March 24, 2023

Becton, Dickinson and Company
Kamisha Gray
Senior Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152-0999

Re: K222559
Trade/Device Name: BD BACTEC Myco/F Lytic Culture Vials
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I, reserved
Product Code: MDB
Dated: August 23, 2022
Received: August 24, 2022

Dear Kamisha Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222559

Device Name
BD BACTEC™ Myco/F Lytic Culture Vial

Indications for Use *(Describe)*

BD BACTEC™ Myco/F Lytic culture medium when used with the BD BACTEC fluorescent series instruments is a nonselective culture medium to be used as an adjunct to aerobic blood culture media for the qualitative culture and recovery of mycobacteria, yeast and fungi from blood. This medium may also be used for the culture of sterile body fluids when yeast or fungi are suspected.

Additional information
The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Summary Preparation Date:
3/23/2023

I Background Information:

A 510(k) Number

K222559

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD BACTEC™ Myco/F Lytic Culture Vials (plastic)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MDB	Class I	21 CFR 866.2560 – Microbial Growth Monitor	MI – Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for a premarket notification for the BD BACTEC™ Myco F/Lytic Culture Vials (plastic).

B Measurand:

Aerobic microorganisms (mycobacteria, yeast, and fungi) from blood
Aerobic microorganisms (yeast, and fungi) from sterile body fluids

C Type of Test:

Liquid culture medium for recovery of microorganisms from blood and sterile body fluids using fluorescent technology to detect decreases in O_2 resulting from the metabolism and growth of microorganisms.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indications(s) for Use:

BD BACTEC™ Myco/F Lytic culture medium when used with the BD BACTEC fluorescent series instruments is a nonselective culture medium to be used as an adjunct to aerobic blood culture media for the qualitative culture and recovery of mycobacteria, yeast and fungi from blood. This medium may also be used for the culture of sterile body fluids when yeast or fungi are suspected.

Additional information

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The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

D Special Instrument Requirements:

BACTEC fluorescent series instruments BACTEC FX, BACTEC FX40, BACTEC 9240 and BACTEC 9050 were evaluated using software versions listed below:

Instrument	Software Version
BACTEC FX	6.40A or 6.40W*
BACTEC 9240	4.95A
BACTEC 9050	2.01A2
BACTEC FX40	3.40A

*6.40W is the Window-based version of 6.40A

IV Device/System Characteristics:

A Device Description:

BD BACTEC™ Myco/F Lytic culture medium is a Middlebrook 7H9 and Brain Heart Infusion broth formulation for the recovery of mycobacteria from blood specimens, and yeast and fungi from blood and sterile body fluids. Specific modifications were made to enhance the growth and recovery of mycobacteria, yeast and fungi. These modifications include ferric ammonium citrate to provide an iron source for specific strains of mycobacteria and fungi, the addition of saponin as a blood lysing agent, and the addition of specific proteins and sugars to provide nutritional supplements. Each vial contains a sensor which can detect decreases in oxygen concentration in the vial resulting from microorganism metabolism and growth. The sensor is monitored by the BD BACTEC fluorescent series instrument for increasing fluorescence, which is due to the decrease in oxygen. A positive determination indicates the presumptive presence of viable microorganisms in the vial.

BD BACTEC Myco/F Lytic Culture Vials are supplied in a carton containing 50 vials. It is a non-sterile product.

B Principle of Operation:

The BD BACTEC Myco/F Lytic Culture Vial is designed for the rapid detection of mycobacteria in blood, and yeast and fungi in blood and sterile body fluids. Specimens are inoculated into the BD BACTEC Myco/F Lytic vial either with a syringe or direct draw with a needle and tubing. The vial is placed into the BD BACTEC fluorescent series instrument and is continuously agitated and incubated at 35 C for maximum recovery. The default testing protocol is 42 days. The recommended testing protocols for the following organisms are 7 days for yeast, 30 days for filamentous fungi and 42 days for mycobacteria and dimorphic fungi. Each vial contains a sensor which can detect decreases in oxygen concentration in the vial resulting from microorganism metabolism and growth. The sensor is monitored by the BD BACTEC fluorescent series instrument every ten minutes. Analysis of the rate of oxygen decrease as measured by increasing fluorescence enables the BD BACTEC fluorescent series instrument to determine if the vial is instrument positive. A positive determination indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in the medium

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at 35 °C. The medium is not selective and will support the growth of other aerobic organisms including bacteria which may interfere, if present, with the recovery of slower growing mycobacteria, yeast and fungi. Culture vials which remain negative after the completion of protocol, and which show no visible sign of positivity are removed from the instrument and sterilized prior to discarding. This qualitative culture functions as an aid to diagnosis and is automated on the BD BACTEC fluorescent series instrument.

V Substantial Equivalence[1] Information:

A Predicate Device Name(s):

BD BACTEC™ Myco/F Lytic Culture Vials

B Predicate 510(k) Number(s):

K970333, K970512

C Comparison with Predicate(s):

Device & Predicate Device(s):	**Device: K222559**	**Predicate: K970333, K970512**
Device Trade Name	BD BACTEC Myco/F Lytic Culture Vial (plastic)	BD BACTEC Myco/F Lytic Culture Vial
General Device Characteristic Similarities		
Regulation	21 CFR § 866.2560	Same
Product Code	MDB	Same
Classification	Class I	Same
Detection used	BD BACTEC™ Fluorescent instrument series	Same
Sample Source	Blood Culture, Sterile Body fluids	Same
Volume	1 mL – 5.0 mL	Same
Protocol Length	42 days for Mycobacteria 7 days for Yeast 30 days for Fungi	Same
Target population	Adult	Same
General Device Characteristic Differences		
Intended Use/Indications for Use	BD BACTEC™ Myco/F Lytic culture medium when used with the BD BACTEC fluorescent series instruments is a nonselective culture medium to be used as an adjunct to aerobic blood culture media for the qualitative culture and recovery of mycobacteria, yeast and fungi from blood. This medium may also be used for the culture of sterile body fluids when yeast or fungi are suspected. **Additional information**	BD BACTEC™ Myco/F Lytic culture medium when used with the BD BACTEC fluorescent series instruments is a nonselective culture medium to be used as an adjunct to aerobic blood culture media for the recovery of mycobacteria, yeast and fungi from blood. This medium may also be used for the culture of sterile body fluids when yeast or fungi are suspected.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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Device & Predicate Device(s):	**Device: K222559**	**Predicate: K970333, K970512**
	The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.	
Vial Material	Plastic	Glass
Vial Weight	21.5 grams	102.05 grams
Vial Height	5.0 inches	5.6 inches
Delayed Vial Entry Studies	Included	Not included

VI Standards/Guidance Documents Referenced:

CLSI. *Principles and Procedures for Blood Cultures*. 2nd ed. CLSI guideline M47. Clinical and Laboratory Standards Institute; 2022.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Blood Volumes

The BACTEC™ Myco/F Lytic (plastic) vial was evaluated at three different blood volumes (1mL, 3mL, 5mL) across three lots in Time-To- Detection (TTD) and Percent Recovery studies. Different lots of key raw materials were used to manufacture each lot of culture media. Inoculum levels of 0-1, 1-10, and 10-100 CFU were used in the analysis. Results of the reproducibility study demonstrated no statistically significant differences in organism detection times or percent recovery with blood specimens between the three different lots of BACTEC™ Myco/F Lytic (plastic) vials.

