May 28, 2026

BD Diagnostic Systems
Susan Kircher
Staff Regulatory Affairs Specialist
7 Loveton Cir.
Sparks, Maryland 21152

Re: K260213
Trade/Device Name: BD BACTEC FXI Culture System
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: Class I, reserved
Product Code: MDB
Dated: April 21, 2026
Received: April 21, 2026

Dear Susan Kircher:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

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

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260213

Device Name
BD BACTEC FXI Culture System

Indications for Use *(Describe)*
The automated BD BACTEC FXI Culture System is designed for the qualitative detection of bacteria and fungi in blood. Samples are collected from patients and injected directly into BD BACTEC culture vials, which are placed into the instrument for incubation and testing.

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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List of Tables

1. 510(k) Summary

Summary Preparation Date

28 May 2026

I. Background Information:

A. 510(k) Number

K260213

B. Applicant

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
Establishment Registration Number: 1119779

Susan Kircher
Staff Regulatory Affairs Specialist
Tel: (410) 259-9251
Email: **susan_m_kircher@bd.com**

Katherine Cicala
Senior Regulatory Affairs Specialist
Tel: (908) 517-6281
Email: **Katherine.Cicala@bd.com**

C. Proprietary and Established Names

BD BACTEC™ FXI Culture System

D. Regulatory Information

Table 1 – Regulatory Information

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

Common name: blood culture instrument

II. Submission/Device Overview:

A. Purpose for Submission:

To obtain a substantial equivalence determination for a premarket notification for the BD BACTEC™ FXI Culture System for use with BD BACTEC™ Plus Aerobic/F, BD BACTEC™ Lytic/10 Anaerobic/F, and BD BACTEC™ Plus Anaerobic/F Culture Vials when used with blood specimens.

B. Measurand:

Aerobic and anaerobic microorganisms from blood

C. Type of Test:

The BD BACTEC™ FXI Culture System is an automated blood culture system used to detect growth of microorganism in liquid culture media containing a fluorescent sensor. As organisms grow CO_2 is produced, which increases fluorescence in the sensor. The fluorescence is monitored by the BD BACTEC™ fluorescent series instrument.

III. Intended use/Indications for Use:

A. Intended Use(s):

The automated BD BACTEC™ FXI Culture System is designed for the qualitative detection of bacteria and fungi in blood. Samples are collected from patients and injected directly into BD BACTEC™ Culture Vials, which are placed into the instrument for incubation and testing.

B. Indication(s) for Use:

Same as Intended Use

C. Special Conditions for Use Statements(s):

Rx- For Prescription Use Only

For *in vitro* diagnostic use only

BACTEC FXI Culture System is indicated for use only with BD BACTEC Plus Aerobic/F, Lytic/10 Anaerobic/F, and Plus Anaerobic/F Culture Vials.

IV. Device/System Characteristics:

A. Device Description:

The BD BACTEC™ FXI Culture System is the next generation of BD BACTEC™ fluorescent series instruments. It detects the presence of microorganisms in blood and provides workflow automation while retaining the same principles of assay method as the BD BACTEC™ fluorescent series instruments.

The device consists of two modules: the Workflow Module and the Analyzer Module. The Workflow Module is responsible for the automated loading of BD BACTEC™ culture vials into the Analyzer Module. The Workflow Module consists of a robotic arm that automates loading and unloading workflows. During vial loading, the vial label image is captured, barcodes are scanned, and the vial is weighed for blood volume measurement. The Workflow Module is also responsible for detection, results generation, automated unloading of blood culture vials, and discarding negative vials to waste. The Analyzer Module consists of two independent drum assemblies which can hold up to 240 vials each for a total capacity of 480 vials. It is responsible for incubation and agitation of the culture vials, acquiring vial measurement readings on a regular interval, via a fly-by measurement system, and allows for the manual loading and unloading of culture vials. The BACTEC™ FXI may consist of either one (total capacity of 480 vials) or two (total capacity of 960 vials) Analyzer Modules connected to a single Workflow Module. In the case of a single Analyzer Module, it may be located on either side of the Workflow Module.

