

No difference in performance was observed for any bottle type for Gram-negative organisms. Lower performance was observed with *Staphylococcus aureus* and *Streptococcus agalactiae* only for the Myco/F Lytic bottles. Lower performance was observed with *Candida tropicalis* but only for the Standard Aerobic and Standard Anaerobic bottles.

e. *Carry-over/Cross Contamination:*

Six different microbial species, three GN and three GP, were used to contrive PBCs using fresh donor blood incubated in the BD BACTEC™ continuous blood culture monitoring system until positive. A negative blood culture bottle using fresh donor blood was incubated for five days to ensure the absence of microorganisms. Alternating positive and negative blood culture samples were processed across three different Accelerate Arc modules to demonstrate lack of intra-instrument carry-over or cross contamination. Positive and negative blood culture samples processed using the Accelerate Arc system were also spotted side-by-side using the

48-spot reusable MBT Biotarget plate and the 96-spot disposable MBT Biotarget plate.

No evidence of carry-over or cross contamination was observed from back-to-back Accelerate Arc system runs and no evidence of carry-over or cross contamination was observed between side-by-side analyte spots on the 48-spot reusable MBT Biotarget plate or the 96-spot disposable MBT Biotarget plate.

f. *Interfering Substances:*

Three representative microbial species, *Klebsiella pneumoniae*, *Staphylococcus aureus*, and *Candida tropicalis*, were used to contrive PBCs using fresh donor blood incubated in the BD BACTEC continuous blood culture monitoring system until positive. PBCs containing interfering substances at the target concentrations indicated in **Table 5** (Routine blood and blood culture media interferents) and **Table 6** (Drug interferents) were processed using the Accelerate Arc system followed by DT and eDT workflow and MBT-CA System with MBT-CA Sepsityper software extension analysis. This study was designed according to CLSI documents EP07-Ed3 (Interference Testing in Clinical Chemistry).

Table 5: Routine blood and blood culture media interferents

Interferent	Test Concentration
Triglyceride-rich lipoproteins	10 g/L
Hemolysate (hemoglobin)	5 g/L
Protein (albumin and gamma-globulin)	120 g/L
Conjugated Bilirubin	0.2 g/L
Unconjugated Bilirubin	0.2 g/L
White Blood Cells (WBC)	$1.5x10^{10}$ cells/L
Sodium Polyanethole Sulfonate (SPS)	0.5 g/L

Table 6: Drug Interferents

Interferent	Description	Test Concentration
Acetaminophen	Analgesic	1.324 mmol/L
Acetylcysteine	Pulmonary medication	10.2 mmol/L
Acetylsalicylic Acid	NSAID	3.62 mmol/L
Cefoxitin (Na)	Antibiotic	1.55 mmol/L
Cyclosporine	Immunosuppressant	5 mg/L
Doxycycline (HCl)	Antibiotic	0.0675 mmol/L
Heparin	Anticoagulant	3,000 U/L
Ibuprofen	NSAID	2.425 mmol/L
Metronidazole	Antibiotic/Antiprotozoal	0.7 mmol/L
Vancomycin	Antibiotic	0.069 mmol/L

No inaccurate identification results were observed from testing of PBC with the Accelerate Arc system followed by DT and eDT workflow and MBT-CA System with MBT-CA Sepsityper software extension analysis.

No evidence of interference was observed from testing of drug and antibiotic interfering substances at the target concentrations (**Table 7**). One of the *Candida tropicalis* replicate tests for Heparin initially produced a no ID result but subsequently produced an accurate High Confidence ID result upon re-spotting of the same Arc-processed sample with DT and eDT workflow and re-analysis with the MBT-CA System with MBT-CA Sepsityper software extension.

For routine blood and blood culture media interferents, all but two substances (see below, Protein and WBC) showed no evidence of interference (**Table 7**). One of the *Staphylococcus aureus* replicate tests for Hemolysate initially produced a no ID result but subsequently produced an accurate High Confidence ID result upon re-spotting of the same Arc-processed sample with DT and eDT workflow and re-analysis with the MBT-CA System with MBT-CA Sepsityper software extension.

Candida tropicalis performance was negatively affected by the "Protein" interferent at the target concentration of 120 g/L protein. Retesting at 60 g/L protein resulted in reportable and accurate ID results in all replicates. This protein concentration in PBC is equivalent to the reference range for whole blood (approximately 60-80 g/L) due to the dilution of whole blood in blood culture media for PBCs (**Table 7**).