Sterile Body Fluid Volumes

The BACTEC™ Myco/F Lytic (plastic) vial was evaluated at three different sterile body fluid types (pleural, synovial, and cerebrospinal), four different volumes (0.5mL, 1mL, 3mL, 5mL) across three lots in Time-To- Detection (TTD) and Percent Recovery studies. Different lots of key raw materials were used to manufacture each lot of culture media. Inoculum levels of 0-1, 1-10, and 10-100 CFU were used in the analysis. Results of the reproducibility study demonstrated no statistically significant differences in organism detection times or percent recovery with sterile body fluid specimens between the three different lots of BACTEC™ Myco/F Lytic (plastic) vials.

2. Linearity:

Not Applicable

3. Analytical Specificity/Interference:

Not Applicable

4. Assay Reportable Range:

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Not Applicable

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

Quality Control

An internal validation study across three lots with a target inoculum level of 10-100 CFU per vial was conducted using organisms listed below:

Table 1: Quality Control Organism and TTD Range

QC Organism ATCC® Strain	Time-To-Detection (TTD) (Days)
Candida glabrata ATCC 15545	<3
Cryptococcus neoformans, ATCC 13690	<3
Mycobacterium fortuitum, ATCC 6841	≤ 21
Mycobacterium intracellulare, ATCC 13950	8-16
Mycobacterium kansasii, ATCC 12478	≤ 21
Mycobacterium tuberculosis ATCC 25177 (H37Ra)	≤ 21

There were a total of 240 replicates of these six QC organisms for the study. Each organism was tested for either 36 (12 replicates x 3 lots) or 60 (20 replicates x 3 lots) replicates. All organisms detected within the specified duration captured in Table 1.

6. Detection Limit:

Blood Volumes

Microbial Detection Limit (MDL, target inoculum level 0-1, 1-10 CFU/vial) in blood

The microbial detection limit study was conducted to assess the capability of the culture media to detect low numbers of organisms (expected target level of 0-1 and 1- 10 CFU/vial) when present in blood. The study included 23 organisms (8 mycobacteria, 10 yeast, 3 filamentous fungi, and 2 dimorphic fungi strains) tested at three blood volumes (1, 3 and 5 mL), each with two inoculum levels of 0-1 and 1-10 CFU/vial and across three lots by one instrument (BACTEC FX):

23 orgs x 3 lots x 3 blood vol x 2 inoculum levels x 1 instrument= 414* paired vials

*Note: Two pairs were discarded due to contamination resulting in 412 paired vials.

The ratio of positive yields was calculated. The combined performance results of 0-1 and 1-10 CFU/vial for each organism type (mycobacteria, yeast, filamentous fungi, and dimorphic fungi) are provided in Table 2, Table 3, Table 4, and Table 5, respectively.

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Table 2: MDL Percent Recovery Results by Blood Volume for Mycobacteria with 0-1 and 1--10 CFU

Organism	*Blood Volume (mL)*	*Paired sets (N)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Organism and Blood Volume	*Per Organism*
Mycobacterium bovis ATCC 35724[1, 2]	1	6	100	83.33	0.83	1.07
	3	6	100	100	1.00	
	5	6	50.00	83.33	1.67	
Mycobacterium tuberculosis ATCC 25177	1	6	100	100	1.00	1.00
	3	6	100	100	1.00	
	5	6	100	100	1.00	
Mycobacterium tuberculosis TB007	1	6	100	100	1.00	1.00
	3	6	100	100	1.00	
	5	6	100	100	1.00	
Mycobacterium abscessus ATCC 19977[1]	1	6	83.33	83.33	1.00	1.08
	3	6	66.67	83.33	1.25	
	5	6	66.67	66.67	1.00	
Mycobacterium chimaera BR0909[2]	1	6	83.33	33.33	0.40	0.73
	3	6	83.33	66.67	0.80	
	5	6	83.33	83.33	1.00	
Mycobacterium fortuitum ATCC 6841[1,2]	1	6	83.33	66.67	0.80	1.00
	3	6	16.67	50.00	3.00	
	5	6	50.00	33.33	0.66	
Mycobacterium intracellulare ATCC 13950[2]	1	6	66.67	50.00	0.75	0.83
	3	4	50.00	25.00	0.50	
	5	6	66.67	66.67	1.00	
Mycobacterium kansasii ATCC 12478[1,2]	1	6	83.33	83.33	1.00	1.00
	3	6	50.00	66.67	1.33	
	5	6	66.67	50.00	0.75	

[1] The percent recovery of these pathogens at some low inoculum levels and blood volume test conditions and test strains were higher with this device compared to the predicate. However, these differences are not statistically significant.

[2] The percent recovery of these pathogens at some low inoculum levels and blood volume test conditions and test strains were lower in the candidate device compared to the predicate device. However, these differences are not statistically significant.

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Table 3: MDL Percent Recovery Results by Blood Volume for Yeast with 0-1 and 1-10 CFU in the FX

Organism	*Blood Volume (mL)*	*Paired sets (N)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Organism and Blood Volume	*Per Organism*
Candida albicans ATCC 10231	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Candida auris AR 0387	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Candida glabrata ATCC 15545	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Candida glabrata ATCC 66032	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Candida krusei ATCC 34135	1	6	50.00	50.00	1.00	1.00
	3	6	66.67	66.67	1.00	
	5	6	50.00	50.00	1.00	
Candida parapsilosis ATCC 10232[1,2]	1	6	50.00	66.67	1.33	1.00
	3	6	50.00	50.00	1.00	
	5	6	66.67	50.00	0.75	
Candida tropicalis ATCC 750	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Cryptococcus neoformans ATCC 13690	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	50.00	1.00	
	5	6	50.00	50.00	1.00	
Malassezia furfur ATCC 14521	1	6	100	100	1.00	1.00
	3	6	100	100	1.00	
	5	6	100	100	1.00	
Saccharomyces cerevisiae ATCC 90146[1,2]	1	6	50.00	50.00	1.00	1.00
	3	6	50.00	33.33	0.67	
	5	6	33.33	50.00	1.50	

[1] The percent recovery of these pathogens at some low inoculum levels and blood volume test conditions and test strains were higher with this device compared to the predicate. However, these differences are not statistically significant.

[2] The percent recovery of these pathogens at some low inoculum levels and blood volume test conditions and test strains were lower in the candidate device compared to the predicate device. However, these differences are not statistically significant.