The BACTEC™ FXI is intended for use by trained laboratory personnel.

B. Principle of Operation:

When microorganisms are present in blood culture vials, they metabolize nutrients in the culture medium, releasing carbon dioxide. A dye in the sensor at the bottom of the vial reacts with CO_2. This modulates the amount of light that is absorbed by a fluorescent material in the sensor. A photo detector at each row of the drum measures the level of fluorescence, which corresponds to the amount of CO_2 released by organisms. Vial measurements are acquired at two separate excitation wavelengths at regular intervals and continuously assessed by the system using pre-programmed positivity algorithms throughout the length of the testing protocol.

At system start-up, the onboard computers in the Workflow Module perform self-diagnostics and prepare the robot for automated vial input/output. Concurrently, the microprocessors in the Analyzer Module begin incubation control, perform agitation, and execute measurement cycles on a 10-minute interval. The Workflow Module synchronizes with the latest measurement data from the Analyzer Module and performs the positivity analysis.

When the instrument identifies positive bottles, the laboratory technologist removes them from the instrument and processes them per their laboratory protocol.

V. Substantial Equivalence[1] Information:

Predicate Device Name: BD BACTEC™ 9050 System

Predicate Device 510(k) Number: K962210

Comparison of the Predicate Device to the Candidate Device

The similarities and differences of the predicate and candidate devices are described in Table 2 and Table 3, respectively.

Table 2 – Similarities of the Predicate and Candidate Devices

Item	Predicate Device: BD BACTEC™ 9050 System	Candidate Device: BD BACTEC™ FXI Culture System
Intended Use	The BACTEC 9050 system is a non-radiometric automated blood culturing system which is designed for the monitoring and detection of clinical cultures of blood for the presence of microorganisms.	The automated BD BACTEC™ FXI Culture System is designed for the qualitative detection of bacteria and fungi in blood. Samples are collected from patients and injected directly into BD BACTEC™ culture vials, which are placed into the instrument for incubation and testing.
Classification	Class I	Same
Product Code	MDB	Same
Regulation	21 CFR 866.2560	Same
Instrument Type	BD BACTEC™ fluorescent series instrument	Same

[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.

Table 3 – Differences between the Predicate and Candidate Devices

Item	Predicate Device: BD BACTEC™ 9050	Candidate Device: BD BACTEC™ FXI Culture System
Specimen Types	Blood/ Blood Products/ Sterile Body Fluids (BD BACTEC Myco/F Lytic only)	Blood only
Media Types	• BD BACTEC™ Plus Aerobic/F • BD BACTEC™ Lytic/10 Anaerobic/F • BD BACTEC™ Plus Anaerobic/F • BD BACTEC™ Peds Plus™/F • BD BACTEC™ Standard/10 Aerobic/F • BD BACTEC™ Standard Anaerobic/F • BD BACTEC™ Myco/F Lytic	• BD BACTEC™ Plus Aerobic/F • BD BACTEC™ Lytic/10 Anaerobic/F • BD BACTEC™ Plus Anaerobic/F
Dimensions (H x W x D)	72.4 cm x 61 cm x 64.8 cm	Analyzer Module (194.3 cm x 63.5 cm x 85.9 cm) Workflow Module (194.3 cm x 49.9 cm x 85.9 cm)
Temperature	35 °C ± 1.5 °C.	35.0 to 36.5°C 36.5°C (default temperature)
Vial Capacity	50	Single Analyzer Module = 480 vials Two Analyzer Modules = 960 vials
Vial Loading	User scans vials one at a time and manually loads into the designated space in the drum.	User places vials individually or in batches on the input/output shelves of the Workflow Module. Vials are then automatically scanned, imaged, weighed and placed into the Analyzer Module using robotics. Manual loading of vials is also available to users.
Vial Unloading	Positive and negative vials are manually scanned and unloaded	Vials can be unloaded automatically based upon configuration, by user request, or manually. The instrument will output the vials to either the input/output shelves or chutes.

