

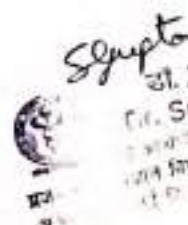
Specifications for Fully Automated Blood Culture System

Quantity required: 01

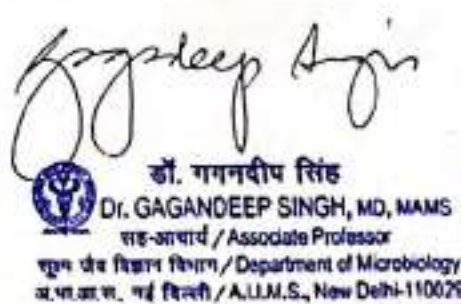
Approximate cost: 15 lacs

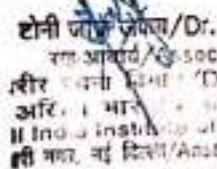
1. Automated Continuous Monitoring Blood Culture System with atleast 120 sample vial capacity.
2. System should be true walk away with a simple user interface and touch screen operations.
3. System should have continuous agitation for optimized recovery of organisms
4. System should have LIS communication capability for quick result information availability.
5. System should be modular and can be upgraded as and when required
6. System should be based on sensitive fluorescence/colorimetric technology for interpretation of results.
7. System must support Lab Quality Control requirements for automated analytics of Blood Volumes being received in the Microbiology Labs. These reports should be auto generated and ready to analyze and send out to Phlebotomy, Nursing and Physicians on a regular basis. (Volume checking)
8. System should have enhanced visual indicators both inside and outside the instrument in the form of different colored LEDS to indicate exact station status -available, ongoing, positive, and negative & anonymous
9. Instrument should have the facility for entering the patient name and sample accession number using bar code reader from a bar coded format
10. System should provide the option of loading of any culture bottle anywhere without any software intervention in order to get the bottles loaded in the instrument round the clock
11. The culture media should be free from substances which inhibits proper interpretation of gram-staining, hence causing any delay in critical callouts. Media should not have any masking effect for easier interpretation of Gram Staining of positive isolates.
12. Should have special media for optimal recovery of yeast and other fungi from blood samples. The system should also be able to support selective growth of yeast and fungus in case of mixed infections. The medium should contain a cocktail of antibiotics (minimum two) in order to suppress bacterial growth and should contain saponin in order to release phagocytosed fungi and yeasts from leukocytes.
13. System should have Auto Quality Control and Calibration facility to avoid any manual daily maintenance. User intervention for routine QC/calibration should not be required.
14. The required blood volume for blood culture should not be more than 10ml.
15. Media bottles should be fully compatible with familiar and widely used Vacutainer Holders without the need for a special adapter to improve workflow and safety.
16. System should be supplied along with on line UPS with 30 minutes back-up.
17. Comprehensive training of Lab staff till familiarity with the system.
18. The machine should be FDA/CE/ISI approved.
19. The vendor should provide five years comprehensive warranty and five years CMC after warranty period.


Certified that the specifications are broad based, general in respect to the requirement and not suit to any particular firm/brand



Dr. Surabhi Gupta
Associate Professor
Dept. of Reproductive Biology
All India Institute of Medical Sciences, New Delhi-110029


Dr. B. Gupta


Dr. GAGANDEEP SINGH, MD, MAMS
सह-आचार्य / Associate Professor
सूक्ष्म जीव विज्ञान विभाग / Department of Microbiology
आ.आ.आ.स. नई दिल्ली / A.I.I.M.S., New Delhi-110029


Dr. Tony George Jacob
Associate Professor
Dept. of Anatomy
All India Institute of Medical Sciences
ए.आ.आ.स. नई दिल्ली / Anand Nagar, New Delhi-29


Dr. HITENDER GAUTAM, MD
सह-आचार्य / Associate Professor
सूक्ष्म जीव विज्ञान विभाग / Department of Microbiology
आ.आ.आ.स. नई दिल्ली / A.I.I.M.S., New Delhi-110029


Dr. Anil Kumar
Associate Professor
Dept. of Microbiology
All India Institute of Medical Sciences, New Delhi-110029

