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

I Background Information:

A 510(k) Number

K240854

B Applicant

Accelerate Diagnostics Inc.

C Proprietary and Established Names

Accelerate Arc System

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Accelerate Arc System for use with the Bruker MALDI Biotyper CA (MBT-CA) system with MBT-CA Sepsityper software extension.

B Measurand:

See Indications for Use

C Type of Test:

Qualitative *in vitro* diagnostic device for automated microbial suspension preparation from positive blood culture samples for identification and differentiation of microorganisms with the Bruker MALDI Biotyper CA (MBT-CA) system with MBT-CA Sepsityper software extension.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IVD - For In Vitro Diagnostic Use Only

-Refer to the Bruker MBT Sepsityper Kit Instructions for Use for limitations related to microorganism ID and the MALDI Biotyper CA System IVD reference library. Refer to the Bruker User Manual of MBT-CA System regarding any specific MALDI spectra limitations.

-Blood culture samples identified as positive by a continuous monitoring blood culture system must be confirmed to demonstrate the presence of a single organism as determined by Gram stain prior to processing with the Accelerate Arc system

-The Accelerate Arc system is not intended for use with sterile body fluids other than blood.

-Positive blood cultures should be subcultured for isolation and identification of organisms not identified by the Bruker MBT-CA System with MBT-CA Sepsityper software extension, of

organisms not indicated for testing with the Bruker MBT-CA System with MBT-CA Sepsityper software extension, for susceptibility testing and differentiation of mixed growth.

D Special Instrument Requirements:

Bruker MBT-CA system with MBT-CA Sepsityper software extension including:

- MALDI Biotyper CA System
- MALDI Biotyper smart CA System
- MALDI Biotyper sirius CA System

IV Device/System Characteristics:

A Device Description:

The Accelerate Arc system is an automated sample processor instrument with associated consumables that uses lysis and centrifugation to prepare microbial suspensions from positive blood culture (PBC) bottles that have rang 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 (MBT-CA) system with MBT-CA Sepsityper software extension for qualitative identification and differentiation of microorganisms to aid in the early diagnosis of bacterial and fungal infections.

The Accelerate Arc system is comprised of the Accelerate Arc instrument (processing module, touchscreen monitor, computing system, and handheld barcode reader), Accelerate Arc system software, and associated consumables (the Accelerate Arc BC kit). The system is compatible with BD BACTEC blood culture bottles.

The Accelerate Arc BC kit is a single-use consumable comprised of a sample capsule and reagent cartridge that includes reagents intended to concentrate and purify microbial cells from PBC. The user manually loads ~2 mL of the PBC sample into the capsule and caps it. The user scans the reagent cartridge barcode using the scanner provided with the Accelerate Arc instrument. The capsule is then inserted into the Accelerate Arc module along with the consumable BC kit reagent cartridge.

Within the Accelerate Arc module, sample processing is performed through automated fluid handling and sequential centrifugation and resuspension cycles to isolate and concentrate microbial cells directly from PBC. The process removes blood cells, cellular debris, and culture media matrix components. This is achieved through the three reagents (ammonium chloride potassium, 60% ethanol, and deionized water) included in the Accelerate Arc BC kit.

The Accelerate Arc module includes an automated pipetting system to perform fluid handling. The instrument uses disposable pipette tips included in the Accelerate Arc BC kit reagent cartridge. The Accelerate Arc module executes a total of five cycles of centrifugation throughout the 72-minute processing procedure. The first three cycles perform red blood cell lysis and removal, the fourth cycle performs an ethanol exposure and wash, and the final cycle performs fluid exchange and wash in DI water. The resulting concentrated microbial suspension sample output can be applied directly to a MALDI-ToF target plate for drying and matrix application in

line with the Bruker MS ID analyzer's instructions for use. Target plates are used for MALDI-ToF microorganism identification/differentiation with the Bruker MBT-CA with MBT-CA Sepsityper software extension.

B Principle of Operation:

See Device Description.

C Instrument Description Information:

1. Instrument Name:

   Accelerate Arc instrument (as part of the Accelerate Arc System)

2. Specimen Identification:

   The user applies a patient barcode label to the sample capsule provided in the Accelerate Arc BC kit. When loading the instrument, the user first scans the reagent cartridge barcode using the provided hand-held scanner to unlock the instrument module. The user then enters the sample information by either scanning the patient barcode label on the capsule or manually entering the information into the software via the user interface. After the final concentrated microbial suspension is ready, the user then follows the steps described in the Bruker MALDI Biotyper CA (MBT-CA) System User Manual to ensure sample traceability during target plate spotting and processing.

3. Specimen Sampling and Handling:

   Positive blood culture (PBC) samples must be processed immediately after ringing positive on a continuous monitoring blood culture system. Should delays be unavoidable, stability studies support that PBC samples should be processed within 16 hours when kept incubating in the continuous monitoring system after positivity, or within 24 hours when stored at room temperature after ringing positive on a continuous monitoring system. The user aseptically transfers ~2 mL of PBC sample from the blood bottle into the sample capsule provided in the Accelerate Arc BC Kit. The user caps the capsule and loads the capsule and reagent cartridge (also provided in the BC Kit) into the Accelerate Arc module. The user then selects "run sample" on the user interface to begin sample processing.

   After the sample run is complete (which takes approximately 72 minutes), the user presses the button on the module to unlock the door, removes and disposes of the reagent cartridge, and removes the sample capsule containing the concentrated microbial suspension. After briefly vortexing the capsule, the user pipettes the suspension in duplicate on a Bruker Biotyper MALDI target plate (i.e., two spots are prepared from one sample).