VI. Standards/Guidance Documents Referenced

- IEC 61010-1: 2010/AMD1:2016, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
- IEC 61010-2-010: 2019, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*
- IEC 61010-2-081: 2015, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*
- IEC 61010-2-101: 2018, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*
- IEC 61326-1: 2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*
- IEC 61326-2-6: 2025, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment*

- IEC 62304: 2015, *Medical device software - Software life cycle processes*
- Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedure for Blood Cultures*. 2nd ed. CLSI guideline M47. Clinical and Laboratory Standards Institute, USA, 2022.

VII. Performance Characteristics:

A. Analytical Performance

1. Precision Study

The within-laboratory precision study was conducted on the BD BACTEC™ FXI Culture System using a multi-factor design method. The study design included three organisms and three lots of each medium type. Testing was performed over 20 days using two instruments and two operators per instrument for a total of 4320 vials per medium type. Table 4, Table 5, and Table 6 summarize the within-laboratory precision for each medium and instrument.

Table 4 – Within-Laboratory Precision Results for Plus Aerobic/F Culture Vials

Organism	CFU Range	Percent Recovery / (N)				Time to Detection (hours)		
		Lot 1	Lot 2	Lot 3	Overall	Median	Mean	Range
Candida albicans	27 - 77	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	22.1	22.0	19.1 - 26.5
Escherichia coli	28 - 53	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	8.5	8.5	7.0 - 10.1
Staphylococcus aureus	31 - 59	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	13.6	13.6	11.7 - 15.6

Table 5 – Within-Laboratory Precision Results for Lytic/10 Anaerobic/F Culture Vials

Organism	CFU Range	Percent Recovery / (N)				Time to Detection (hours)		
		Lot 1	Lot 2	Lot 3	Overall	Median	Mean	Range
Bacteroides fragilis	49 - 98	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	18.6	18.5	16.1 - 20.3
Escherichia coli	28 - 53	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	8.2	8.1	5.5 - 9.7
Streptococcus pneumoniae	13 - 94	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	13.4	13.5	11.6 - 15.8

Table 6 f– Within-Laboratory Precision Results for Plus Anaerobic/F Culture Vials

Organism	CFU Range	Percent Recovery / (N)				Time to Detection (hours)		
		Lot 1	Lot 2	Lot 3	Overall	Median	Mean	Range
Bacteroides fragilis	46 - 91	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	23.0	23.0	11.9 -50.3
Escherichia coli	21 - 89	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	8.2	8.1	6.2 - 9.7
Streptococcus pneumoniae	15 - 98	100.0 (480/480)	100.0 (480/480)	100.0 (480/480)	100.0 (1440/1440)	12.2	12.3	9.6 - 14.7

2. Reproducibility:

Reproducibility studies using the Plus Aerobic/F and Lytic/10 Anaerobic/F Culture Vials were conducted on the BD BACTEC™ FXI Culture System at three sites (two external and one internal). Reproducibility studies using the Plus Anaerobic/F Culture Vials were conducted at the internal site, where three separate operators using three separate instruments performed the testing. All testing was conducted over five days using four lots of culture vials. Testing also included

seeded organisms, diluted to 10-100 CFU/vial, as well as negative controls. There was 100% recovery (instrument positive and Gram stain/subculture positive) across three sites. All negative controls remained instrument negative through the 5-day protocol. Table 7, Table 8, and Table 9 summarize the reproducibility for each organism and medium type on the BD BACTEC™ FXI Culture System.

Table 7 – Reproducibility Results for Plus Aerobic/F Culture Vials on the BD BACTEC™ FXI Culture System

Organism	Percent Recovery / (N), (95% CI)				Time to Detection (Hours)		
	Site 1	Site 2	Site 3	Overall	Mean	Median	Range
Candida albicans	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	25.1	25.6	8.5 - 28.8
Escherichia coli	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	8.9	8.9	8.0 - 10.0
Haemophilus influenzae	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	16.4	16.6	13.7 - 19.2
Pseudomonas aeruginosa	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	14.7	14.4	13.2 - 17.1
Staphylococcus aureus	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	10.2	10.2	9.2 - 11.4
Streptococcus pneumoniae	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	13.0	12.9	11.4 - 14.9