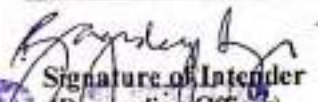


**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029**


RESEARCH SECTION

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. required along with specification	Automated Blood Culture System BACTEC FX-40
2.	Is the item a spare part(s) attachment or accessory for an existing equipment	No (It's a new equipment)
3.	Name of manufacturers/supplier of the item proposed by the indenter	M/s. Becton Dickinson, USA
4.	Are they sole manufacturers/distributors of the items	Yes
5.	Is there any other item with similar/equivalent specification available in the market to meet the job requirement envisaged? If Yes, why the same can't be procured. Demanding officer should bring out comparative functional advantages/cost effectiveness of the recommended item from these offered by other	NO
6.	What were the efforts made to locate alternative source of supply or use other substitutes	The items mentioned in col.1 are proprietary of M/s Becton Dickinson, USA and are exclusively distributed by M/s. Becton Dickinson India Pvt. Ltd. only. Thus no other supplier provides the said items. Also, for the better reproducibility of results other substitutes could not be used.
7.	Why open/limited tender can't be resorted to, for locating alternative source.	As the said items are proprietary and no other supplier provides the same therefore open/limited tender was not restored.
8.	Are the proprietary items certifying that the rates are reasonable or not.	Rates are reasonable (certificate attached)
9.	Any other justification for procuring item from single source	As said above, for the better reproducibility of results and no other firm manufactures the said system required for fungal isolation and antifungal steward ship and these are closed system items. Hence, they were procured from single source only.


Signature of Indenter
(Demanding Officer)


Counter Sign
(Head of the Department)

 **Dr. Rama Chaudhry**
Professor & Head
Department of Microbiology

I certify that the item(s) at Sr. No. 1 above is required to be procured on the single tender basis as the source of supply is definitely known/the specific brand proposed is the only one in meeting our functional requirements and limited tender could be dispensed with as they would serve no useful purpose in this particular case.






Becton Dickinson India Pvt. Ltd.
Head Office: 5th & 6th Floor,
Signature Tower B, South City I,
Gurgaon - 122001, Haryana, India
tel: +91-124-3949390
fax: +91-124-2383224/5/6

Regd. Office : 204, Tolstoy House,
15, Tolstoy Marg, New Delhi-110001, INDIA
CIN: U74899DL1995PTC064117
bd.com



Sl. No.	Item Description	Price/ Unit (In Rs)*
1.	BD BACTEC™ FX 40*3 (with all std. accessories)	14,40,780/-

Taxes will be charge extra – GST 18% or as applicable

Consumables: (As per your contracted prices):

Cat No	Description	Pack Size	HS Code	Price Per Pack (INR)	Tax Rate
442192	PLUS AEROBIC	50 bottles	38210000	10500	18%
442193	PLUS ANAEROBIC	50 bottles	38210000	10750	18%
442194	PEDS PLUS	50 bottles	38210000	10500	18%
442206	MYCOSIS ICF	50 bottles	38210000	12500	18%
442288	MYCO-F-LYTIC	50 bottles	38210000	14172	18%

Taxes will be charge extra – GST 18% or as applicable

Please note that Bactec FX System is auto calibrated – No additional Calibrator is required which will save your approx. Rs.60,000/- per year.

Terms & Conditions

- Taxes will be charged extra- GST 18% or as applicable
- Warranty – 5 Year from the date of installation.
- AMC & CMC:-

AMC (Annual Maintenance Contract)	45,000
CMC (Comprehensive Maintenance Contract)	90,000
GST Extra	18%

- Supply of Consumables: Through our authorized distributor.
- BD reserves the right to increase the prices of reagents and consumables quoted in view of Forex change.
- Delivery: Within 2 weeks from the date of receipt confirmed order at our end
- Payment Terms – System – 100% advance along with order
- Payment Terms – Media – Within 30 days from the date of invoicing
- Valid Till : 31st March, 2020

Hope you will find above information in order. In case of any further clarifications, please feel free to contact us.

Thanking You.

For BECTON DICKINSON INDIA Pvt. Ltd.