   The user then follows the instructions in the Bruker MBT-CA System User Manual to prepare samples for ID by MALDI-MS. One sample spot is allowed to air dry (direct transfer method, DT) and the other is overlaid with 70% formic acid (extended direct transfer method, eDT) and then allowed to air dry. Both sample spots are overlaid with HCCA matrix. Once matrix has been applied, sample spots should be analyzed with the downstream

MS analyzer within 24 hours. Spots should be analyzed with the Bruker MBT-CA system with MBT-CA Sepsityper software extension.

4. Calibration:

   There are no operator required calibrations on the Accelerate Arc system. The Accelerate Arc module does not perform any measurements, and therefore does not require calibration.

   Calibration of the downstream MS analyzer is achieved using the US IVD Bacterial Test Standard (BTS), as described in the Bruker MBT-CA System User Manual. The Accelerate Arc System labeling instructs the user to spot the US IVD BTS onto target plates along with Arc-processed samples and follow the Bruker MBT-CA System User Manual instructions to ensure MS instrument calibration is achieved.

5. Quality Control:

   No external quality control procedures for Accelerate Arc BC Kit consumables are required.

   Module quality hardware performance checks are performed throughout each procedure to ensure the Accelerate Arc module is functioning as expected. All quality checks must pass for successful run completion. The Arc report will display the Pass/Fail status of each quality check.

   Use of the Bruker US IVD Bacterial Test Standard (BTS) is required to obtain valid identification results when using Arc-prepared samples with the Bruker MBT-CA system with MBT-CA Sepsityper software extension. The user is instructed to apply US IVD BTS to target plates during processing.

   During performance validation testing, process controls were performed daily to ensure the Accelerate Arc and consumables were performing appropriately. Frozen aliquots of PBC containing either gram positive or gram negative controls strains were thawed and processed with Accelerate Arc BC Kits and the Arc instrument. Arc-prepared suspensions were identified with the Bruker MBT-CA system with MBT-CA Sepsityper software extension. All process control results were acceptable. The use of frozen samples was supported by a fresh versus frozen study. Frozen samples were strictly used for process control during validation testing; the Accelerate Arc system is not intended to process frozen clinical specimens.

   During general use, the user will follow local, state and/or federal regulations for Quality Control requirements.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Bruker Daltonik GmbH MBT Sepsityper

B Predicate 510(k) Number(s):
K193419

C Comparison with Predicate(s):

Device & Predicate Device(s):	Accelerate Arc System K240854	Bruker MBT Sepsityper K193419
Device Trade Name	Accelerate Arc System	MBT Sepsityper
General Device Characteristic Similarities		
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. 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	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 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

Device & Predicate Device(s):	Accelerate Arc System K240854	Bruker MBT Sepsityper K193419
	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.	conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and yeast bloodstream infections. Organisms recovered from positive blood culture bottles that are suitable for identification using the MBT Sepsityper include: [Refer to the K193419 Decision Summary for a complete list of organisms.]
Regulation	21 CFR 866.3378 – Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates	Same
Product Code	QNJ	Same
Sample Type	Positive blood culture	Same
Matrix	α-Cyano-4-hydroxycinnamic acid (HCCA)	Same
MALDI-ToF MS Instrument / analyzer	MALDI Biotyper CA System (microflex ST/H, sirius, sirius one instruments)	Same
MALDI-ToF MS instrument software	MBT-CA System with MBT-CA Sepsityper software extension	Same
Target Organisms	Bacteria and yeast	Same
Reference Library	MALDI Biotyper for Clinical Applications (MBT-CA)	Same
MALDI Target Plate	US IVD 48 Spot Target (48 position reusable steel target) MBT Biotarget 96 US IVD (96 position disposable target)	Same
MALDI calibration/QC	Bruker US IVD Bacterial Test Standard (BTS), manual spotting	Same
Results Reported	When used with MBT-CA System with MBT-CA Sepsityper software extension, organism ID	Same
General Device Characteristic Differences		
Compatible Blood Culture Bottles	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	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 • BD BACTEC – Mycosis IC

Device & Predicate Device(s):	Accelerate Arc System K240854	Bruker MBT Sepsityper K193419
		bioMérieux BacT/ALERT system blood culture bottles: • BacT/ALERT SA • BacT/ALERT SN • BacT/ALERT FA • BacT/ALERT FN • BacT/ALERT PF Thermo Scientific VersaTREK system blood culture bottles: • VersaTREK REDOX 1 • VersaTREK REDOX 2
Sample preparation instrument	Accelerate Arc module	None
Sample Preparation Reagents	Accelerate Arc BC kit	MBT Sepsityper Kit US IVD
Technology	Automated PBC processing and manual target preparation for downstream MALDI-TOF MS organism identification	Manual PBC processing and target preparation of targets for MALDI-TOF MS organism identification

VI Standards/Guidance Documents Referenced:

Conformity:

- ANSI UL 61010-1 3rd Ed (May 12, 2012) Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

General use:

- ISO 15223-1 Fourth Edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- CLSI AUTO12-A Specimen Labels: Content and Location Fonts and Label Orientation
- ANSI AAMI IEC 62304:2006/1:2016 Medical device software – Software life cycle processes
- ISO 14971 Third Edition 2019-12 Medical devices – Application of risk management to medical devices

VII Performance Characteristics (if/when applicable):

The performance of the Accelerate Arc system was evaluated in conjunction with the Bruker MALDI Biotyper CA (MBT-CA) system with MBT-CA Sepsityper software extension using the confidence level and interpretive criteria for species identification as described in the Bruker MBT Sepsityper labeling, summarized in **Table 1.**

Table 1. Interpretive criteria for species identification using the Bruker MBT-CA system with MBT-CA Sepsityper software extension

Confidence level	Log(score) Value
High	1.80 – 3.00
Low	1.60 – 1.79
No identification	0.00 – 1.59

Arc-prepared microbial suspensions were spotted using the direct transfer (DT) and extended direct transfer (eDT) workflows in accordance with the Bruker MBT-CA and MBT Sepsityper instructions for use.