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Table 4: MDL Percent Recovery Results by Blood Volume for Filamentous Fungi with 0-1 and 1-10 CFU

Organism	*Blood Volume (mL)*	*Paired sets (N)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Organism and Blood Volume	*Per Organism*
Aspergillus fumigatus ATCC 13073	1	6	66.67	100	1.50	1.31
	3	6	100	100	1.00	
	5	6	50.00	83.33	1.67	
Talaromyces marneffei ATCC 64101	1	6	100	100	1.00	0.94
	3	6	100	100	1.00	
	5	6	100	83.33	0.83	
Rhizopus oryzae ATCC 66275	1	6	100	100	1.00	1.00
	3	6	100	100	1.00	
	5	6	100	100	1.00	

Table 5: MDL Percent Recovery Results by Blood Volume for Dimorphic Fungi with 0-1 and 1-10 CFU in the FX

Organism	*Blood Volume (mL)*	*Paired sets (N)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Organism and Blood Volume	*Per Organism*
Blastomyces dermatitidis ATCC 18188	1	6	16.67	0	0.00	0.33
	3	6	16.67	0	0.00	
	5	6	66.67	33.33	0.50	
Histoplasma capsulatum ATCC 26032	1	6	100	83.33	0.83	0.94
	3	6	100	100	1.00	
	5	6	100	100	1.00	

The MDL study with blood demonstrated that the plastic device performed equivalently based on a value of close to 1 or higher when compared to the predicate glass device at low target inoculum levels for all organisms with the exception of *Blastomyces dermatitidis*. The *Blastomyces dermatitidis* resulted in a ratio of positive yields of 0.33. The culture medium of BD BACTEC Myco/F Lytic displays inconsistent growth of *Blastomyces dermatitidis*. Information about this organism was noted as a limitation in the product insert.

Sterile Body Fluid Volumes

Microbial Detection Limit (MDL, target inoculum level 0-1, 1-10 CFU/vial) with Sterile Body Fluid (SBF)

The microbial detection limit study was conducted to assess the capability of the culture media to detect low numbers of organisms (expected target level of 0-1 and 1- 10 CFU/vial) when present in sterile body fluid (pleural, synovial, and cerebrospinal). Five organisms (1 filamentous fungi, 2 yeast, and 2 dimorphic fungi strains) were tested with cerebrospinal fluid (CSF) and three organisms (1 filamentous fungi and 2 yeast strains) were tested with pleural

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and synovial fluid at four sterile body fluid volumes (0.5, 1, 3 and 5 mL), each with two inoculum levels of 0-1 and 1-10 CFU/vial and across three lots by one instrument (BACTEC FX).

3 organisms x 3 lots x 4 SBF volumes x 2 inoculum levels x 1 instrument x 2 SBF (pleural & synovial fluid) = 144 paired vials

5 organisms x 3 lots x 4 SBF volumes x 2 inoculum levels x 1 instrument x 1 SBF (cerebrospinal fluid) = 120 paired vials

Total =264 paired vials

The ratio of positive yields was calculated to assess performance. The detection results of 0-1 and 1-10 CFU/vial were evaluated for each organism and organism group (mycobacteria, yeast, filamentous fungi, and dimorphic fungi) in Table 7.

Table 6: MDL Percent Recovery Results by Organisms at Target Inoculum 0-1 and 1-10 CFU in SBF

Organism	*SBF Type*	*Vial Type*	*N*	*Percent Recovery (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Condition	*Per Organism*
Aspergillus fumigatus ATCC 13073	CSF	Glass	24	79.17	1.05	1.00
		Plastic	24	83.33		
	Pleural Fluid	Glass	24	75.00	1.00	
		Plastic	24	75.00		
	Synovial Fluid	Glass	24	66.67	0.94	
		Plastic	24	62.50		
Candida auris AR 0387	CSF	Glass	24	75.00	1.00	1.04
		Plastic	24	75.00		
	Pleural Fluid	Glass	24	70.83	1.12	
		Plastic	24	79.17		
	Synovial Fluid	Glass	24	75.00	1.00	
		Plastic	24	75.00		
Cryptococcus neoformans ATCC 13690	CSF	Glass	24	54.17	1.31	1.18
		Plastic	24	70.83		
	Pleural Fluid	Glass	24	58.33	1.29	
		Plastic	24	75.00		
	Synovial Fluid	Glass	24	70.83	1.00	
		Plastic	24	70.83		
Blastomyces dermatitidis ATCC 18188	CSF	Glass	24	58.33	0.86	0.86
		Plastic	24	50.00		
	CSF	Glass	24	54.17	1.08	1.08

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Organism	*SBF Type*	*Vial Type*	*N*	*Percent Recovery (%)*	*Ratio of Positive Yields (Plastic/Glass)*	
					Per Condition	*Per Organism*
Histoplasma capsulatum ATCC 18188		Plastic	24	58.33		

The MDL study with sterile body fluid demonstrated that the modified plastic device performed equivalently based on a value of 1 or higher when compared to the predicate glass device at low target inoculum levels for all organisms with the exception of *Blastomyces dermatitidis*. The Blastomyces dermatitidis resulted in a ratio of positive yields of 0.86. The culture medium of BD BACTEC Myco/F Lytic displays inconsistent growth of *Blastomyces dermatitidis* at low target inoculum of 0-1 or 1-10 CFU/vial. Information about this organism was noted as a limitation in the product insert.

7. Assay cut-off

   Not Applicable

8. Delayed Entry in blood for Mycobacteria

   As a way to assess the potential effects from delay which may occur in practice, an internal study was conducted to evaluate the effect of recovery, from the time the plastic Myco/F Lytic culture vial was inoculated, to the time the vial was placed on the instrument. This seeded study was conducted using three lots of the plastic Myco/ F Lytic culture vials. The delayed vial entry study was conducted using the following mycobacterium at target concentrations of 10-100 CFU/vial: *Mycobacterium abscessus, Mycobacterium bovis, Mycobacterium chimaera, Mycobacterium fortuitum, Mycobacterium intracellulare, Mycobacterium kansasii,* and 2 strains of *Mycobacterium tuberculosis*. Vials were prepared in 1-, 3-, and 5-mL human blood. All samples were held at the specified temperatures and times prior to loading into the BD BACTEC fluorescent instrument. Percent recovery and Time-To-Detection reflects time to positive flagged by the instrument. The study demonstrated that all delayed entry conditions showed 100% percent recovery of the 8 strains of mycobacterium evaluated. These results are acceptable. Study results are presented in Table 8, below.

Table 7: Delayed Entry Summary (Plastic Bottle)

Delay Time in Hours	*Delay Temperature (°C)*	*Percent Recovery (%)*	*Median Instrument TTD in Hours (Range)*
No Delay	Control	100 (72/72)	370.2 (71.1-650.2)
12	34.5-37.5	100 (72/72)	346.3 (58.2-642.4)
12	20-25	100 (70/70)	370.4 (63.2-642.3)
24	20-25	100 (72/72)	362.2 (55.1-706.4)
48	20-25	100 (71/71)	346.2 (42.1-732.4)
72	20-25	100 (71/71)	338.2 (32.1-618.4)
96	20-25	100 (72/72)	330.2 (21.2-610.2)

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The Product Insert recommends that the inoculated culture bottles are placed in the BD BACTEC fluorescent series instrument as soon as possible after collection: "BD recommends that inoculated culture bottles be placed into the BD BACTEC fluorescent series instruments as soon as possible after collection. But, in the unavoidable cases when there is a delay in bottle receipt by the laboratory, delayed entry information is provided from seeded studies for mycobacterium in the 'Expected Values and Specific Performance Characteristics (Blood Cultures)' section. Medium has not been evaluated for delayed vial entry for yeast, fungi, or sterile body fluids."