Performance across all organisms was negatively affected by the white blood cell interferent at the elevated target concentration of $1.5x10^{10}$ cells/L. Reportable and accurate ID results were achieved across all organisms at a white blood cell concentration of $3.75x10^{9}$ cells/L. This white blood cell concentration in PBC is equivalent to the reference range for whole blood (approximately $4\text{-}11x10^{9}$ cells/L) due to the dilution of whole blood in blood culture media for PBCs (**Table 7**). One of the *Candida tropicalis* replicate tests at the $3.75x10^{9}$ cells/L concentration initially produced a no ID result but subsequently produced an accurate High Confidence ID result upon re-spotting of the same Arc-processed sample with DT and eDT workflow and re-analysis with the MBT-CA System with MBT-CA Sepsityper software extension.

Table 7: Results for all Interfering Substance testing. The results under the Number of High or Low confidence or no ID results per replicate for a given condition (H | L | No) header show the number of replicate tests for each organism condition that produced either high confidence (H = ≥ 1.80 log score), low confidence (L = 1.60-1.79 log score), or no ID (No < 1.60 log score). In all cases, each reportable ID, high or low confidence, produced the

correct species level ID expected for each of the organisms tested. N/A indicates conditions that did not require testing.

Conditions Tested		Number of High or Low confidence or no ID results per replicate for a given condition (H | L | No)		
Interferent	**Test Concentration**	***Candida tropicalis***	***Klebsiella pneumoniae***	***Staphylococcus aureus***
Triglyceride-rich lipoproteins	10 g/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Hemolysate (hemoglobin)	5 g/L	3 | 0 | 0	3 | 0 | 0	2 | 0 | 1*
Protein	120 g/L	0 | 0 | 3	3 | 0 | 0	3 | 0 | 0
Protein	60 g/L	3 | 0 | 0	N/A	N/A
Conjugated Bilirubin	0.2 g/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Unconjugated Bilirubin	0.2 g/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
White Blood Cells	$1.5x10^{10}$ cells/L	0 | 0 | 3	0 | 1 | 2	0 | 0 | 3
White Blood Cells	$7.5x10^{9}$ cells/L	0 | 0 | 3	0 | 1 | 2	2 | 0 | 1
White Blood Cells	$3.75x10^{9}$ cells/L	2 | 0 | 1*	3 | 0 | 0	3 | 0 | 0
Sodium Polyanethole Sulfonate (SPS)	0.5 g/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Acetaminophen	1.324 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Acetylcysteine	10.2 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Acetylsalicylic Acid	3.62 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Cefoxitin (Na)	1.55 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Cyclosporine	5 mg/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Doxycycline (HCl)	0.0675 mmol/L	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0
Heparin	3,000 U/L	2 | 0 | 1*	3 | 0 | 0	3 | 0 | 0
Ibuprofen	2.425 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Metronidazole	0.7 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Vancomycin	0.069 mmol/L	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0

*Indicates test conditions that produced an accurate High Confidence ID result upon re-spotting

g. *Polymicrobial Interference:*

The Accelerate Arc system is not intended to be used for processing PBC samples containing more than one microbe. Inaccurate or no identification of a PBC containing multiple organisms may lead to inappropriate patient care or delayed sample results. For this reason, samples should be confirmed to contain a single organism as determined by Gram stain before being processed using the

Accelerate Arc system. However, Gram stain does not prevent the exclusion of a sample containing multiple gram-similar microbial species especially in the context of Gram-positive (GP) organisms co-cultured with common skin contaminants.

A polymicrobial interference study was conducted to demonstrate that no inaccurate identification results are observed when PBC samples containing a mixture of two microbes at varying concentrations are processed using the Accelerate Arc system. PBC samples were contrived using fresh, negative donor blood, inoculated with a representative organisms, and incubated until positive in the BD BACTEC™ FX blood culture monitoring system. Polymicrobial mixtures were prepared at five different concentration ratios (5:0, 5:1, 1:1, 1:5, 0:5) containing two different representative microbial species indicated in **Table 8**. All samples were processed using the Accelerate Arc system followed by DT and eDT workflow and MBT-CA System with MBT-CA Sepsityper software extension analysis.