Results were considered reportable when one of the workflows (DT or eDT) provides a high confidence result and identical IDs are found when comparing the two workflows (should they both produce ID results). Only reportable results were assessed for accuracy. Accuracy was defined as a matching sample ID from Arc-processed PBC samples compared to ID result from testing of colonies subcultured from the PBC sample and tested with the Bruker MBT-CA; or, as applicable, accuracy was defined as a matching sample ID from Arc-processed samples compared to the known reference ID.

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility of MALDI-TOF MS-based microbial identification using microbial suspensions prepared by the Accelerate Arc system was evaluated across three sites in the US (two external and one internal). Ten clinically representative microorganisms (four gram negative, four gram positive, and two yeast) were used to contrive triplicate PBC samples (**Table 2**). Operators were blinded to the spiked organism ID. Bottles were grown to positivity on a continuous monitoring system and tested across three non-consecutive days.

Table 2. Organisms included in reproducibility testing

Group	Organism
Gram negative	*E. cloacae* complex *K. pneumoniae, P. mirabilis, P. aeruginosa*
Gram positive	*E. faecalis, S. aureus, S. epidermidis, S. agalactiae*
Yeast	*C. albicans, C. tropicalis*

PBC samples were processed using the Accelerate Arc system and microbial suspensions were spotted onto MALDI target plates using the DT and eDT workflows (two spots per suspension), in accordance with the Bruker MBT Sepsityper instructions for use. Microbial ID was determined using the Bruker MBT-CA system with MBT-CA Sepsityper software extension.

A total of nine Accelerate Arc instrument modules and BC kit lots were used for testing (three at each site). Two operators at each site executed testing on alternate days. The study generated 90 results per site (10 organisms x 3 replicates x 3 days) for a total of 270 results

(90 results/site x 3 sites). Reportability and accuracy of identification was determined for each site, operator, and species. In line with the Bruker MBT Sepsityper instructions for use, results were considered reportable when one of the workflows (DT or eDT) provided a high confidence result and identical IDs are found when comparing the two workflows (should they both produce ID results). Only reportable results were assessed for accuracy. Accuracy was defined as a matching sample ID from Arc-processed PBC samples compared the known reference ID.

Reportability was ≥85% across all samples at each site (**Table 3**). When stratified by species, reportability was ≥85% for all species except for *S. agalactiae* (74.1%) and *C. albicans* (63.0%) (**Table 4**). None of these samples generated incorrect IDs – accurate low-confidence IDs were observed for these samples. These data were deemed acceptable due to the overall inter-site reproducibility performance and the existing mitigations included in the Bruker MBT Sepsityper Instructions for Use, which instructs users to perform alternative workflows or follow up testing for samples that do not generate a high confidence ID. Overall, the reproducibility data are acceptable.

Table 3. Reproducibility of Arc-prepared samples – stratified by site, operator, and day

DT + eDT Result	Operator 1				Operator 2				Operators Combined			
	D1	D2	D3	All	D1	D2	D3	All	D1	D2	D3	All
SITE 1												
High	100%	94.4%	100%	97.9%	73.3%	66.7%	100%	81.0%	86.7%	83.3%	100%	90.0%
Low	0.0%	0.0%	0.0%	0.0%	13.3%	25.0%	0.0%	11.9%	6.7%	10.0%	0.0%	5.6%
No ID	0.0%	5.6%	0.0%	2.1%	13.3%	8.3%	0.0%	7.1%	6.7%	6.7%	0.0%	4.4%
SITE 2												
High	100%	83.3%	66.7%	83.3%	86.7%	91.7%	100%	92.9%	93.3%	86.7%	83.3%	87.8%
Low	0.0%	5.6%	13.3%	6.3%	6.7%	0.0%	0.0%	2.4%	3.3%	3.3%	6.7%	4.4%
No ID	0.0%	11.1%	20.0%	10.4%	6.7%	8.3%	0.0%	4.8%	3.3%	10.0%	10.0%	7.8%
SITE 3												
High	100%	100%	100%	100%	100%	83.3%	100%	95.2%	100%	93.3%	100%	97.8%
Low	0.0%	0.0%	0.0%	0.0%	0.0%	16.7%	0.0%	4.8%	0.0%	6.7%	0.0%	2.2%
No ID	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ALL SITES COMBINED												
High	100%	92.6%	88.9%	93.8%	86.7%	80.6%	100%	89.7%	93.3%	87.8%	94.4%	91.9%
Low	0.0%	1.9%	4.4%	2.1%	6.7%	13.9%	0.0%	6.3%	3.3%	6.7%	2.2%	4.1%
No ID	0.0%	5.6%	6.7%	4.2%	6.7%	5.6%	0.0%	4.0%	3.3%	5.6%	3.3%	4.1%

DT = direct transfer workflow eDT = extended direct transfer workflow
High = high confidence ID result (≥ 1.80 log score) Low = low confidence ID result (1.60-1.79 log score)
No ID = no ID result (< 1.60 log score, discordant DT/eDT IDs, or no peaks) D = day of testing