B Comparison studies:

Performance of the BD BACTEC Myco/F Lytic Culture Vial (plastic) was evaluated in seeded internal analytical studies to demonstrate comparable performance to the predicate device, the BD BACTEC Myco/F Lytic Culture Vial (glass). Comparison results were acceptable. The comparisons were made using the following parameters: time to detection, percent recovery, false negative rate, and false positive rate.

1. Method Comparison with Predicate Device:

Instrument Time to Detection (TTD) study in blood

The TTD (in hours) was recorded as part of the combined Percent Recovery and the Microbial Detection Limit studies using the BD BACTEC FX at three inoculum levels, across three blood volumes (1 mL, 3 mL and 5 mL) over three media lots. The Percent Recovery study represented by the standard inoculum of 10 to 100 CFU per vial and the Microbial Detection Limit study represented by the challenge inoculum levels of 0 to 1 and 1 to 10 CFU per vial.

The data was analyzed using the 95% confidence interval with the bootstrap method. The TTD data was stratified by organism group, target inoculum level, and blood volume. The results are shown in Table 9.

The TTD study demonstrated that the plastic device performed equivalently when compared to the predicate glass device when stratified by organism group (Dimorphic Fungi, Filamentous, Fungi, Yeast and Mycobacteria), inoculum concentration (0-1, 1-10, 10-100), and blood volume (1 mL, 3 mL and 5 mL). The results show that the test vial performed equivalently to or better than the predicate vial for all conditions, with the exception of Dimorphic Fungi at an inoculum concentration of 0-1 CFU/vial at 1 mL blood volume and Mycobacteria at an inoculum concentration of 1-10 CFU/vial and blood volume of 1mL. The data was statistically analyzed by means of 95% CI with the bootstrap method, where the 95% CI for equivalent median detection times versus the predicate vial contains zero and the 95% CI for median detection times shorter than the predicate contains only negative values.

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Table 8: Summary of TTD Study Results by Organism Group, Target Inoculum Levels, and Blood Volumes[1]

Organism Group	*Inoculum Concentration (CFU/Vial)*	*Blood Volume (mL)*	*Median TTD for Glass (Predicate) (95% CI) [N]*	*Median TTD for Plastic (Modified) (95% CI) [N]*	*Median of TTD difference[2] (95% CI) [N]*
Dimorphic Fungi	0-1	1	820.10 (722.121, 918.132) [2]	960.15 (954.154, 966.151) [2]	140.00 (36.021, 244.029) [2]
		3	490.00 (458.100, 930.150) [3]	698.10 (482.130, 754.140) [3]	24.00 (-176.01, 208.01) [3]
		5	442.10 (442.112, 514.146) [3]	418.10 (394.111, 458.116) [3]	-48.00 (-96.036, 16.002) [3]
	1-10	1	514.30 (514.091, 602.092) [3]	578.10 (530.090, 642.258) [3]	64.00 (-72.002, 128.006) [3]
		3	370.06 (354.054, 386.061) [3]	338.10 (322.054, 418.064) [3]	-32.00 (-32.000, 32.003) [3]
		5	370.10 (314.064, 462.163) [5]	362.00 (338.070, 866.230) [5]	40.10 (-24.000, 404.070) [5]
	10-100	1	354.00 (338.140, 858.230) [5]	450.10 (330.140, 754.227) [5]	-8.00 (-376.016, 112.005) [5]
		3	450.00 (262.150, 850.300) [6]	282.10 (262.148, 538.169) [6]	-104.10 (-384.080, 8.000) [6]
		5	258.10 (250.159, 318.114) [6]	266.10 (258.159, 374.116) [6]	8.00 (-24.001, 88.002) [6]
Filamentous Fungi	0-1	1	80.00 (26.08, 514.30) [7]	57.00 (26.08, 530.30) [7]	-3.00 (-32.006, 1.999) [7]
		3	82.20 (26.069, 410.246) [9]	74.20 (26.066, 314.236) [9]	-2.00 (-96.010, 17.015) [9]
		5	32.10 (25.054, 234.214) [5]	26.10 (25.053, 290.220) [5]	-1.00 (-16.054, 72.061) [5]
	1-10	1	53.10 (23.085, 162.201) [9]	53.20 (22.084, 202.176) [9]	-0.00 (-5.001, 31.999) [9]
		3	52.10 (22.075, 218.167) [9]	57.10 (22.072, 138.165) [9]	-1.00 (-24.001, 4.999) [9]
		5	52.10 (23.061, 114.151) [9]	44.10 (23.057, 114.152) [9]	-1.00 (-10.001, -0.001) [9]
	10-100	1	37.10 (19.126, 106.140) [9]	36.10 (19.125, 106.141) [9]	-0.00 (-1.001, -0.001) [9]
		3	37.10 (19.119, 98.133) [9]	37.10 (19.119, 98.132) [9]	-0.00 (-1.001, -0.001) [9]
		5	37.10 (19.113, 98.124) [9]	36.10 (19.112, 98.125) [9]	-0.00 (-1.001, 0.999) [9]
Yeast	0-1	1	70.12 (70.120, 73.131) [3]	70.12 (70.121, 72.126) [3]	-0.00 (-3.008, 2.006) [3]
		3	64.10 (61.107, 65.109) [3]	66.10 (64.108, 67.106) [3]	2.00 (-1.001, 5.999) [3]
		5	62.10 (61.094, 65.092) [3]	63.09 (61.095, 65.091) [3]	-0.00 (-1.001, 1.999) [3]
	1-10	1	31.06 (30.123, 49.144) [29]	30.24 (28.059, 52.146) [29]	-0.00 (-0.002, 0.999) [29]