Sanjeev Sharma
M- 8826613441 E- Sanjeev.Sharma@bd.com
Sr. Area Sales Manager - CM
BD Diagnostics - Diagnostic System



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Becton Dickinson India Pvt. Ltd.
Head Office: 5th & 6th Floor,
Signature Tower B, South City I,
Gurgaon - 122001, Haryana, India
tel: +91-0124-4124300
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Regd. Office : 204, Tolstoy House,
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CIN: U74899DL1995PTC064117
bd.com



BACTEC™ FX40 PREINSTALLATION

The BACTEC FX40 system should be installed on a level surface in an area that is free from undue vibration, external air flow, direct sunlight, direct heat, high humidity, dust, extreme temperatures, and corrosive or explosive vapors or gases.

ENVIRONMENTAL REQUIREMENTS

Environmental Specifications	
Non-Operating Storage	
Temperature	-17.8° to 65° C (0° to 149° F)
Humidity	20% to 80% RH, non-condensing
Operating Conditions	
Temperature	18° to 30° C (64.4° to 86° F)
Humidity	25% to 80% RH, non-condensing
Locations	Level surface, no direct sunlight, no direct heat or other external air source, no high humidity, dust, extreme temperatures or corrosive or explosive vapors or gases.
Noise @ 1 m	≤55 dBA using ANSI type 2 sound meter
Altitude	Evaluated for safety to 2,000 m
Instrument shall withstand thermal decontamination at 65° C for 10 hours.	
Instrument shall withstand Para Formaldehyde treatment as used for mycobacterial decontamination.	
Installation Category II and Pollution Degree 2 as per IEC 664	

3.2 ELECTRICAL REQUIREMENTS

Input Voltage	100 – 240 VAC ± 10 %
Peak Current	3.0 amperes, nominal @ 115VAC, 60Hz
Input Line Frequency	50/60 Hz
Power	250 W
Heat	307 btu/hr

BD recommends a dedicated 15A line for BACTEC FX40 system.

3.3 CLEARANCE REQUIREMENTS

Table 1 provides dimensions for single instrument and stack. A clearance of thirty (30) cm on the right side of the instrument is required to install the tablet supporting arm, barcode scanner and printer.

Table 1		
Physical Dimensions	Single Instrument	Stack
Height	39.1 cm (15.4 in)	77.5 cm (30.5 in)
Width	67.5 cm (26.6 in)	67.5 cm (26.6 in)
Depth	58.5 cm (23.0 in)	58.5 cm (23.0 in)
Clearance (rear, left, right)	0 cm, 7 cm, 0 cm	0 cm, 7 cm, 0 cm
Clearance (front)	61.0 cm (24 in)	61.0 cm (24 in)
Weight (empty)	31.8 kg (70.1 lb)	64.4 kg (142.4 lb)
Weight (full) + 10 ml blood	38.0 kg (83.7 lb)	76.9 kg (169.6 lb)



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CIN: U74899DL1995PTC064117
bd.com



Date: 04.12.2019

BD/BC/AIIMSMCB/SS/PAC/19-12

To,
The HOD
Deptt of Microbiology, AIIMS,
Ansari Nagar, New Delhi-110029

Sub: Proposal for BD Bactec™ FX Automated Blood & Sterile Body Fluid Culture System

Dear Sir,

We acknowledge with thanks, the faith and interest shown by your organization in our products and technologies. We are pleased to inform you that in pursuit of offering value addition in our support and services to our customers, BD India Pvt. Ltd hereby offers a special offer to AIIMS for BD Bactec™ FX Automated Blood & Sterile Body Fluid Culture System,

Technical features

- Automated Blood & Sterile Body Fluid Culture System.
- Positions – 40-160 (Please refer table below - upgradable up-to 160 positions)
- Continuous monitoring and Continuous Agitation
- Throughput :8-32 Culture Bottles/ day (with 5 days negative protocol)
- Technology- Sensitive Fluorescent Technology
- Monitoring of each Position: in every 10 minutes.
- True Non Invasive Technology and Advanced Media Specific Algorithm
- More than 16 algorithms to monitor growth patterns in case of Positive samples
- Customized Reporting and Control Module
- Stand Alone Module
- Bi-Directional Interface ready, Onsite upgradable
- Exclusive BD Vacutainer Safety Lock
- FDA Cleared and Approved
- Patented Resin Technology – For the complete neutralization of Antibiotics in blood stream
- Blood Volume Monitoring (optional with Epicenter)
- Delayed Vial Entry (DVM)
- LIS communication capability for quick result information availability
- BD Bactec™ FX has enhanced visual indicators both inside and outside the instrument in the form of different colored LEDs to indicate exact station status –available, ongoing, positive, and negative & anonymous
- BD Bactec™ FX provides the option of loading of any culture bottle anywhere without any software intervention in order to get the bottles loaded in the instrument round the clock