Table 4. Reproducibility of Arc-prepared samples – stratified by species

Organism	DT			eDT			DT + eDT			
	High	Low	No ID	High	Low	No ID	# Reportable	% Reportable	ID Agreement	% Accuracy
Enterobacter cloacae complex	27	0	0	27	0	0	27	100.0%	27	100.0%
Klebsiella pneumoniae	27	0	0	23	3	0	26	96.3%	26	100.0%
Proteus mirabilis	27	0	0	26	0	0	27	100.0%	27	100.0%
Pseudomonas aeruginosa	27	0	0	24	1	0	27	100.0%	27	100.0%

Organism	DT			eDT			DT + eDT			
	High	Low	No ID	High	Low	No ID	# Reportable	% Reportable	ID Agreement	% Accuracy
Enterococcus faecalis	0	5	0	26	1	0	26	96.3%	26	100.0%
Staphylococcus aureus	3	1	0	27	0	0	27	100.0%	27	100.0%
Staphylococcus epidermidis	6	1	1	27	0	0	27	100.0%	27	100.0%
Streptococcus agalactiae	0	1	0	20	6	0	20	74.1%	20	100.0%
Candida albicans	6	2	0	16	4	0	17	63.0%	17	100.0%
Candida tropicalis	2	3	0	23	2	0	23	85.2%	23	100.0%

DT = direct transfer workflow
eDT = extended direct transfer workflow
High = high confidence ID result (≥ 1.80 log score)
Low = low confidence ID result (1.60-1.79 log score)
No ID = no ID result (< 1.60 log score or no peaks)

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Endogenous/Exogenous Substance Interference

An interference study was conducted to evaluate the effects of substances encountered in blood and blood culture media on ID results from Arc-prepared samples. Substances were tested with blood culture bottles spiked with three representative species: *Klebsiella pneumoniae, Staphylococcus aureus,* and *Candida tropicalis.* PBC samples from each interferent-species combination were processed in triplicate on the Accelerate Arc System. Microbial suspensions were spotted according to the DT and eDT Sepsityper workflows, for a total of two spots per sample. The Bruker MBT-CA system with MBT-CA Sepsityper software extension was used to determine sample ID, and ID results from samples with interferent were compared to ID results from interferent-free controls. Results are summarized in **Table 5**. No interference was observed with the following exceptions:

- White blood cells negatively affected reportability across all organisms at concentrations of 1.5×10^{10} cells/mL. No effect was observed when white blood cells were tested at a concentration of 3.75×10^{9} cells/mL. Considering both data points and the dilution of whole blood into blood culture media for PBC, the data are acceptable.
- Protein (albumin and gamma-globulin) negatively affected *C. tropicalis* reportability at 120 g/L concentrations. Interference was not observed when testing with 60 g/L protein. According to *CLSI EP07-A2: Interference Testing in Clinical Chemistry, 3rd edition*, the reference range of protein in whole blood is approximately 60-80 g/L. The data are acceptable.

Overall, reportability and accuracy were acceptable for all interferent-species combinations. No incorrect identifications were observed. Components routinely found in blood and blood culture media are not expected to negatively impact the identification of microorganisms from Arc-prepared samples at clinically relevant concentrations.

Table 5. Interference testing results

Interferent	Tested Conc.	*K. pneumoniae*			*S. aureus*			*C. tropicalis*		
		High	Low	No ID	High	Low	No ID	High	Low	No ID
Triglyceride-rich lipoproteins	10 g/L	3	0	0	3	0	0	3	0	0
Hemolysate (hemoglobin)	5 g/L	3	0	0	2	0	1*	3	0	0
Protein (albumin and gamma-globulin)	120 g/L	2	0	1*	3	0	0	0	0	3
	60 g/L	-	-	-	-	-	-	3	0	0
Conjugated bilirubin	200 mg/L	3	0	0	3	0	0	3	0	0
Unconjugated bilirubin	200 mg/L	3	0	0	3	0	0	3	0	0
White blood cells	1.5×10^{10} cells/mL	0	1	2	0	0	3	0	0	3
	7.5×10^{9} cells/mL	0	1	2	2	0	1	0	0	3
	3.75×10^{9} cells/mL	3	0	0	3	0	0	2	0	1*
SPS (sodium polyanethole sulfonate)	0.5 mg/mL	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	2	1	0	3	0	0
Heparin	3,000 U/L	3	0	0	3	0	0	2	0	1*
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

ID results above represent the final result from the DT + eDT workflows, interpreted in line with the Bruker MBT-CA with Sepsityper instructions for use. High = high confidence ID result (≥ 1.80 log score), Low = low confidence ID result (1.60-1.79 log score), No ID = no ID result (< 1.60 log score or no peaks)

***** This sample replicate initially did not produce an ID; DT and eDT spots were retested from the same Arc-prepared sample. Retesting data yielded high confidence results with an accurate ID. This is included for informational purposes only – the original data is included above.

Polymicrobial Sample Interference

The Accelerate Arc system is not intended for use with PBC samples containing more than one microbe, and polymicrobial samples are excluded by Gram stain. However, polymicrobial samples may not always be detected by Gram stain (i.e., samples with multiple gram-similar microbial species, or samples with mixtures of non-gram-similar organisms at vastly different concentrations) and may subsequently be processed with the Accelerate Arc system. The Bruker MBT-CA Sepsityper software extension includes a mixed culture hint to warn users of possible polymicrobial samples. A polymicrobial sample interference study

was conducted to evaluate the performance of Arc-prepared samples in cases where Gram stain fails to screen/eliminate polymicrobial samples.

Blood culture bottles were spiked, grown to positivity, and used to contrive polymicrobial samples as shown in **Table 6**. Each polymicrobial sample was prepared at five concentration ratios: 5:0, 5:1, 1:1, 1:5, and 0:5. Samples were processed in triplicate on the Accelerate Arc system for a total of 15 ID results per polymicrobial organism combination (5 concentration ratios x 3 replicates). Microbial suspensions were spotted according to the DT and eDT workflows, for a total of two spots per sample. The Bruker MBT-CA system with MBT-CA Sepsityper extension was used to determine sample identification.