Table 8 – Reproducibility Results for Lytic/10 Anaerobic/F Culture Vials on the BD BACTEC™ FXI Culture System

Organism	Percent Recovery / (N), (95% CI)				Time to Detection (Hours)		
	Site 1	Site 2	Site 3	Overall	Mean	Median	Range
Bacteroides fragilis	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	20.5	18.7	9.0 - 42.6
Clostridium perfringens	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	8.0	7.9	7.0 - 12.0
Enterococcus faecalis	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	9.9	9.9	9.2 - 10.5
Escherichia coli	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	8.9	8.9	8.0 - 9.9
Staphylococcus aureus	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	10.8	10.7	9.7 - 11.9
Streptococcus pneumoniae	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0, 100.0)	15.3	15.2	6.0 - 37.1

Table 9 – Reproducibility Results for Plus Anaerobic/F Culture Vials on the BD BACTEC™ FXI Culture System

Organism	Percent Recovery / (N), (95% CI)				Time to Detection (hours)		
	Instrument 1	Instrument 2	Instrument 3	Overall	Mean	Median	Range
Bacteroides fragilis	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	26.4	23.0	19.3 – 81.2
Clostridium perfringens	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	9.2	9.2	8.2 – 10.6
Enterococcus faecalis	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	10.1	10.2	9.2 – 10.9

Organism	Percent Recovery / (N), (95% CI)				Time to Detection (hours)		
	Instrument 1	Instrument 2	Instrument 3	Overall	Mean	Median	Range
Escherichia coli	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	9.6	9.4	8.9 – 10.7
Staphylococcus aureus	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	11.0	10.9	9.6 – 13.6
Streptococcus pneumoniae	100.0 (20/20)	100.0 (20/20)	100.0 (20/20)	100.0 (60/60) (94.0 -100.0)	13.5	13.5	12.2 – 15.4

3. Limit of Detection (LOD):

In-house seeded studies were conducted using three lots of each medium and 30 replicates per organism. The limit of detection was determined at the inoculum where at least 95% of vials detected positive. For Plus Aerobic/F culture vials, human blood was added to support growth of *S. pneumoniae* and *H. influenzae*. Table 10, Table 11, and Table 12 display the LOD for each organism, medium type and instrument.

Table 10 – Limit of Detection for Plus Aerobic/F Culture Vials on the BD BACTEC™ FX and BD BACTEC™ FXI Culture System

Organism	ATCC®	BD BACTEC™ FXI Culture System (CFU/Vial)	BD BACTEC™ FX (CFU/Vial)
Candida albicans	18804	6	6
Enterococcus faecalis	29212	8	8
Escherichia coli	25922	2	2
Haemophilus influenzae	19418	10*	10*
Pseudomonas aeruginosa	27853	7	7
Staphylococcus aureus	25923	5	5
Streptococcus pneumoniae	6305	7*	7*

* Minimum volume (3 mL) of blood added

Table 11 – Limit of Detection for Lytic/10 Anaerobic/F Culture Vials on the BD BACTEC™ FX and BD BACTEC™ FXI Culture System

Organism	ATCC®	BD BACTEC™ FXI Culture System (CFU/Vial)	BD BACTEC™ FX (CFU/Vial)
Bacteroides fragilis	25285	2	2
Clostridium perfringens	13124	4	4
Enterococcus faecalis	29212	6	6
Escherichia coli	25922	2	2
Staphylococcus aureus	25923	8	8
Streptococcus pneumoniae	6305	4	4

Table 12 – Limit of Detection for Plus Anaerobic/F Culture Vials on the BD BACTEC™ FX and BD BACTEC™ FXI Culture System

Organism	ATCC®	BD BACTEC™ FXI Culture System (CFU/Vial)	BD BACTEC™ FX (CFU/Vial)
Bacteroides fragilis	25285	3	3
Clostridium perfringens	13124	2	2
Enterococcus faecalis	29212	8	8
Escherichia coli	25922	3	3
Staphylococcus aureus	25923	6	6
Streptococcus pneumoniae	6305	7	7

4. Delayed Vial Entry (DVE):

It is best practice to load inoculated culture vials into a BD BACTEC™ fluorescent series instrument as soon as possible; however, if delays occur the data obtained in this study can be referenced.