Rapid Culturing

- Rapid Blood Culture
- Rapid Fungal Culture from Blood Specimen
- Rapid Yeast Culture from Blood Sample
- Rapid Sterile Body Fluid Culture

Culture Bottles (Available in Glass and Plastic options)

- Pediatric Culture Bottles – For Pediatric samples and sterile body fluids
- Adult Aerobic Culture Bottles – For Aerobic Bacteria and Yeasts
- Adult Anaerobic Culture Bottles – For Anaerobic Bacteria and Yeasts
- Special Fungal Culture Bottles – For Mixed infection cases
- Special Culture Bottles for Mycobacterium from Blood Sample
- Special Lytic Culture bottle for Anaerobic Culture

BD Bactec Culture bottles are available in both the Glass and Plastic Options

Plus bottles uses Patented Resin Technology – For the complete neutralization Antibiotics in blood stream



Advancing the world of health

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15, Tolstoy Marg, New Delhi-110001, INDIA
CIN: U74899DL1995PTC064117
www.bd.com/India



Date: 13.12.2019

To,
The HOD
Deptt of Microbiology, AIIMS,
Ansari Nagar, New Delhi-110029

Sub: Like to Like Comparison for BD Bactec™ FX Automated Blood & Sterile Body Fluid Culture System

Dear Sir,

This has reference to the above mentioned subject, we are pleased to submit our like to like price comparison along with order copy for your kind perusal as:-

Sr. No.	Name of Item	AIIMS offer Unit Price	AIIMS offer Price including GST (Total Qty. 03 Nos.)	CDSA offer Unit Price	CDSA offer price including GST (Total Qty. 04 Nos.)
	Year of order				03.09.2019
	Warranty		5 Years		3 Years
1.	Automated Blood & Sterile Body Fluid Culture System BD BACTEC FX40*3	4,07,000.00 + 18% GST	14,40,780.00	4,07,000.00 + 18% GST	19,21,040.00
	CMC after 5 th Year Onwards	90,000/annu m			They did not take CMC till date.


NOTE: AMC/CMC Price was offered in the main quote.

We hope you will find above justification and like to like comparison in line to your requirement.

We look forward to receiving your valuable purchase order at the earliest.


Thanking You.

For BECTON DICKINSON INDIA Pvt. Ltd.


Vineet Nair
M- 9599978110, 8826613441
E- vineet.nair@bd.com, Sanjay.Sharma@bd.com
Branch Manager
BD Diagnostics - Diagnostic System

Encl: Copy of Supply order CDSA




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BD India Pvt Ltd
Head Office: 5th & 6th Floor,
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Gurgaon - 122001, Haryana, India
tel: +91-124-3949390
fax: +91-124-2383224/5/6

Regd. Office : 204, Tolstoy House,
15, Tolstoy Marg, New Delhi-110001, INDIA
CIN: U74899DL1995PTC064117
www.bd.com/india

Date: 13.12.2019

To,
The HOD
Deptt of Microbiology, AIIMS,
Ansari Nagar, New Delhi-110029

Sub: Like to Like Comparison for BD Bactec™ FX Automated Blood & Sterile Body Fluid Culture System

Dear Sir,

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We look forward to receiving your valuable purchase order at the earliest.

Thanking You.

For BECTON DICKINSON INDIA PVT. LTD.