Table 6. Polymicrobial test organisms

Polymicrobial Sample Type	Organism 1	Organism 2
Gram-similar microbial species (gram positive)	*Staphylococcus aureus*	*Enterococcus faecalis*
Gram-similar microbial species (gram negative)	*Klebsiella pneumoniae*	*Pseudomonas aeruginosa*
Gram-positive species with skin contaminant	*Staphylococcus aureus*	*Staphylococcus epidermidis*
Gram-negative species with skin contaminant	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Gram-positive species with yeast	*Staphylococcus aureus*	*Candida tropicalis*
Gram-negative species with yeast	*Klebsiella pneumoniae*	*Candida tropicalis*

The "presumptive mixture" warning generated by the Bruker MBT-CA Sepsityper software extension was not used to determine the accuracy of test results. All single-species control samples (i.e., 5:0 and 0:5 ratios) produced reportable and accurate results. For multi-species samples (i.e., 5:1, 1:1, and 1:5 ratios), there were no inaccurate identification results. Some mixed cultures gave a reportable ID result for a single species. In accordance with the Accelerate Arc System indications for use and Bruker MBT-CA instructions for use, blood culture identification must be confirmed by purity plate. In the case of mixed cultures, the identification of all colony morphologies is confirmed using the Bruker MBT-CA system. The data are acceptable. Polymicrobial samples missed by Gram stain are not expected to negatively impact the identification of microorganisms from Arc-prepared samples.

Analytical Inclusivity

The Accelerate Arc system is intended for use with the species included in the Bruker MBT-CA reference library when used with the MBT-CA Sepsityper software extension. Analytical inclusivity and specificity of Arc-prepared samples was deemed acceptable on the basis of the method comparison study. The user should refer to the labeling of the Bruker MBT Sepsityper and Bruker MBT-CA for species inclusivity.

4. Assay Reportable Range:

Not applicable to the Accelerate Arc System, as the system does not report a result. The reportable range of the Bruker MBT-CA system with MBT-CA Sepsityper software extension, as described in the K193419 Decision Summary, is as follows:

MBT Sepsityper: 4,000 – 15,000 *m/z*

MBT Sepsityper Sample Results:

- High Confidence ID: 1.80 – 3.00
- Low Confidence ID: 1.60 – 1.79
- No Organism ID Possible: 0.00 – 1.59

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

Stability summary

Sample stability studies were conducted to assess the performance of Accelerate Arc System samples under various conditions:

(1) *Post-positivity* – after ringing positive, PBCs are stable up to 16 hours when kept in the blood culture bottle incubator, and up to 24 hours when kept at ambient temperature (20-25°C) prior to use with the Accelerate Arc System.
(2) *Post-processing* – after being processed by the Accelerate Arc System, microbial suspensions are stable up to 8 hours when kept refrigerated (2-8°C) or at ambient temperature (20-25°C).
(3) *Post-spotting* – after being spotted on a MALDI target plate and coated with matrix, sample spots are stable up to 24 hours at ambient temperature (20-25°C).

In all studies, contrived positive samples were prepared with four representative microorganisms (*K. pneumoniae, S. aureus, C. tropicalis,* and *H. influenzae*). Bottles were grown to positivity and stored or processed according to each study design described below. All microbial suspensions were spotted according to the DT and eDT Sepsityper workflows, for a total of two spots per sample. The Bruker MBT-CA system with MBT-CA Sepsityper software extension was used to determine sample identification.

Post-positivity stability

Blood bottles were spiked with the four representative organisms in triplicate and incubated on a continuous monitoring system. After flagging positive, bottles were either left to incubate within the blood culture incubator or were removed from the incubator and left at ambient temperature (20-25°C). Bottles were processed with the Accelerate Arc System within one hour of flagging positive (baseline) or after 8, 16, and 17.5 hours for bottles within the blood culture incubator or after 12, 14, and 26.5 hours for bottles outside the blood culture incubator at ambient temperature.

Results are summarized in **Table 7**. All samples produced correct ID results, with the exception of one replicate of *C. tropicalis* at baseline. This is in line with the LoD study results, which showed that *C. tropicalis* detection improves with continued incubation time. There were no incorrect identifications. The data are acceptable and support PBC sample stability up to 16 hours when kept in the blood culture incubator after flagging positive and up to 24 hours when removed from the incubator and kept at ambient temperature after flagging positive.

Table 7. Post-positivity PBC stability results

Storage Condition	Incubation Time (hr)	*K. pneumoniae*			*S. aureus*			*C. tropicalis*			*H. influenzae*		
		High	Low	No ID	High	Low	No ID	High	Low	No ID	High	Low	No ID
Baseline	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
	16	3	0	0	3	0	0	2	1	0	3	0	0
	17.5	3	0	0	3	0	0	3	0	0	1	2	0
Ambient	12	3	0	0	3	0	0	2	1	0	3	0	0
	24	3	0	0	3	0	0	3	0	0	2	1	0
	26.5	3	0	0	3	0	0	3	0	0	2	1	0

Post-processing stability

Blood bottles were spiked with the four representative organisms, incubated on a continuous monitoring system until positivity, and processed with the Accelerate Arc System in triplicate. After processing, samples were spotted within an hour (baseline) or after 4-, 8-, or 9-hours post-processing. Processed samples were stored both refrigerated (2-8°C) and at ambient (20-25°C) temperature.