The following statement is also included in each culture vial package insert and the BD BACTEC™ FXI Culture System User's Manual: CAUTION: Culture vials held at room temperature for longer than 24 hours before loading may not detect microorganisms and should be subcultured.

An analytical study was performed to evaluate potential effects on vial/instrument performance for vials that are delayed between specimen collection and loading onto the BACTEC FXI and FX systems. The following delay conditions were evaluated:

- Control: no delay
- 20-25°C for 24 hours
- 20-25°C for 36 hours
- 35±1°C for 12 hours

Testing was conducted using vials containing 3 and/or 10 mL pooled fresh human blood seeded with target organism concentrations of 10-100 CFU/vial. The study included three lots for each vial type and a minimum of three vials for each combination of vial type, organism, hold time, temperature condition and blood volume for a total of 264 vials for aerobic and 144 vials for anaerobic culture vials. For calculation of percent recovery, positive results reflect a positive flag by the instrument. One positive vial from each unique inoculum preparation (vials inoculated at the same time with the same blood source and organism inoculum) was subcultured to confirm purity and the presence of the appropriate test organism. Vials flagged negative at the end of the 5-day protocol were subcultured to assess false negative rates.

The study demonstrated >95% recovery at the recommended conditions (20-25°C for 24 hours) for both FXI and FX instruments and the results support equivalency between the systems.

5. Linearity/assay reportable range:

Not Applicable

6. Analytical specificity

Not Applicable

7. Assay cut-off

Not Applicable

B. Comparison Studies:

1. Method Comparison with Predicate Device:

Comparison Study/Growth Performance

In-house seeded studies were conducted to assess organism recovery and time to detection. Three lots of each medium type were tested in triplicate. Culture vials were inoculated with organism concentrations of 10-100 and 1-10 CFU/vial and included the minimum (3 mL) and maximum (10 mL) recommended blood volumes. All paired vials were inoculated at the same time from the same organism inoculum preparation and blood source. Vials were incubated in the BD BACTEC™ FXI Culture System or the BD BACTEC™ FX until a final result of positive or negative was determined. At the end of the 5-day protocol, all negative vials were subcultured.

Testing included standardized suspensions of well characterized strains. The aerobic and anaerobic organism panels are listed in Table 13 and Table 14, respectively.

Table 13 – Aerobic Organisms

Organism	ATCC
Abiotrophia defectiva	49176
Acinetobacter lwoffii	17925
Aerococcus viridans	11563
Aggregatibacter actinomycetemcomitans	NCTC 9710
Alcaligenes faecalis	8750
Bacillus subtilis	82
Candida albicans	18804
Candida auris	2370
Candida glabrata	66032
Cardiobacterium hominis	15826
Citrobacter freundii	8090
Corynebacterium jeikeium	43216
Cryptococcus neoformans	32045
Eikinella corrodens	23834
Enterobacter cloacae	35030
Enterococcus faecalis	29212
Escherichia coli	25922
Granulicatella adiacens	43205
Haemophilus influenzae	19418
Haemophilus influenzae, type a	9006
Haemophilus influenzae, type b	10211
Haemophilus parainfluenzae	33392
Kingella kingae	23330
Klebsiella pneumoniae	33495
Leuconostoc mesenteroides	11449
Listeria monocytogenes	19115
Micrococcus luteus	4698
Neisseria gonorrhoeae	10150
Neisseria meningitidis	13090
Pediococcus acidilactici	25740
Proteus mirabilis	8259
Providencia stuartii	25825
Pseudomonas aeruginosa	27853
Saccharomyces cerevisiae	9763
Stomatococcus (Rothia) mucilaginosa	NCTC 10663
Salmonella enterica	13311
Staphylococcus aureus	25923