Table 8: Representative organisms used for preparation of polymicrobial samples

Polymicrobial sample type	Organism 1	Organism 2
Gram-similar microbial species	*Staphylococcus aureus*	*Enterococcus faecalis*
Gram-similar microbial species	*Klebsiella pneumoniae*	*Pseudomonas aeruginosa*
Gram-positive with skin contaminant	*Staphylococcus aureus*	*Staphylococcus epidermidis*
Gram-negative with skin contaminant	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Gram-positive with yeast	*Staphylococcus aureus*	*Candida tropicalis*
Gram-negative with yeast	*Klebsiella pneumoniae*	*Candida tropicalis*

No inaccurate identification results were observed from testing of PBC with the Accelerate Arc system followed by DT and eDT workflow and MBT-CA System with MBT-CA Sepsityper software extension analysis.

All control tests (representing the 5:0 and 0:5 ratio conditions) produced accurate and reportable ID results. Results from PBC samples containing two different microbial species (5:1, 1:1, 1:5) produced either accurate reportable ID results or no identification results. In all cases, reportable ID results produced by individual DT and eDT spot tests or from DT PLUS eDT results corresponded to accurate species identification of at least one of the test organisms.

2. Comparison Studies:

a. *Method Comparison:*

Samples for evaluation of Accelerate Arc system performance were collected from three (3) clinical sites: In total, 343 specimens were evaluated for performance, 99 fresh prospective and 244 contrived. Altogether 41 different species were identified during the clinical tests. 172 Gram negative isolates, 154 Gram positive isolates, and 17 yeast isolates (**Table 9**).

For all PBC samples processed using the Accelerate Arc system, Direct Transfer (DT) and extended Direct Transfer (eDT) workflows were applied with final results interpretation being "DT PLUS eDT" [best log(score) is used for the final result] according to MBT-CA System with MBT-CA Sepsityper software extension analysis and interpretation of results.

Table 9 shows a summary of performance results from the Method Comparison study testing. Two sample types were tested using the Accelerate Arc system, prospective "fresh" patient positive blood culture samples and seeded or "contrived" positive blood culture samples using stock isolates. Fresh sample testing was performed at two external clinical sites and contrived testing was performed at two external sites and one internal site. **Table 9** shows performance results from "fresh" only, "contrived" only, and fresh and contrived samples combined. Each sample was processed using the Accelerate Arc system and prepared for MBT-CA System and MBT-CA Sepsityper software extension analysis using the MBT-CA System DT and eDT workflows. The final log score and identification result for each sample used for performance evaluation was the highest of the DT and eDT test results. Performance evaluation results are shown as the percentage of the total number of sample tested that produced a final High Confidence ID result (1.8 – 3.0 log score), a final High or Low Confidence (High & Low) result (1.6 – 3.0 log score), or no identification (no ID) result (< 1.6 log score).

For all samples that produced valid identification results from both Accelerate Arc system testing and reference testing using MBT-CA System DT and eDT workflow and analysis from isolated colonies, there were no instances of inaccurate results. Accuracy was 100% from reportable identification results using Accelerate Arc-prepared samples and MBT-CA with Sepsityper software extension analysis with MBT-CA System "DT PLUS eDT" workflow.

Across all three sample type evaluations (combined, fresh only, and contrived only), Gram-negative (GN) performance was consistently the highest among the three organism types, ranging from ~90% to ~99% of samples producing a High or Low confidence ID result.

Contrived Gram-positive (GP) performance was ~93% producing an identification result compared to about ~78% in fresh samples. Yeast performance

was lowest with less than ~67% of contrived samples producing an identification result and no ID reported from fresh samples tested. The combined performance across all organism types was around ~91% of all samples tested producing a high or low confidence result and ~85% of all samples producing a high confidence identification result.

Table 9: Accelerate Arc system clinical performance. All results are from samples prepared on the Accelerate Arc system followed by interpretation of results from combined MBT-CA System preparation ("DT PLUS eDT") and analysis with the MBT-CA System with MBT-CA Sepsityper software extension. Left side table shows performance for all sample types combined. Middle table shows performance for prospectively collected "fresh" positive blood culture samples and right table shows only seeded or "contrived" samples, For each of these sample types, the percentage of samples that produced either a High Confidence only (High), High or Low Confidence (High & Low), or no identification (no ID) result from the combined "DT PLUS eDT" workflow and Sepsityper analysis is shown per organism type. (GN: Gram positive bacteria, GP: Gram negative bacteria, All bacteria (GN + GP combined), yeast, and All samples (GN + GP + yeast combined)