Results are summarized in **Table 8**. All samples produced correct ID results, with the exception of one replicate of *H. influenzae* stored for 8 hours in 2-8°C and one replicate of *H. influenzae* stored for 4 hours at ambient temperature. However, the same samples produced correct IDs at later timepoints. There were no incorrect identifications. The data are acceptable and support processed sample stability up to 8 hours when kept refrigerated (2-8°C) or at ambient temperature (20-25°C) after processing with the Accelerate Arc.

Table 8. Post-processing sample stability results

Storage Condition	Incubation Time (hr)	*K. pneumoniae*			*S. aureus*			*C. tropicalis*			*H. influenzae*		
		High	Low	No ID	High	Low	No ID	High	Low	No ID	High	Low	No ID
Baseline	0	3	0	0	3	0	0	3	0	0	3	0	0
Refrigerated (2-8°C)	4	3	0	0	3	0	0	3	0	0	3	0	0
	8	3	0	0	3	0	0	3	0	0	2	0	1
	9	3	0	0	3	0	0	3	0	0	3	0	0
Ambient (20-25°C)	4	3	0	0	3	0	0	3	0	0	2	0	1
	8	3	0	0	3	0	0	3	0	0	3	0	0
	9	3	0	0	3	0	0	3	0	0	3	0	0

Post-spotting stability

Blood bottles were spiked with the four representative organisms, incubated on a continuous monitoring system until positivity, and processed with the Accelerate Arc System in triplicate. After processing, samples were spotted and coated with HCCA matrix. Target plates were stored at ambient temperature (20-25°C) until testing. Results are summarized in **Table 9**. All samples produced correct ID results. The data are acceptable and support processed matrix-coated spot stability up to 24 hours when kept at ambient temperature (20-25°C).

Table 9. Post-spotting sample stability results

Storage Condition	Incubation Time (hr)	*K. pneumoniae*			*S. aureus*			*C. tropicalis*			*H. influenzae*		
		High	Low	No ID	High	Low	No ID	High	Low	No ID	High	Low	No ID
Baseline	0	3	0	0	3	0	0	3	0	0	3	0	0
Ambient (20-25°C)	12	3	0	0	3	0	0	3	0	0	3	0	0
	24	3	0	0	3	0	0	3	0	0	3	0	0
	26.5	3	0	0	3	0	0	3	0	0	3	0	0

6. Detection Limit:

A study analogous to a limit of detection (LoD) study was conducted to evaluate the ability of the Accelerate Arc system to isolate sufficient biological material for reportable and accurate ID of microorganisms in PBC. Five representative microorganisms (*K. pneumoniae, P. aeruginosa, S. agalactiae, S. aureus,* and *C. tropicalis*) were used to contrive blood culture bottles that were incubated to positivity on a continuous monitoring blood culture system. Ten replicates of each species were included. Undiluted and 1:10 diluted PBC samples were processed and tested at the time of positivity or up to 1 hour after the time of positivity.

Data are summarized in **Table 10**. At the time of positivity, 100% of Arc-prepared replicates of *S. agalactiae, K. pneumoniae*, and *P. aeruginosa* demonstrated reportable and accurate identifications. For *S. aureus*, 80% of Arc-prepared replicates demonstrated reportable and accurate identifications at the time of positivity. None of the ten replicates of *C. tropicalis* at the time of positivity yielded a successful ID. When tested after 1-hour post-positivity, 90% of Arc-prepared replicates demonstrated reportable and accurate IDs. Reduced performance has been observed with yeast with the Bruker MBT-CA system with MBT-CA Sepsityper software extension as compared to colony testing, as noted in the Bruker MBT Sepsityper Instructions for Use. Considering this and the mitigations included the Sepsityper and MBT-CA labeling surrounding how users should interpret "No ID" results, the data were deemed acceptable.

Diluted samples did not always provide an identification. However, these dilutions demonstrated that lower concentrations of microorganisms did not produce any incorrect identifications. Therefore, risk of false identification of a sample below the detection limit is low. In summary, the LoD study is acceptable.

Table 10. Limit of detection study results

Organism	TPP	Dilution	MALDI ID Result (DT + eDT)				Reportability	% ID Accuracy
			High	Low	No ID	No peaks		
C. tropicalis	0 h *	None	0	0	28	2	0%	-
		1:10	0	0	28	2	0%	-
	1 h	None	9	1	0	0	90%	100% (9/9)
		1:10	0	0	6	4	0%	-
S. aureus	0 h	None	8	1	1[#]	0	90%	100% (9/9)
		1:10	7	0	1	2	70%	100% (7/7)
S. agalactiae	0 h	None	10	0	0	0	100%	100% (10/10)
		1:10	2	1	6	1	20%	100% (2/2)

Organism	TPP	Dilution	MALDI ID Result (DT + eDT)				Reportability	% ID Accuracy
			High	Low	No ID	No peaks		
K. pneumoniae	0 h	None	10	0	0	0	100%	100% (10/10)
		1:10	7	1	0	2	70%	100% (7/7)
P. aeruginosa	0 h	None	10	0	0	0	100%	100% (10/10)
		1:10	1	3	3	3	10%	100% (1/1)

TPP = time post-positivity
* *C. tropicalis* results at 0h TPP were re-tested twice after inconclusive results were observed during initial testing for a total of 30 tests (n=10 for original testing; n=10 for first re-testing; n=10 for second re-testing); the same 10 blood bottle samples were used for re-testing
# *S. aureus* yielded one No ID result at 0h; re-testing of the same sample yielded an accurate high confidence ID

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable. The accuracy of MALDI-TOF ID from Arc-prepared samples was assessed in the Method Comparison study (see Section VII.B.1).