Vineet Nair
M- 9599978110, 8826613441
E- vineet.nair@bd.com, Sanjeev.Sharma@bd.com
Branch Manager
BD Diagnostics - Diagnostic System

Encl: Copy of Supply order CDSA

Advancing the world of health

PURCHASE ORDER

Order No.: CDSA/4.29.4/1

September 03, 2019

M/s Becton Dickinson India Pvt. Ltd.
 6th Floor, Signature Tower B,
 South City 1, Gurgaon - 122001 (Haryana)
 Email id: Kalinga.kumar.ray@bd.com
 Contact No. +0124-2383566

Dear Sir/Madam,

Ref: Tender No. 2019_THSTI_488659_1

We are pleased to place an order for the supply of the equipment as per terms and conditions given below: -

S. No.	Description of Articles	Model No.	Make	Qty.	Total Value (Inc of all taxes)
1	Fully automated blood culture system	BD BACTEC™ FX40	Make# Authentic Instruments USA	4	Rs. 19,21,040.00

Warranty: 36 months from the date of installation

Total Value - INR 19,21,040/- (In words Rupees Nineteen Lakhs Twenty One Forty only)

Terms & Conditions

1. All items are as per price Bid/Quotation no. 2019_THSTI_488659_1 Dated 02/08/2019
2. Total order value of INR 1,921,040/- F.O.R inclusive of Cost, labor, cartage, Insurance, etc. up to respective sites.
3. **Billing Address:** - Program Director, Translational Health Science and Technology Institute (THSTI), NCR-Biotech Science Cluster, 3rd Milestone Faridabad-Gurugram Expressway, P.O. Box NO. 04, Faridabad-121001 (Haryana).


Clinical Development Services Agency

(An extramural unit of THSTI, Department of Biotechnology, Ministry of Science and Technology, Government of India)
 NCR Biotech Science Cluster, THSTI Building, 3rd Milestone, Faridabad - Gurugram Expressway, Faridabad - 121001 (Haryana)

+91 129 287 6455 | www.cdscindia.in

Delivery Address: - The equipment will be delivered at the following locations

Sr. No.	Name of the Site	No. of Equipment	Name of the Contact person	Email Id. & Contact No.
1	All India Institute of Medical Science (AIIMS), Great Eastern Rd, Tatibandh, Raipur, Chhattisgarh 492099	One	Dr. Atul Jindal	8224014667 dratuljindal@gmail.com
2	Government Medical College and Hospital (GMCH), Chandi Path, Sector 32, Chandigarh, 160047	One	Dr. Deepak Chawla	9646121559 drdeepak.chawla@gmail.com
3	Assam Medical College and Hospital, Barbari, Dibrugarh, Assam, PIN - 786 002	One	Dr. Reeta Bora	9435394313 bora64reeta@gmail.com
4	All India Institute of Medical Science (AIIMS) Jodhpur, Basni Industrial Area, MIA 2nd Phase, Basni, Jodhpur, Rajasthan 342005	One	Dr. Neeraj Gupta	8003996908 neerajpgi@yahoo.co.in

Delivery of the above-ordered items must be made by 27/09/2019.

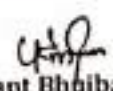
1. The payment will be made after the receipt of full supply.
2. Performance Security: 10% of total order value in form of the bank performance guarantee drawn from a nationalized bank for a validity period of 39 months will be submitted by supplier.
3. Please submit Invoice/Bill in duplicate and pre-receipted along with a certified copy successful installation and operationalization duly certified by Site Investigator to the undersigned.
4. The supply order is subject to standard terms and conditions of Tender ref. no. 2019_THISTI_488659_1

Kindly acknowledge the receipt of this order.

CDSA GSTIN: - 06AACAT0292J17G



Yours Sincerely,


 Mr. Prashant Bhojbal
 Admin & Finance Manager, CDSA

Becton Dickinson India Pvt. Ltd.
Head Office: 5th & 6th Floor,
Signature Tower B, South City I,
Gurgaon - 122001, Haryana, India
tel: +91-0124-4124300
fax : +91-124-2383224/5/6

Regd. Office : 204, Tolstoy House,
15, Tolstoy Marg, New Delhi-110001, INDIA
CIN: U74899DL1995PTC064117
bd.com



Date: 02.12.2019

Rate Certificate

To Whom It May Concern

This is to certify that the rates which we have offered you are not more than the other offered in Government or Private Institutions on the same terms & conditions.

Thanking you,

Yours truly,

For Becton Dickinson India Pvt. Ltd.