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Organism Group	*Inoculum Concentration (CFU/Vial)*	*Blood Volume (mL)*	*Median TTD for Glass (Predicate) (95% CI) [N]*	*Median TTD for Plastic (Modified) (95% CI) [N]*	*Median of TTD difference[2] (95% CI) [N]*
		3	30.11 (29.111, 33.123) [29]	30.11 (29.065, 35.121) [29]	-0.00 (-0.002, 0.999) [29]
		5	30.05 (27.102, 31.114) [29]	30.22 (28.103, 32.051) [29]	-0.00 (-0.001, -0.001) [29]
	10-100	1	26.27 (26.083, 38.140) [30]	26.27 (26.086, 44.141) [30]	0.00 (-0.001, 1.000) [30]
		3	26.67 (25.079, 30.150) [30]	26.17 (24.086, 31.648) [30]	-0.00 (-0.001, -0.001) [30]
		5	26.66 (24.075, 28.111) [30]	26.66 (25.073, 29.143) [30]	-0.00 (-0.001, -0.001) [30]
Mycobacteria	0-1	1	638.20 (307.655, 674.177) [12]	662.20 (297.150, 702.200) [12]	8.50 (-16.002, 39.999) [12]
		3	698.20 (626.208, 722.163) [11]	682.20 (642.207, 714.166) [11]	-16.00 (-40.001, 15.999) [11]
		5	554.10 (338.130, 642.126) [9]	610.20 (338.134, 650.191) [9]	56.00 (-32.002, 79.974) [9]
	1-10	1	426.10 (250.133, 562.164) [23]	450.10 (266.126, 578.141) [23]	16.00 (2.999, 23.999) [23]
		3	562.20 (378.128, 594.186) [20]	79.10 (418.126, 602.142) [20]	8.00 (-11.001, 28.000) [20]
		5	394.10 (306.137, 522.158) [23]	434.10 (314.131, 546.140) [23]	8.00 (-4.001, 31.998) [23]
	10-100	1	414.10 (226.163, 482.089) [24]	410.10 (242.162, 498.164) [24]	12.00 (-0.001, 23.999) [24]
		3	390.10 (234.167, 506.158) [24]	370.20 (250.155, 474.121) [24]	8.00 (-2.001, 11.999) [24]
		5	346.20 (290.092, 426.111) [24]	330.20 (290.091, 450.109) [24]	1.00 (-0.001, 15.999) [24]

[1] All lots combined.
[2] Median of the difference between Glass (Predicate) and Plastic (Modified) devices.

Instrument Time to Detection (TTD) study in SBF

The TTD (in hours) was recorded as part of the combined Percent Recovery and the Microbial Detection Limit studies using the BD BACTEC FX at three inoculum levels, three sterile body fluid types (pleural, synovial, and cerebrospinal) across four sterile body fluid volumes (0.5 mL, 1 mL, 3 mL and 5 mL) over three media lots. The Percent Recovery study represented by the standard inoculum of 10 to 100 CFU per vial and the Microbial Detection Limit study represented by the challenge inoculum levels of 0 to 1 and 1 to 10 CFU per vial.

The data was analyzed using the 95% confidence interval with the bootstrap method. The TTD data was stratified by target inoculum level, sterile body fluid volume or organism. The results are shown in Table 10.

The TTD study demonstrated that the plastic device performed equivalently when compared to the predicate glass device when stratified by organism group (Dimorphic Fungi, Filamentous, Fungi, and Yeast), inoculum concentration (0-1, 1-10, 10-100), and sterile body fluid volume (0.5 mL, 1 mL, 3 mL and 5 mL). The results show that the test vial performed

equivalently to or better than the predicate vial for all conditions, with the exception of Dimorphic Fungi under some test conditions. The data was statistically analyzed by means of 95% CI with the bootstrap method, where the 95% CI for equivalent median detection times versus the predicate vial contains zero and the 95% CI for the median detection times shorter than the predicate contains only negative values.

Table 9: Summary of TTD Study Results by Organism Group, Target Inoculum Levels, and SBF Volumes[1]

Organism Group	*Inoculum Concentration (CFU/Vial)*	*SBF Volume (mL)*	*Median TTD for Glass (95% CI) [N]*	*Median TTD for Plastic (95% CI) [N]*	*Median of TTD difference[2] (95% CI) [N]*
Dimorphic Fungi	0-1	0.5	No paired detections[3]	No paired detections[3]	N/A
		1	No paired detections[3]	No paired detections[3]	N/A
		3	No paired detections[3]	No paired detections[3]	N/A
		5	Only 1 paired detection[3]	Only 1 paired detection[3]	N/A
	1-10	0.5	656.20 (414.218, 726.233) [6]	677.20 (614.251, 816.239) [6]	117.00 (-50.002, 244.036) [6]
		1	607.20 (442.18, 726.240) [6]	680.20 (502.224, 798.242) [6]	53.00 (10.000, 142.034) [6]
		3	786.00 (538.26, 924.26) [3]	720.00 (378.20, 816.25) [3]	-108.00 (-160.063, -66.001) [3]
		5	645.00 (426.18, 990.44) [4]	626.20 (466.185, 840.263) [4]	29.00 (-404.19, 198.06) [4]
	10-100	0.5	318.10 (250.132, 546.184) [6]	522.20 (382.134, 633.189) [6]	142.00 (17.001, 264.075) [6]
		1	394.10 (218.116, 509.180) [6]	605.20 (450.157, 636.201) [6]	210.00 (108.004, 252.075) [6]
		3	533.20 (390.104, 603.214) [6]	506.20 (474.193, 589.196) [6]	48.00 (-129.021, 124.070) [6]
		5	558.20 (434.134, 649.223) [6]	485.20 (373.098, 570.220) [6]	-72.00 (-156.039, 15.000) [6]
Filamentous Fungi	0-1	0.5	Only 1 paired detection*	Only 1 paired detection*	N/A
		1	82.09 (80.088, 84.094) [2]	70.59 (69.093, 72.087) [2]	-11.50 (-15.001, -8.001) [2]
		3	81.07 (73.195, 83.077) [3]	65.07 (58.194, 72.075) [3]	-15.00 (-16.001, -11.001) [3]
		5	72.56 (61.056, 98.063) [4]	64.56 (54.057, 82.055) [4]	-12.00 (-36.001, 21.000) [4]
	1-10	0.5	60.07 (49.289, 64.075) [9]	49.08 (48.074, 54.072) [9]	-8.00 (-14.999, 1.999) [9]
		1	54.06 (51.275, 59.068) [9]	49.06 (47.065, 62.069) [9]	-2.00 (-8.999, 5.999) [9]
		3	51.06 (47.068, 61.052) [9]	52.05 (47.264, 59.070) [9]	-0.00 (-7.001, 10.999) [9]

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Organism Group	*Inoculum Concentration (CFU/Vial)*	*SBF Volume (mL)*	*Median TTD for Glass (95% CI) [N]*	*Median TTD for Plastic (95% CI) [N]*	*Median of TTD difference[2] (95% CI) [N]*
		5	62.05 (45.255, 59.064) [9]	48.05 (46.061, 52.063) [9]	-3.00 (-13.001, 5.999) [9]
	10-100	0.5	41.11 (39.078, 44.108) [9]	38.074 (36.079, 38.176) [9]	-4.00 (-6.002, -2.001) [9]
		1	40.07 (35.145, 43.106) [9]	37.07 (35.146, 38.102) [9]	-3.00 (-6.001, 0.999) [9]
		3	37.06 (33.137, 41.096) [9]	36.13 (34.059, 38.097) [9]	-1.00 (-3.001, 0.999) [9]
		5	36.05 (33.114, 39.083) [9]	35.09 (34.111, 38.085) [9]	-0.00 (-2.001, 0.999) [9]
Yeast	0-1	0.5	29.10 (28.081, 77.111) [5]	28.10 (28.079, 73.112) [5]	-1.00 (-4.001, 0.001) [5]
		1	30.60 (29.099, 81.119) [4]	29.60 (28.117, 83.120) [4]	-0.50 (-2.000, 2.001) [4]
		3	Only 1 paired detection[3]	Only 1 paired detection[3]	N/A
		5	29.09 (29.091, 29.095) [2]	28.09 (28.091, 28.094) [2]	-1.00 (-1.001, -1.001) [2]
	1-10	0.5	45.87 (27.273, 66.215) [18]	47.29 (26.772, 69.711) [18]	0.00 (-1.501, 2.001) [18]
		1	28.13 (27.092, 71.117) [17]	28.42 (27.093, 70.120) [17]	-0.00 (-1.002, 1.001) [17]
		3	46.68 (27.587, 72.113) [18]	46.68 (27.085, 70.607) [18]	-1.00 (-1.998, -0.001) [18]
		5	45.60 (27.569, 70.616) [18]	47.11 (27.076, 72.596) [18]	-0.00 (-1.001, 0.001) [18]
	10-100	0.5	40.12 (24.088, 59.156) [18]	40.12 (24.089, 58.639) [18]	0.00 (-0.002, 0.001) [18]
		1	41.13 (24.110, 59.150) [18]	40.63 (24.104, 58.649) [18]	-0.50 (-1.001, 0.001) [18]
		3	61.17 (24.121, 62.164) [17]	58.17 (24.120, 61.164) [17]	-1.00 (-2.001, 0.001) [17]
		5	42.63 (24.133, 63.144) [18]	42.16 (24.133, 62.130) [18]	-0.00 (-1.001, 0.001) [18]

