

### ALL INDIA INSTITUTE OF MEDICAL SCIENCES, VIJAYPUR, JAMMU- 184120

## DEPARTMENT OF MICROBIOLOGY

#### CALL FOR OBJECTION NOTICE

#### No.-AIIMS/JMU/Micro/FA/2025/03

Reference Government of India Ministry of Finance Department of Expenditure letter no 4/1/2023-PPD (pt) 28th June 2024 (Proprietary Article) Procurement through Rate Contract against device BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system for Department of Microbiology in AIIMS, Vijaypur, Jammu.

Subject: Call for objection against procurement through Rate Contract against device BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system for Department of Microbiology in AIIMS, Vijaypur, Jammu.

It is intended to procure BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system on proprietary basis as per provision of GFR, 2017 rule 166, directly from M/S Becton, Dickinson and Company against their proposal submitted and by accepting M/s Becton Dickinson India Private Limited (BD INDIA) as the sole supplier of equipment BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system for the Department of Microbiology which satisfies all requirements of being a proprietary item.

Relevant documents are published on Institute website & CPP portal for inviting objections/ claims/ comments if any, from eligible manufacturer/ supplier, before accepting the claim of earlier said manufacturer and accordingly making procurement under Proprietary article.

Objections/ claims/ comments should be sent to the office of Deputy Director (Admin), AIIMS, Vijaypur, Jammu in a sealed envelope with above mentioned subject & reference number, or by e-mail at dda@aiimsjammu.edu.in within 14 days from the date of publication of this notice i.e. on or before 13/02/2025 upto 05:00 PM.

After due date, it will be assumed that no manufacturer/ supplier has any objection/ claim against above mentioned equipment article and same will be considered as Proprietary article.

#### Enclosure:

PAC certificate by manufacturer

PACcentificate by Department (Form P-3)

Form P-2 with technical specifications

Procure कि कि प्रिप्ति ent Officer

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अखिल भारती**र्य अधिकान्य संस्थाम्, बिजयपुर** जम्मू-१८४१२० All India Institute of Medical Sciences, Vijaypur, Jammu-184120

Date: 30/01/2025

# AIIMS, VIJAYPUR, JAMMU-184120

# INDENT FOR PURCHASE OF STORES (FORM P-2)

1. Please fill a separate from for each item

2. Please fill completely in triplicate. Incomplete from and those with eligible writing may not be accepted.

Name of items with full specifications required accessories	& Quantity (in figures and words)	Cost per unit (approx.) in foreign currency and rupees	Total cost (approx.).
BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system	01(ONE)	Approx. Rs 65,00,000/ (Rupees Sixty five lakhs only)	Rs 65,00,000/ (Rupees Sixty five lakhs only)

## 3. For equipment, please provide the following information

Detailed description of the actual use of the equipment Is the equipment to be used for patient care or research. Yes

### Is this /similar equipment already available in the department? NO

When purchased?

Cost at that time:

Present functional status

Test/procedures done on this equipment in, last year: Not available with the

Department

Revenue generated by this equipment in last year: N/A

If yes, what is the justification for this purchase? N/A

Is this /similar equipment available in any other department in the institute? No

If yes, what is the justification for this purchase? N/A

4. For Consumable, please provide following information: N/A

Description of stocks available:

When was it last purchased?

In what quantity?

Cost:

Source

Test/ procedures done in this period:

Average annual consumption Shelf life

Period for which this purchase will last Number of tests likely to be done with this quantity:

5. For furniture, please provide the following information: N/A

Exact location and use

Existing furniture at that place

Justification for this purchase

Possible source (name all source you know) form where item may be obtained (name, address, phone no, fax no, email, etc. of contact person)

**INDENTOR** 

Signature

Name- Den Spriya

Designation Assistant Pro

Department of Wichobiology

AIIMS, VIJAYPUR, JAMMU-184120

HEAD OF DEPARTMENT/ SECTION

Signature

Name- Dr Manist Rangen

Designation - Associate Professor & off Lload

Department of Microbiology

AIIMS, VIJAYPUR, JAMMU-184120

#### P-3 FORM

(To be attached with P-2 form for proprietary items)
AIIMS, Vijaypur, Jammu-184120
PROPRIETARY ARTICLE CERTIFICATE