Organism	ATCC
Staphylococcus epidermidis	12228
Stenotrophomonas maltophilia	13637
Streptococcus agalactiae (Group B)	12928
Streptococcus pneumoniae	6305
Streptococcus pyogenes	19615
Streptococcus sanguinis	10556

Table 14 – Anaerobic Organisms

Organism	ATCC
Bacteroides fragilis	25285
Bacteroides ovatus	8483
Bacteroides thetaiotaomicron	29741
Phocaeicola vulgatus	8482
Hatheway histolyticum	19401
Clostridium novyi	17861
Clostridium perfringens	13124
Enterococcus faecalis	29212
Enterococcus faecium	19434
Escherichia coli	25922
Fusobacterium nucleatum	10953
Klebsiella pneumoniae	33495
Porphyromonas asaccharolytica	25260
Staphylococcus aureus	25923
Staphylococcus epidermidis	12228
Streptococcus agalactiae (Group B)	12928
Streptococcus pneumoniae	6305
Streptococcus pyogenes	19615
Veillonella parvula	10790

Table 15, Table 16, and Table 17 summarize the performance of the Plus Aerobic/F, Lytic/10 Anaerobic/F and Plus Anaerobic/F culture vials, respectively.

Table 15 – Growth Performance for All Organisms at Combined Blood Volumes for Plus Aerobic/F

BD BACTEC™ FX				BD BACTEC™ FXI Culture System			
Target CFU/vial	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**	**Target CFU/vial**	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**
10-100	100.0 (769/769)	20.1	8.8 – 64.2	10-100	100.0 (773/773)	19.9	7.2 – 73.9
1-10	96.9 (748/772)	22.0	9.6 – 82.8	1-10	97.7 (754/772)	22.1	8.2 – 104.2

Table 16 – Growth Performance for All Organisms at Combined Blood Volumes for Lytic/10 Anaerobic/F

BD BACTEC™ FX				BD BACTEC™ FXI Culture System			
Target CFU/vial	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**	**Target CFU/vial**	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**
10-100	98.8 (338/342)	20.2	7.6 – 69.2	10-100	100.0 (342/342)	18.4	6.9 – 57.3
1-10	88.3 (301/341)*	21.6	8.6 – 73.1	1-10	89.1 (304/341)*	19.9	7.2 – 119.6

* One paired set inoculated with *S. aureus* was excluded due to database technical issue.

Table 17 – Growth Performance for All Organisms at Combined Blood Volumes for Plus Anaerobic/F

BD BACTEC™ FX				BD BACTEC™ FXI Culture System			
Target CFU/vial	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**	**Target CFU/vial**	**Percent Recovery / (N)**	**Mean TTD (hours)**	**Range TTD (hours)**
10-100	97.4 (333/342)	24.1	8.3 – 105.3	10-100	96.2 (329/342)	21.0	7.2 – 108.4
1-10	86.2 (293/340)*	23.2	9.6 – 112.1	1-10	88.8 (302/340)*	21.0	8.4 – 111.7

* Two paired sets inoculated with *S. aureus* were excluded due to database technical issue.

C. Clinical Studies

A clinical performance study was conducted to evaluate the safety and efficacy of the BD BACTEC FXI Culture System for the qualitative detection of bacteria and fungi in blood specimens. The study compared the BD BACTEC FXI Culture System to the BD BACTEC FX using blood samples collected from patients, processed with BD BACTEC™ Plus Aerobic/F and BD BACTEC™ Lytic/10 Anaerobic/F Culture vials. The clinical data for the BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials is representative of the performance of the BD BACTEC™ Plus Anaerobic/F Culture Vials as supported by seeded internal equivalency studies.

This was a multicenter study which included nine clinical sites, seven in the U.S. and two in the EU. Blood cultures were collected prospectively from patients suspected of bloodstream infections. Matched pairs of culture vials included one vial incubated in the BD BACTEC™ FX and one vial in the BD BACTEC™ FXI Culture System. Fill volume requirements ensured consistency between paired samples.