9. Carry-Over:

   A study was conducted to evaluate the potential for carry-over or cross-contamination during processing of PBC samples with the Accelerate Arc system and between analyte spots on the MALDI target plates. Six different microorganisms (three gram positive, three gram-negative) were cultivated in blood culture bottles and incubated on a continuous blood culture monitoring system until positive. A blood culture bottle with fresh donor blood only was incubated for five days to ensure the absence of microorganisms and used for negative control samples. Samples from the negative and positive bottles were alternately processed across three Accelerate Arc instruments using the Arc BC kit. Microbial suspensions from negative and positive samples were alternately spotted side-by-side on a MTB Biotarget 96 spot target plate (disposable) and US IVD 48 spot target plate (reusable). All positive sample spots produced reportable and accurate identifications. No inaccurate identification results were observed from any of the samples tested, including the negative sample spots which produced "No ID" results. No carry-over or cross-contamination was observed.

B Comparison Studies:

1. Method Comparison:

   A method comparison study was conducted to evaluate the performance of the Accelerate Arc System with clinical samples. PBC samples were processed using the Accelerate Arc System followed by ID using the Bruker MBT-CA system with MBT-CA Sepsityper software extension.

   Fresh, prospectively collected PBC samples from patients suspected of bacteremia were included in the study. Samples were only included if Arc testing was initiated within the appropriate post-positivity stability timeframes (≤16 hours post positivity when held in the incubator or ≤24 hours post positive when held at room temperature), samples were

identified as monomicrobial by Gram stain, and the blood bottle media was compatible. Contrived clinical blood cultures were used to supplement the testing with fresh samples and provide analysis of lower prevalence species. Samples were collected and tested across three sites.

All Arc-prepared suspensions were spotted on MALDI target plates using the direct transfer (DT) and extended direct transfer (eDT) spotting workflows in line with the Bruker MBT Sepsityper instructions for use. ID results from Arc-processed PBC samples were compared to ID results with isolated colonies from overnight culture of the same PBC sample when tested on the Bruker MBT-CA system using the DT/eDT workflows. A process control was run on each day of testing.

A total of 349 fresh and contrived positive blood cultures were enrolled and tested throughout the study. Six samples were excluded due to sample processing errors, identification of polymicrobial sample, system error, or lack of reference testing ID. Of the 343 eligible samples, 99 (29%) were fresh clinical blood cultures and 244 (71%) were contrived clinical samples. Site 1 tested 62 samples, site 2 tested 61 samples, and site 3 tested 220 samples.

During the study, 41 different species were identified from the 343 eligible samples (**Table 11**). ID results from Arc-prepared samples stratified by workflow are summarized in **Table 12.** Of the 343 Arc-prepared samples, a total of 311 gave a high or low confidence ID result; for these results, Arc sample ID accuracy was compared to MBT-CA colony ID as summarized in **Table 13**. All identifications were concordant between Arc-prepared samples and colony testing, with the exception of two gram-positive specimens. These specimens were correctly identified to a genus level of *Streptococcus*, but not at the species level. One sample had different organism identifications for the DT and eDT workflows, which is reported as a No ID result in line with the Bruker MBT Sepsityper instructions for use. Additionally, the approved Bruker MBT-CA system with MBT-CA Sepsityper software extension IVD library used during testing includes limitations regarding the differentiation of some *Streptococcus* species. When considering the ID results and applicable limitations, the results were not considered misidentifications. Of samples that gave high or low confidence ID results, 100% of ID results were accurate compared to colony testing.

The data demonstrate that Arc-prepared samples are expected to yield reportable and accurate ID results when used with the Bruker MBT-CA system with MBT-CA Sepsityper software extension.

Table 11. Breakdown of clinical study organisms

Species	**#**		**Species**	**#**
Acinetobacter baumannii / nosocomialis group	10		*Klebsiella variicola*	7
Bacteroides fragilis	6		*Micrococcus luteus*	11
Bacteroides ovatus group	1		*Morganella morganii*	5
Candida albicans	6		*Proteus mirabilis*	12
Candida glabrata	5		*Proteus vulgaris* group	6
Candida parapsilosis	1		*Pseudomonas aeruginosa*	15
Candida tropicalis	5		*Salmonella sp*	1
Citrobacter freundii complex	11		*Serratia marcescens*	10
Citrobacter koseri	5		*Staphylococcus aureus*	23

Species	#		Species	#
Clostridium tertium	1		*Staphylococcus capitis*	9
Corynebacterium minutissimum	1		*Staphylococcus epidermidis*	21
Cutibacterium acnes	2		*Staphylococcus hominis*	14
Enterobacter cloacae complex	12		*Staphylococcus pseudintermedius*	1
Enterococcus durans	1		*Streptococcus agalactiae*	12
Enterococcus faecalis	16		*Streptococcus dysgalactiae*	2
Enterococcus faecium	15		*Streptococcus mitis / oralis* group	7
Escherichia coli	28		*Streptococcus pneumoniae*	9
Haemophilus influenzae	7		*Streptococcus pyogenes*	7
Klebsiella aerogenes	10		*Streptococcus salivarius / vestibularis* group	1
Klebsiella oxytoca / Raoultella ornithinolytica	10		*Streptococcus sanguinis*	1
Klebsiella pneumoniae	16			

Table 12. Results of Arc samples tested with the Bruker MBT-CA system with MBT-CA Sepsityper software extension