Authorized Signatory



[Handwritten signatures]

Advancing the world of health



BD

Helping all people
live healthy lives

MANUFACTURER'S AUTHORISATION

To, Whomsoever it may concern

Dear Sir,

Ref : Manufacturers authorization Letter for PhoenixTM & BactecTM MGITTM 960

We, Becton Dickinson and Company – Diagnostic Systems 7 Loveton Circle Sparks, MD USA 21152 who are proven and reputable manufacturer's of PhoenixTM & BactecTM MGITTM 960 hereby authorize M/s. Becton Dickinson India Pvt.Ltd. (A 100% direct subsidiary of Becton Dickinson and Company) to submit a tender, process the same further and enter into a contract for sales and service with customers in India for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than M/s Becton Dickinson India Pvt.Ltd. is authorized to participate or bid for tenders for the products mentioned above.

Yours faithfully,



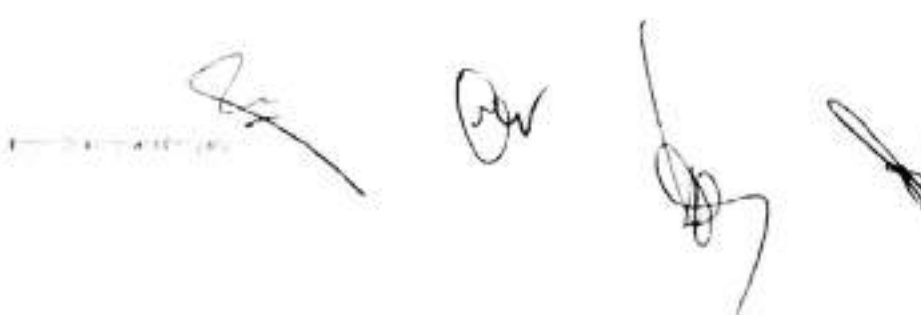
Signature

VICE PRESIDENT, WORLD WIDE MARKETING
Title

March 14/08

Date

For and on behalf of Messrs: Becton, Dickinson and Company
BD Diagnostic Systems
7 Loveton Circle
Sparks, Maryland USA 21152



1 Becton Drive
Franklin Lakes, NJ USA 07417
tel 201 847 6800
www.bd.com



BD

Helping all people
live healthy lives

TO WHOMSOEVER IT MAY CONCERN

This is to state that Becton Dickinson India Pvt. Ltd. is a 100% group subsidiary of Becton, Dickinson and Company, located at 1 Becton Drive, Franklin Lakes, New Jersey, 07417 USA and is authorized by Becton, Dickinson and Company, to deal with their full product range in India, Nepal, Bangladesh, Sri Lanka, Bhutan & Maldives.

For Becton, Dickinson and Company

By

Dean J. Paranicas
Vice President, Corporate Secretary
and Public Policy

Becton Dickinson and Company

Encouraging Endurance

bsi.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks
Maryland
21152
USA

Holds Certificate Number:

MD 595740

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices. These devices include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, and identification of hematological parameters, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, ancillary devices and instrument software, and reagents used in the diagnosis of newborn infant screening.

Stewart Brain

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-03-14

Latest Revision Date: 2018-10-11

Effective Date: 2018-10-11

Expiry Date: 2021-10-10

Page: 1 of 2



...making excellence a habit™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated online.

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

[Signature]

[Signature]

[Signature]



Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
USA
Tel: 410-316-4000
Fax: 410-316-4188

bd.com

**Proprietary Certificate
To whomsoever it may concern**

We hereby declare that the below listed Consumables/Reagents/Kits used along with BACTEC™ 9050, BACTEC™ 9120 and BACTEC™ FX Blood Culture System systems/ Instruments are a registered trademark of Becton, Dickinson and Company. All trademarks mentioned below are proprietary items under international intellectual property rights.