	All Samples Combined				Fresh Samples Only				Contrived Samples Only			
Organism Type	**#**	**High**	**High & Low**	**No ID**	**#**	**High**	**High & Low**	**No ID**	**#**	**High**	**High & Low**	**No ID**
Gram-negative	172	95.9%	97.1%	2.9%	39	87.2%	89.7%	10.3%	133	98.5%	99.2%	0.8%
Gram-positive	154	77.9%	87.0%	13.0%	58	72.4%	77.6%	22.4%	96	81.3%	92.7%	7.3%
Yeast	17	47.1%	58.8%	41.2%	2	0.0%	0.0%	100%	15	53.3%	66.7%	33.3%
All Samples	**343**	**85.4%**	**90.7%**	**9.3%**	**99**	**76.8%**	**80.8%**	**19.2%**	**244**	**88.9%**	**94.7%**	**5.3%**

Table 10 shows ID performance results for all organisms that provided a reference result from positive blood culture samples evaluated.

Table 10: **Isolate results of the Accelerate Arc System Method Comparison Study for all sample types tested by reference organism detected. For each reference organism detected, the percentage of Arc-processed samples that produced either a High Confidence (High), Low Confidence (Low), or no identification (no ID) result from the combined "DT PLUS eDT" workflow**

and MBT-CA System with MBT-CA Sepsityper software extension analysis is shown.

Organism ID Result for Reference Testing	# of Isolates	High	Low	No ID
Acinetobacter baumannii / nosocomialis group	10	100.0%	0.0%	0.0%
Bacteroides fragilis	6	100.0%	0.0%	0.0%
Bacteroides ovatus group	1	100.0%	0.0%	0.0%
Candida albicans	6	66.7%	0.0%	33.3%
Candida glabrata	5	60.0%	20.0%	20.0%
Candida parapsilosis	1	0.0%	0.0%	100.0%
Candida tropicalis	5	20.0%	20.0%	60.0%
Citrobacter freundii complex	11	100.0%	0.0%	0.0%
Citrobacter koseri	5	100.0%	0.0%	0.0%
Clostridium tertium	1	100.0%	0.0%	0.0%
Corynebacterium minutissimum	1	0.0%	0.0%	100.0%
Cutibacterium acnes	2	0.0%	0.0%	100.0%
Enterobacter cloacae complex	12	83.3%	8.3%	8.3%
Enterococcus durans	1	100.0%	0.0%	0.0%
Enterococcus faecalis	16	93.8%	0.0%	6.3%
Enterococcus faecium	15	73.3%	20.0%	6.7%
Escherichia coli	28	96.4%	0.0%	3.6%
Haemophilus influenzae	7	71.4%	14.3%	14.3%
Klebsiella aerogenes	10	100.0%	0.0%	0.0%
Klebsiella oxytoca / Raoultella ornithinolytica	10	100.0%	0.0%	0.0%
Klebsiella pneumoniae	16	100.0%	0.0%	0.0%
Klebsiella variicola	7	100.0%	0.0%	0.0%
Micrococcus luteus	11	45.5%	18.2%	36.4%
Morganella morganii	5	100.0%	0.0%	0.0%
Proteus mirabilis	12	100.0%	0.0%	0.0%
Proteus vulgaris group	6	100.0%	0.0%	0.0%
Pseudomonas aeruginosa	15	86.7%	0.0%	13.3%
Salmonella sp*	1	100.0%	0.0%	0.0%
Serratia marcescens	10	100.0%	0.0%	0.0%
Staphylococcus aureus	23	95.7%	0.0%	4.3%
Staphylococcus capitis	9	100.0%	0.0%	0.0%
Staphylococcus epidermidis	21	71.4%	14.3%	14.3%
Staphylococcus hominis	14	92.9%	0.0%	7.1%
Staphylococcus pseudintermedius	1	0.0%	0.0%	100.0%
Streptococcus agalactiae	12	91.7%	8.3%	0.0%

Organism ID Result for Reference Testing	# of Isolates	High	Low	No ID
Streptococcus dysgalactiae	2	0.0%	50.0%	50.0%
Streptococcus mitis / oralis group	7	71.4%	14.3%	14.3%
Streptococcus pneumoniae	9	66.7%	11.1%	22.2%
Streptococcus pyogenes	7	71.4%	28.6%	0.0%
Streptococcus salivarius / vestibularis group	1	0.0%	0.0%	100.0%
Streptococcus sanguinis	1	100.0%	0.0%	0.0%
All Isolates	**343**	**85.4%**	**5.2%**	**9.3%**

N. Conclusion

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