Organisms	# tested	DT			eDT			DT + eDT		
		High	High + Low	No ID*	High	High + Low	No ID*	High	High + Low	No ID*
Gram negative	172	163 (94.8%)	167 (97.1%)	5 (2.9%)	147 (85.5%)	158 (91.9%)	14 (8.1%)	165 (95.9%)	167 (97.1%)	5 (2.9%)
Gram positive	154	26 (16.9%)	50 (32.5%)	104 (67.5%)	118 (76.6%)	129 (83.7%)	25 (16.2%0	120 (77.9%)	134 (87.0%)	20 (12.9%)
Yeast	17	0 (0%)	0 (0%)	17 (100%)	8 (47.0%)	10 (58.76%)	7 (41.2%)	8 (47.1%)	10 (58.9%)	7 (41.1%)
Total	343	189 (55.1%)	217 (63.3%)	126 (36.7%)	273 (79.6%)	297 (86.6%)	46 (13.4%)	293 (85.4%)	311 (90.7%)	32 (9.3%)

DT = direct transfer eDT = extended direct transfer

* No acceptable ID provided by Sepsityper software extension or conflicting IDs from the two

Table 13. Agreement between Arc sample ID (tested with MBT-CA system with MBT-CA Sepsityper software extension) and colony ID (tested with MBT-CA system)

Organism	No. of samples	ID Agreement *
Gram negative	167	100%
Gram positive	134	100%
Yeast	10	100%
Total	311	100%

*ID agreement was assessed for both low and high confidence IDs from Arc-prepared samples and compared to MBT-CA ID of colony isolates. Arc-prepared PBC samples that yielded No ID (n=32) were not included in accuracy analysis.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

See Section VII.B.1 Method Comparison above.

2. Clinical Specificity:

   See Section VII.B.1 Method Comparison above.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

See Section VII.A.4 Assay Reportability Range above.

E Expected Values/Reference Range:

See Section VII.A.4 Assay Reportability Range above.

F Other Supportive Instrument Performance Characteristics Data:

Blood Bottle Compatibility

Seven different blood culture bottle types from the BD BACTEC blood culture system were evaluated with the Accelerate Arc system to determine if bottle type impacted MS ID results from Arc-prepared samples. The following blood culture media/bottle types were tested:

- BD BACTEC Standard/10 Aerobic/F medium
- BD BACTEC Standard Anaerobic/F medium
- BD BACTEC Plus Aerobic/F medium
- BD BACTEC Plus Anaerobic/F medium
- BD BACTEC PEDS PLUS/F medium
- BD BACTEC Lytic/10 Anaerobic/F medium
- BD BACTEC Myco/F Lytic medium

Blood culture bottles were seeded with five representative microorganisms (two gram negative, two gram positive, and one yeast) in triplicate, incubated to positivity on the BD BACTEC continuous monitoring system, and processed with the Accelerate Arc system. Arc-prepared samples were tested using the DT and eDT workflows and analyzed using the Bruker MBT-CA system with MBT-CA Sepsityper software extension. Some organism-bottle combinations did not yield results, as not all blood culture media types supported growth for the tested organisms. Results are summarized in **Table 14**. ID results from Arc-prepared samples with each bottle type were compared to the expected organism ID. Results were as expected with the following exceptions:

- Myco/F Lytic bottle type yielded lower reportability for gram positive species (3/3 No ID results for *S. aureus*, 2/3 No ID results for *S. agalactiae*). As no incorrect results were observed and this bottle type is not intended to be used with gram positive species, the results are acceptable.
- Lower reportability was observed with *C. tropicalis* grown with Standard Aerobic and Standard Anaerobic bottles, and only two Standard Anaerobic bottles rang positive. No incorrect results were observed. Reduced performance has been observed with yeast with the Bruker MBT-CA system with MBT-CA Sepsityper software extension as compared to colony testing, as noted in the MBT Sepsityper Instructions for Use. Considering this

and the mitigations included the MBT-CA labeling surrounding how users should interpret "No ID" results, the data were deemed acceptable.

Overall, the blood bottle compatibility study results are acceptable. No incorrect identifications were observed. The tested bottle types are not expected to negatively impact the identification of microorganisms from Arc-prepared samples.

Table 14. Blood bottle compatibility study results

BD BACTEC Bottle Type	**ID Results High Confidence | Low Confidence | No ID**				
	S. aureus	***S. agalactiae***	***K. pneumoniae***	***P. aeruginosa***	***C. tropicalis***
Standard Aerobic	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	2 | 1 | 0	1 | 1 | 1
Standard Anaerobic	3 | 0 | 0	2 | 1 | 0	3 | 0 | 0	N/A*	0 | 0 | 2*
Plus Aerobic	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Plus Anaerobic	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	N/A*	2 | 1 | 0
Peds Plus	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0
Lytic Anaerobic	3 | 0 | 0	3 | 0 | 0	3 | 0 | 0	N/A*	N/A*
Myco Lytic	0 | 0 | 3	0 | 1 | 2	2 | 1 | 0	3 | 0 | 0	2 | 1 | 0

*Organism/bottle combination did not produce a PBC

Stability of Frozen PBC Samples for Process Control Testing

A study was conducted to demonstrate equivalency between fresh and frozen blood culture samples to support the use of frozen samples in analytical studies and the use of frozen PBC samples for process control testing during analytical and clinical validation. Blood culture bottles were contrived with *E. coli, S. aureus*, and *E. faecalis* and incubated on a continuous blood culture monitoring system until positivity. Bottles contrived with the same organism were pooled and aliquots were made for fresh sample testing and for storage at -80°C (frozen). On each day of testing, three aliquots per organism were processed with the Accelerate Arc System and identified with the Bruker MBT-CA system with MBT-CA Sepsityper software extension. All fresh and frozen PBC samples produced high confidence accurate results across all replicates up to six weeks of storage at -80°C.

VIII Proposed Labeling:

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

IX Conclusion:

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