Cat No.	Description	Intended Use
442260	BD BACTEC™ Standard/10 Aerobic/F Culture Vials	BD BACTEC™ Standard/10 Aerobic/F culture vials (enriched Soybean-Casein Digest broth with CO ₂) are for aerobic blood cultures. Principal use is with BACTEC fluorescent series Instruments for qualitative culture and recovery of aerobic microorganism (bacteria and yeast) from blood
442191	BD BACTEC™ Standard Anaerobic/F Culture Vials	BD BACTEC™ Standard Anaerobic/F culture Vials (pre-reduced enriched Soybean-Casein Digest broth with CO ₂) are for anaerobic blood cultures. Principal use is with the BD BACTEC fluorescent series Instruments for qualitative culture and recovery of anaerobic microorganisms from blood.
442192	BD BACTEC™ Plus Aerobic/F Culture Vials	BD BACTEC™ Peds Plus Aerobic/F and BD BACTEC™ Plus Anaerobic/F media are used in the qualitative procedure for the aerobic and anaerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principle use of these media is with BD BACTEC fluorescent series Instruments.
442193	BD BACTEC™ Plus Anaerobic/F Culture Vials	
442194	BD BACTEC™ Peds Plus™/F Culture Vials	BD BACTEC™ Peds Plus™/F culture vials (enriched Soybean-Casein Digest broth with CO ₂) are for aerobic blood cultures. Principle use is with the BD BACTEC fluorescent series Instruments for the qualitative culture and recovery of aerobic microorganism (mainly bacteria and yeast) from pediatric and other blood specimens which are generally less than 3 mL in volume.
442265	BD BACTEC™ Lytic/10 Anaerobic/ F Culture Vials	BD BACTEC™ Lytic/10 Anaerobic F culture vials (pre-reduced enriched Soybean-Casein Digest broth with CO ₂) are for anaerobic blood cultures. Principal use is with the BD BACTEC fluorescent series Instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.
442003	BD BACTEC™ Myco/F Lytic Culture Vials (case of 25 vials)	BD BACTEC™ Myco/F Lytic culture medium when used with the BD BACTEC fluorescent series Instruments is a



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USA
Tel: 410-316-4000
Fax: 410-316-4188

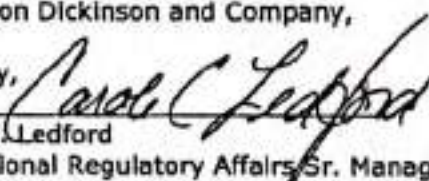
bd.com

442288	BD BACTEC™ Myco/F Lytic Culture Vials (case of 50 vials)	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.
✓ 442026	BD BACTEC™ Mycosis-IC/F Culture Vials (case of 25 vials)	BD BACTEC™ Mycosis-IC/F culture vials are for aerobic blood cultures. Principal use is with the BACTEC fluorescent series Instruments for the selective culture and recovery of yeasts and fungi from blood.
✓ 442206	BD BACTEC™ Mycosis-IC/F Culture Vials (case of 50 vials)	
442023	BD BACTEC™ Plus Aerobic/F Culture Vials (PLASTIC)	BD BACTEC™ Plus Aerobic/F medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC fluorescent series Instruments
442021	BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials (PLASTIC)	BD BACTEC™ Lytic/10 Anaerobic/F culture vials (pre-reduced enriched Soybean-Casein Digest broth with CO ₂) are for anaerobic blood cultures. Principal use is with the BD BACTEC fluorescent series Instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.

The above mentioned products are exclusively manufactured by Becton, Dickinson and Company as on date. We confirm that Becton Dickinson India Private Limited (BD India) is our 100% subsidiary in India and is authorized to market this product as a proprietary item and provide necessary services in terms of product knowledge and training.

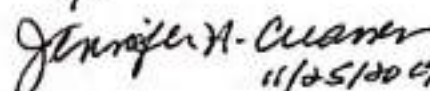
For Becton Dickinson and Company,

Sincerely,


Carole E. Ledford
International Regulatory Affairs Sr. Manager

Date

November 25, 2019


Jennifer A. Creamer
11/25/2019

JENNIFER A. CREAMER
NOTARY PUBLIC
BALTIMORE COUNTY
MARYLAND
MY COMMISSION EXPIRES OCTOBER 19, 2023

State of Maryland
County of Baltimore
On this 16 day of Oct, 2018.
I hereby certify that the attached document is
a true copy made by me from a record in my
fair register of official acts.

Jennifer A. Creamer
Notary Public, Maryland
Baltimore County
My Commission Expires:
October 18, 2019

Certificate No: **MD 595740**

Jennifer A. Creamer

Location

Registered Activities

Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks
Maryland
21152
USA

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices. These devices include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, and identification of hematological parameters, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, ancillary devices and instrument software, and reagents used in the diagnosis of newborn infant screening.

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Original Registration Date: 2013-03-14
Latest Revision Date: 2018-10-11

Effective Date: 2018-10-11
Expiry Date: 2021-10-10

Page: 2 of 2

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[Handwritten signatures]