[1] All lots combined.
[2] Median of the difference between Glass (Predicate) and Plastic (Modified) devices.
[3] At least two distinct values are required to generate a confidence interval.

Percent Recovery (Detection) Study in Blood

The percent recovery (detection) was evaluated in a study of 207 paired sets at the standard inoculum level of 10 to 100 CFU/vial on one instrument across three lots using a diverse set of microorganisms frequently isolated in blood. The study included 23 microorganisms (8 mycobacteria, 10 yeast, 3 filamentous fungi, and 2 dimorphic fungi strains) tested at three blood volumes (1, 3 and 5 mL).

23 organisms x 3 lots x 3 blood volumes x 1 instrument= 207 paired sets

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The performance of each organism type (mycobacteria, yeast, filamentous fungi, and dimorphic fungi) at inoculum of 10 to 100 CFU per vial are shown in Table 11 – Table 14. The results for all data combined are shown in Table 15.

Table 10: Percent Recovery Study Results by Blood Volume for Mycobacteria with 10-100 CFU in the FX

Organism	*Blood Volume (mL)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*
Mycobacterium bovis ATCC 35724	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium tuberculosis ATCC 25177	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium tuberculosis TB007	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium abscessus ATCC 19977	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium chimaera BR0909	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium fortuitum ATCC 6841	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium intracellulare ATCC 13950	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Mycobacterium kansasii ATCC 12478	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00

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Table 11: Percent Recovery Study Results by Blood Volume for Yeast with 10-100 CFU in the FX

Organism	***Blood Volume (mL)***	***Percent Recovery for Glass (Predicate) (%)***	***Percent Recovery for Plastic (Modified) (%)***	***Ratio of Positive Yields (Plastic/Glass)***
Candida albicans ATCC 10231	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida auris AR 0387	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida glabrata ATCC 15545	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida glabrata ATCC 66032	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida krusei ATCC 34135	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida parapsilosis ATCC 10232	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida tropicalis ATCC 750	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Cryptococcus neoformans ATCC 13690	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Malassezia furfur ATCC 14521	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Saccharomyces cerevisiae ATCC 90146	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00

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Table 12: Percent Recovery Study Results by Blood Volume for Filamentous Fungi with 10-100 CFU in the FX

Organism	*Blood Volume (mL)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*
Aspergillus fumigatus ATCC 13073	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Talaromyces marneffei ATCC 64101	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Rhizopus oryzae ATCC 66275	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00

Table 13: Percent Recovery Study Results by Blood Volume for Dimorphic Fungi with 10-100 CFU in the FX

Organism	*Blood Volume (mL)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*
Blastomyces dermatitidis ATCC 18188	1	100	66.67	0.67
	3	100	100	1.00
	5	100	100	1.00
Histoplasma capsulatum ATCC 26032	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00

Table 14: Percent Recovery (10-100 CFU/Vial) Summary

10-100 CFU with 1-5 mL blood in the FX		*Predicate (Glass) Vials*		
		Positive	*Negative*	*Total*
Plastic Vials	**Positive**	206	0	206
	Negative	1	0	1
	Total	207	0	207
% Glass recovery:			100%	
% Plastic recovery:			99.52%	
Ratio of positive yields:			1.00	

Of the 207 paired sets, 206 sets recovered organisms in both the plastic vial and the predicate glass vial. In only one paired set was there a single negative result between the plastic vial and predicate glass vial. The single negative result was in the plastic vial inoculated with *Blastomyces dermatitidis* with 1 mL blood. The culture medium of BD BACTEC Myco/F Lytic displays inconsistent growth of *Blastomyces dermatitidis*. Information about this organism was noted as a limitation in the product insert.

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Percent Recovery (Detection) Study in Sterile Body fluid

The percent recovery (detection) was evaluated in a study of 207 paired sets at the standard inoculum level of 10 to 100 CFU/vial on one instrument across three lots using microorganisms frequently isolated in sterile body fluid. Five microorganisms (1 filamentous fungi, 2 yeast, and 2 dimorphic fungi strains) were tested with cerebrospinal fluid and three organisms (1 filamentous fungi, and 2 yeast strains) were tested with pleural and synovial fluid at four sterile body fluid volumes (0.5, 1, 3 and 5 mL).

3 organisms x 3 lots x 4 SBF volumes x 1 inoculum level x 1 instrument x 2 SBF Types = 72

5 organisms x 3 lots x 4 SBF volumes x 1 inoculum level x 1 instrument x 1 SBF Type = 60

Total =132 paired sets

The performance of each organism type (filamentous fungi, yeast and dimorphic fungi) at inoculum of 10 to 100 CFU per vial are shown in Table 16. The results for all data combined are shown in Table 17.

Table 15: Percent Recovery Study Results by Organism and SBF Volumes with 10-100 CFU in the FX

Organism	*SBF Volume (mL)*	*Percent Recovery for Glass (Predicate) (%)*	*Percent Recovery for Plastic (Modified) (%)*	*Ratio of Positive Yields (Plastic/Glass)*
Aspergillus fumigatus ATCC 13073	0.5	100	100	1.00
	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Candida auris AR 0387	0.5	100	100	1.00
	1	100	100	1.00
	3	89[1]	100	1.13
	5	100	100	1.00
Cryptococcus neoformans ATCC 13690	0.5	100	100	1.00
	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Blastomyces dermatitidis ATCC 18188	0.5	100	100	1.00
	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00
Histoplasma capsulatum ATCC 26032	0.5	100	100	1.00
	1	100	100	1.00
	3	100	100	1.00
	5	100	100	1.00

[1] The one (1) bottle that did not detect was C. auris AR0387 with 3 mL of synovial fluid.