The study assessed the ratio of true positive (TP) rates between the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX for all compliant samples with isolates characterized as significant, as well as overall (isolates characterized as significant, contaminant, or unknown combined).

True positives were defined as instrument (BD BACTEC™ FXI Culture System or the BD BACTEC™ FX) positive with subculture positive and thus a clinical determination of positive. All vials flagging as positive on the BD BACTEC™ FXI Culture System or the BD BACTEC™ FX were Gram stained and subcultured and identified to the species level, where possible. Isolates were then characterized as significant, contaminant, or unknown. All BD BACTEC™ FXI Culture System negative vials were terminally subcultured and at least 30% of the BD BACTEC FX negative vials were subcultured to assess the false negative rate.

A total of 1171 subjects were included in the study, yielding 1139 and 1136 subjects with matched pairs meeting inclusion and exclusion criteria for Plus Aerobic/F and Lytic/10 Anaerobic/F culture vials, respectively.

BD BACTEC™ Plus Aerobic/F Culture Vials

Enrolled subjects provided 939 compliant matched pairs. A total of 124 isolates were recovered from all compliant pairs with a positive status for a total of 949 results. A total of 114 matched pairs recovered at least one isolate (104 recovered a single isolate and 10 matched pairs recovered 2 isolates). The Plus Aerobic/F culture vials recovered 57

concordant positives (49 significant, 8 contaminant), 92 BD BACTEC™ FX positive (64 significant, 26 contaminant, 2 unknown), and 87 BD BACTEC™ FXI Culture System positive (62 significant, 24 contaminant, 1 unknown). True positive rate and ratio of true positive rate were calculated for the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX. Table 18 summarizes compliant vials containing any number of isolates (single and polymicrobial specimens).

Table 18 – True Positive (TP) Rate and Ratio of True Positive Rate for Plus Aerobic/F culture vials for all Compliant Samples Yielding Any Number of Isolates on Subculture

Isolate Characterization	Number of TP for BACTEC™ FXI	Percentage of TP for BACTEC™ FXI*	Number of TP for BACTEC™ FX	Percentage of TP for BACTEC™ FX*	Ratio of TP (FXI/FX)	95% CI for Ratio
Significant	62	6.5 (62/949)	64	6.7 (64/949)	0.969	(0.814, 1.150)
Contaminant	24	2.5 (24/949)	26	2.7 (26/949)	0.923	(0.582, 1.461)
Unknown	1	0.1 (1/949)	2	0.2 (2/949)	0.500	(0.066, 3.816)
Total	87	9.2 (87/949)	92	9.7 (92/949)	0.946	(0.790, 1.131)

*The denominator is based on all compliant matched pairs (at the isolate level).

False positives, identified as instrument positive vials that were subculture negative, yielded 0.1% (1/949) and 0.5% (5/949) for the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX, respectively.

Terminal subcultures were performed on 569 Plus Aerobic/F vial pairs that were negative on both BD BACTEC™ FXI and BD BACTEC™ FX. False negative results were observed for both BD BACTEC™ FXI and BD BACTEC™ FX vials of one vial pair. For negative vial pairs for which both vials were subcultured, the false negative rate based on instrument negative and subculture positive was 0.2% (1/569) for the BD BACTEC™ FXI Culture System and 0.4% (2/569) for the BD BACTEC™ FX.

Microorganisms recovered during this study on the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX are presented in Table 19.

Table 19 – Summary of Microorganisms Recovered in Plus Aerobic/F culture vials by Organism Group

Microorganism Group	BD BACTEC™ FXI Culture System	BD BACTEC™ FX
Coagulase-negative *Staphylococcus*	31	29
Enterobacterales	22	19
Enterococcus species	2	2
Nonfermenting Gram Negative Bacilli	4	8
Staphylococcus aureus	12	14
Streptococcus species	11	13
Other Gram Positive	2	3
Yeasts	3	4
Total	87	92

BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials

Enrolled subjects provided 982 compliant matched pairs. A total of 134 isolates were recovered from all compliant pairs with a positive status for a total of 1000 results. A total of 116 matched pairs recovered at least one isolate (99 recovered a single isolate, 16 recovered two isolates and 1 matched pair recovered 3 isolates). The BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials recovered 60 concordant positives (56 significant, 4

contaminant), 92 BD BACTEC™ FX positive (72 significant, 18 contaminant, 2 unknown), and 92 BD BACTEC™ FXI Culture System positive (67 significant, 22 contaminant, 3 unknown). True positive rate and ratio of true positive rate were calculated for the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX. Table 20 summarizes compliant vials containing any number of isolates (single and polymicrobial specimens).

Table 20 – True Positive (TP) Rate and Ratio of True Positive Rate for Lytic/10 Anaerobic/F for all Compliant Samples Yielding Any Number of Isolates on Subculture

Isolate Characterization	Number of TP for BACTEC™ FXI	Percentage of TP for BACTEC™ FXI*	Number of TP for BACTEC™ FX	Percentage of TP for BACTEC™ FX*	Ratio of TP (FXI/FX)	95% CI for Ratio
Significant	67	6.7 (67/1000)	72	7.2 (72/1000)	0.931	(0.795, 1.082)
Contaminant	22	2.2 (22/1000)	18	1.8 (18/1000)	1.222	(0.702, 2.134)
Unknown	3	0.3 (3/1000)	2	0.2 (2/1000)	1.500	(0.300, 7.502)
Total	92	9.2 (92/1000)	92	9.2 (92/1000)	1.000	(0.841, 1.189)

*The denominator is based on all compliant matched pairs (at the isolate level).

False positives identified as instrument positive vials that were subculture negative, yielded 0.2% (2/1000) and 0.1% (1/1000) for the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX, respectively.

Terminal subcultures were performed on 588 Lytic/10 Anaerobic/F vial pairs that were negative on both BD BACTEC™ FXI and BD BACTEC™ FX. False negative results were observed for both BD BACTEC™ FXI and BD BACTEC™ FX vials of two vial pairs. For negative vial pairs for which both vials were subcultured, the false negative rate based on instrument negative and subculture positive was 0.7% (4/588) for the BD BACTEC™ FXI Culture System and 1.2% (7/588) for the BD BACTEC™ FX.

Microorganisms recovered during this study on the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX are presented in Table 21.

Table 21 – Summary of Microorganisms Recovered in Lytic/10 Anaerobic/F culture vials by Organism Group

Microorganism Group	BACTEC™ FXI	BACTEC™ FX
Anaerobes	5	6
Coagulase-negative *Staphylococcus*	26	24
Enterobacterales	26	23
Enterococcus species	4	4
Staphylococcus aureus	10	10
Streptococcus species	15	19
Other Gram Negative	4	4
Other Gram Positive	1	1
Yeast	1	1
Total	92	92

This multi-center paired study demonstrated equivalent performance between the BD BACTEC™ FXI Culture System and the BD BACTEC™ FX when tested with blood culture samples in the BD BACTEC™ Plus Aerobic/F and BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials.

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

   Quality Control testing was conducted during the external clinical studies on the BD BACTEC™ FXI Culture System using Plus Aerobic/F and Lytic/10

Anaerobic/F culture vials. QC was performed each day subject samples were entered into the instrument. QC consisted of one positive and one negative control vial. Each positive seeded vial contained a target inoculum of 10-100 CFU/vial, which was confirmed by colony count procedure. The Plus Aerobic/F organisms included one obligate aerobe (*Pseudomonas aeruginosa,* ATCC 27853) and one facultative organism (*Escherichia coli,* ATCC 25922). The Lytic/10 Anaerobic/F vials included one obligate anaerobe (*Clostridium perfringens*, ATCC 13124) and one facultative organism (*Escherichia coli,* ATCC 25922). For each media type, organisms alternated between the two strains each day QC was performed. An uninoculated negative control vial was also included each day QC was performed. Positive QC results were within the expected TTD (≤ 72 hours) >95% of the time.

D. Clinical cut-off:

Not applicable