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Table 16: Percent Recovery (10-100 CFU/Vial) Summary

10-100 CFU with 0.5-5 mL SBF in the FX		*Predicate (Glass) Vials*		
		Positive	*Negative*	*Total*
Plastic Vials	**Positive**	131	1	132
	Negative	0	0	0
	Total	131	1	132
% Glass recovery:			99.24%	
% Plastic recovery:			100%	
Ratio of positive yields:			1.01	

Of the 132 paired sets, 131 sets recovered organisms in both the plastic vial and the predicate glass vial. In only one paired set was there a single negative result between the plastic vial and predicate glass vial. The single negative result was in the glass vial inoculated with *Candida auris*.

False Positive Rates (Instrument-positive, subculture-negative) in Blood

False positive was defined as instrument positive but subculture negative in the evaluation. False positivity was assessed with vials inoculated with fresh blood of 3, 5, and 7 mL, but no organisms were added to the vials. There were a total of 144 paired sets across three lots using BACTEC FX and BACTEC 9240 and completed at the default 42-day protocol.

8 vials x 3 blood volumes x 3 lots x 2 instruments= 144* paired sets

*Note: One lot pair with 7mL blood was excluded due to contamination resulting in 143 paired vials.

There were no false positives observed for the plastic vials with 1 mL and 5 mL fresh blood. There was one false positive observed for the plastic vials with 7 mL fresh blood. There were no false positives observed for the predicate (glass) vial in 1 mL fresh blood. There were two false positives observed for the predicate (glass) vial in 5 mL of fresh blood and thirty-five observed in 7 mL of fresh blood. Majority of the false positives were observed in the higher blood volumes. The false positive rate for the plastic vial for all fresh blood volume combined was 0.70%, which is lower than the 25.87% for the predicate vials (glass). The Myco/F Lytic plastic vials (test) therefore met the threshold of equivalent to or better than Myco/F Lytic glass vials (predicate) performance. The Myco/F Lytic glass product insert includes the following statement “false positivity most likely will increase when the blood volume is above 5 mL” to address the high false positive rate at higher volume. This limitation is also included in the plastic labeling. The False Positive Rates stratified by blood volume is presented in Table 18.

Table 17: False Positive Rates in Blood

Fresh Blood Volume (mL)	*Number of Vials*	*False Positive Rate for Glass (Predicate) (%)*	*False Positive Rate for Plastic (Modified) (%)*
1	48	0	0
5	48	4.17	0
7	47	74.47	2.13
All Blood Volumes	143	25.87	0.70

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False Positive Rates (Instrument-positive, subculture-negative) in Sterile Body Fluid

False positive was defined as instrument positive but subculture negative in the evaluation. False positivity was assessed with vials inoculated with sterile body fluid of 0.5, 5, and 7 mL, but no organisms were added to the vials. There were a total of 432 pair sets across three lots using BACTEC FX and BACTEC 9240 and completed at the default 42-day protocol.

8 vials x 3 SBF volumes x 3 lots x 2 instruments* 3 SBF types= 432* paired sets

*Note: 15 vials (7 glass and 8 plastic) were excluded due to contamination resulting in 425/424 paired vials.

A total of 432 vial pairs were inoculated with sterile body fluid. Fifteen vials were excluded due to contamination. No false positives occurred in the test vial (plastic) or predicate vial (glass) with 0.5 mL of any sterile body fluid. At the 5-mL sterile body fluid level there was only a single false positive with synovial fluid in the predicate vial (glass). The 7-mL overfill level produced four false positives, all with synovial fluid, three in the test vial (plastic) and one in the predicate vial (glass). The false positive rate for all sterile body fluids combined was 0.71% in the predicate vial (glass) and 0.47% in the test vial (plastic). The False Positive Rates stratified by blood sterile body fluid volume and SBF type is presented in Table 19.

Table 18: False Positive Rates in Sterile Body Fluid

Fresh Blood Volume (mL)	*SBF Type*	*Number of Vials (Glass/Plastic)*	*False Positive Rate for Glass (Predicate) (%)*	*False Positive Rate for Plastic (Modified) (%)*
1	CSF	47/48	0	0
	Pleural Fluid	48/48	0	0
	Synovial Fluid	48/48	0	0
5	CSF	48/48	0	0
	Pleural Fluid	48/48	0	0
	Synovial Fluid	46/44	0	2.27
7	CSF	48/48	0	0
	Pleural Fluid	48/48	0	0
	Synovial Fluid	44/44	6.82	2.27
All Blood Volumes	All SBF Types	425/424	0.71	0.47

False Negative Rates (Instrument-negative, subculture-positive) in Blood

All inoculated paired sets (414 from the Recovery study + 205 from the Microbial Detection Limit study =619 paired sets) that were instrument negative at the end of default protocol (42 days) were subcultured onto appropriate culture media plates. This combined data set was evaluated for the false negative rates. A false negative is a vial that was instrument-negative at the end of protocol yet contains viable organisms upon subculturing onto appropriate culture media. A total of seven false negatives were identified from growth on sub-culture of terminal negatives. Four were *Blastomyces dermatitidis* across a range of inoculum levels and

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blood volumes, one in the predicate (glass) vial and three in the plastic vials. The remaining three were *Mycobacterium bovis* at the 0-1 CFU target inoculum with 5 mL blood, two in the predicate (glass) and one in the plastic vials. False negative rates for the predicate (glass) vial and plastic vial were low and comparable based on a rate of 0.48% (3/619) and 0.65% (4/619), respectively. The difference in false negative rates for Myco/F Lytic glass (predicate vial) and Myco/F Lytic plastic vial (test vial) were not statistically significant. The False Negative Rates for each vial type is presented in Table 20.

Table 19: False Negative Rates in Blood

Total Lot Pairs with Blood	*Glass False Negative Rate with Blood*	*Plastic False Negative Rate with Blood*	*Plastic minus Glass False Negative Rates with Blood*	*Fisher's Exact Test*
619	0.48% (3/619)	0.65% (4/619)	0.17%	P = 1

False Negative Rates (Instrument-negative, subculture-positive) in Sterile Body Fluid

All inoculated paired sets (132 from the Recovery study + 264 from the Microbial Detection Limit study =396 paired sets) that were instrument negative at the end of the default protocol (42 days) were subcultured onto appropriate culture media plates. This combined data set was evaluated for the false negative rates. A false negative is a vial that was instrument-negative at the end of protocol yet contains viable organisms upon subculturing onto appropriate culture media. A total of ten false negatives were identified from growth on sub-culture of terminal negatives. All ten false negatives were dimorphic fungi (9 were *H. capsulatum* and one *Blastomyces dermatitidis)* at the lower inoculum levels (0-1 or 1-10 CFU). False negative rates for the predicate (glass) vial and plastic vial were comparable based on a rate of 1.01% (4/396) and 1.52% (6/396), respectively. The difference in false negative rates for Myco/F Lytic glass (predicate vial) and Myco/F Lytic plastic vial (test vial) were not statistically significant. The False Negative Rates for each vial type is presented in Table 21.

Table 20: False Negative Rates in Sterile Body Fluid

Total Lot Pairs with SBF	*Glass False Negative Rate with SBF*	*Plastic False Negative Rate with SBF*	*Plastic minus Glass False Negative Rates with SBF*	*Fisher's Exact Test*
396	1.01% (4/396)	1.52% (6/396)	0.51%	P = 0.7523

BD BACTEC Instrument Compatibility Study

The BD BACTEC instrument compatibility study evaluated three lots of BD BACTEC Myco/F Lytic Culture Vials (plastic) and three lots of BD BACTEC Myco/F Lytic Culture Vials (glass) using four of the BACTEC fluorescent instruments (FX, FX-40, 9240, and 9050). A total of 6 organisms (*Mycobacterium tuberculosis, Mycobacterium fortuitum, Candida albicans, Candida auris, Cryptococcus neoformans, and Aspergillus fumigatus)* were evaluated at three different blood volumes (1 mL, 3mL and 5mL) and one target inoculum concentration (10-100). The BACTEC instrument compatibility study Percent Recovery results are shown in Table 22 and the Time-To-Detection results are shown in Table 23.

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Table 21: Summary of Instrument Compatibility Percent Recovery Results in Blood

Blood Volume (mL)	*BACTEC Instrument*	*Paired Sets (N)*	*Recovery*				*Ratio of Positive Yields*	
			Glass Negatives	*Glass Percent Recovery (%)*	*Plastic Negatives*	*Plastic Percent Recovery (%)*	*Per Instrument*	*Per Blood Volume*
1	FX	18	0	100	0	100	1.00	1.00
	FX40	18	0	100	0	100	1.00	
	9240	18	0	100	0	100	1.00	
	9050	18	0	100	0	100	1.00	
3	FX	18	0	100	0	100	1.00	1.00
	FX40	18	0	100	0	100	1.00	
	9240	18	0	100	0	100	1.00	
	9050	18	0	100	0	100	1.00	
5	FX	18	0	100	0	100	1.00	0.99
	FX40	18	0	100	1	94.44	0.94	
	9240	17	0	100	0	100	1.00	
	9050	18	0	100	0	100	1.00	

Table 22: Summary of Instrument Compatibility TTD Results in Blood

BACTEC Instrument	*Paired Sets (N)*	*Glass Median TTD (95% CI)*	*Plastic Median TTD (95% CI)*	*Median of TTD differences (95% CI)*
FX	54	45.1 (36.61, 52.57)	44.1 (36.10, 51.65)	-0.00 (-0.584, 0.999)
FX40	53	50.6 (35.17, 53.62)	50.1 (35.16, 53.06)	-0.00 (-0.011, -0.001)
9240	53	49.0 (36.01, 53.05)	48.0 (35.01, 53.05)	0.00 (-1.000, 0.000)
9050	54	49.7 (44.50, 52.33)	50.8 (44.50, 57.50)	0.00 (0.00, 0.916)

The study demonstrated that the four instruments performed equivalently, and they are compatible with the BD BACTEC Myco/F Lytic culture medium in plastic vials.

BD BACTEC Instrument Compatibility Study with Sterile Body Fluids

The BD BACTEC instrument compatibility study evaluated three lots of BD BACTEC Myco/F Lytic Culture Vials (plastic) and three lots of BD BACTEC Myco/F Lytic Culture Vials (glass) using four of the BACTEC fluorescent instruments (FX, FX40, 9240, and 9050). A total of 4 organisms (*Candida glabrata, Candida auris, Cryptococcus neoformans, and Aspergillus fumigatus)* were evaluated at four different sterile body fluid volumes (0.5, 1 mL, 3mL and 5mL) and one target inoculum concentration (10-100). The BACTEC instrument compatibility study Percent Recovery results are shown in Table 24 and the Time-To-Detection results are shown in Table 25.

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Table 23: Summary of Instrument Compatibility Percent Recovery Results in SBF

Pleural Fluid Volume (mL)	*BACTEC Instrument*	*N*	*Recovery*				*Ratio of Positive Yields*	
			Glass Negatives	*Glass Percent Recovery (%)*	*Plastic Negatives*	*Plastic Percent Recovery (%)*	*Per Instrument*	*Per Pleural Fluid Volume*
0.5	FX	12	0	100	0	100	1.00	1.00
	FX40	12	0	100	0	100	1.00	
	9240	12	0	100	0	100	1.00	
	9050	12	0	100	0	100	1.00	
1	FX	12	0	100	0	100	1.00	1.00
	FX40	12	0	100	0	100	1.00	
	9240	12	0	100	0	100	1.00	
	9050	12	0	100	0	100	1.00	
3	FX	12	0	100	0	100	1.00	1.00
	FX40	12	0	100	0	100	1.00	
	9240	12	0	100	0	100	1.00	
	9050	12	0	100	0	100	1.00	
5	FX	12	0	100	0	100	1.00	1.00
	FX40	12	0	100	0	100	1.00	
	9240	12	0	100	0	100	1.00	
	9050	12	0	100	0	100	1.00	

Table 24: Summary of Instrument Compatibility TTD Results in SBF

BACTEC Instrument	*N*	*Glass Median dTTD (95% CI)*	*Plastic Median dTTD (95% CI)*	*Median of TTD differences (95% CI)*
FX	48	30.70 (25.317, 38.066)	30.18 (25.321, 36.079)	-0.001 (-1.001, -0.001)
FX40	48	30.13 (24.443, 38.200)	29.14 (24.674, 38.199)	-0.002 (-1.001, -0.002)
9240	48	30.50 (23.003, 43.005)	30.00 (23.003, 38.005)	-1.000 (-1.500, -1.000)
9050	48	32.25 (23.834, 53.167)	32.25 (23.822, 54.167)	0.000 (-1.000, 0.000)

The study demonstrated that the four instruments performed equivalently, and they are compatible with the BD BACTEC Myco/F Lytic culture medium in plastic vials.

2. Matrix Comparison:

Testing with Blood

In seeded analytical studies, the performance of BD BACTEC Myco/F Lytic culture medium in plastic vial was compared to that in glass vial, with three human blood volumes, 8 mycobacteria, 10 yeasts and 5 dimorphic fungi across four fluorescent series instruments: BACTEC FX, FX40, BACTEC 9240, and BACTEC 9050.

Testing with Sterile Body Fluid (SBF)

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In seeded analytical studies, the performance of BD BACTEC Myco/F Lytic culture medium in plastic vial was compared to that in glass vial, with four sterile body fluid volumes, 3 yeasts and 3 dimorphic fungi using the BD BACTEC fluorescent series instruments.

C Clinical Studies:

Not applicable; seeded analytical studies were performed to compare the new plastic blood culture vials to the glass blood culture vials (predicate).

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

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

   Not applicable

D Clinical cut-off:

Not applicable.

E Expected Values/Reference Range:

Seeded analytical studies demonstrated equivalent performance of the BD BACTEC Myco/F Lytic (plastic) blood culture medium when compared to the BD BACTEC Myco/F Lytic (glass) blood culture medium.

VIII Proposed Labeling:

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

IX Conclusion:

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