It is certified that the items (BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system) required in the P-2 form should be purchased from M/S M/s Becton Dickinson India Private Limited (BD INDIA) which is a 100% subsidiary of M/S Becton, Dickinson and Company 7 Loveton circle, Sparks, MD-21152, USA who are proven and reputable manufacturer of items BD Bactec MGIT 960 Automated TB liquid culture and drug sensitivity system having factories in USA etc. to the best of my knowledge, M/s Becton Dickinson India Private Limited (BD INDIA) is an authorized dealer of M/S Becton, Dickinson and Company 7 Loveton circle, Sparks, MD-21152, USA.

Similar items manufactured by another firm (s) shall not be suitable for our purpose for the following reasons: This is a Proprietary item, and the automated system will significantly enhance our capability in Mycobacteriological diagnostics, leading to improved patient outcome and fostering innovative research.

(Sig of Indenter)

Dated: Inuary 2025

Department of Microbiology

AIMS, Very Would and 184120

Recommended by:

Signature of Head of Department/Section

Department of Microbiology

प्रिकृतिकार्य (Microbiology)
Department of Microbiology
प्रिकृतिकार्य अनुविधान संस्थान, विजयपुर ज्ञान-१८०१२०
अधिका वार्राय अनुविधान संस्थान, विजयपुर ज्ञान-१८०१२०
अधिका वार्राय अनुविधान संस्थान, विजयपुर ज्ञान-१८०१२०
अधिका संस्थान

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# FORMAT FOR THE STATEMENT OF CASE (SOC)

Case Title: Procurement of Automated TB culture and drug sensitivity detection

		Details
S. No.	Item	Department of Microbiology
1.	Section/Department/Division initiating the SOC	Automated TB culture and drug sensitivity detection
2.	Name of the item(s)/services being procured	system  Medical Equipment
3.	Category of item (Furniture, Stationery, Services, IT, Medical Equipment, Medical consumables, Medicines, etc.)	
	(a) Name/List of items to be enclosed.	- Itum of
4.	Justification for procurement	No machine is available in department for culture of
	i. Which item was serving the purpose	TB and doing drug sensitivity
	(ii) Broad purpose of items being procured, with detailed justification.	Appendix A
5.	(i) Category of proposal –  • Fresh purchase	Fresh purchase
	<ul><li>Up gradation</li><li>Replacement</li><li>Maintenance</li></ul>	
	Repair     Any other (to be specified)	TB culture was not being done till now in the
	(ii) If it is a fresh purchase, how wasthe purpose being served till date?	department
6.	Quantity  (a) Basis for working out the quantity against each item – (formula, methodology, etc.).	01 (One) 1- Mycobacteriology Lab
	(b) Details like authorized holdings, existing holdings, deficiency etc. (NAC from Store Section to be enclosed).	•
	(c) Calculation sheet to be enclosed.	-
	(d) Proposed distribution of items being bought with justification.	Appendix A
7.	Estimated cost of proposal along with basis for the same (GeM rate, LPP, Quotations, etc.).	Appendix B
3.	Details of the last purchase:	N. ( Dans as for
	(a) The Quantity and dates on which similar items were procured in last one year.	Not Done so far
		- 0
	Mode of Tendering:	11 - Kansas
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-	(a) GeM portal	
	(i) Under Rule 149 (i) or 149 (ii) or 149 (iii) of GFR-2017.	-
	(ii) Relevant documents/screenshots etc. to be enclosed.	-
	(b) Non-GeM	
	Reasons for not procuring through GeM portal.	The item being procured is a PAC item.
	If not available on GeM portal, GeMAR&PTS to be enclosed.	
	(ii) e-Tendering, or 'e-publishing and offline bidding'.	
	(iii) Offline bidding (permitted only when items are not available on GeM portal and amount of proposal is upto Rs 2,50,000/-).	-
10.	Draft RFP to be enclosed	Appendix A

## Format for Quantity and Cost of proposal (S. Nos. 6 & 7 of SOC):-

S. No.	Name of items	Quantity	Rates (in Rs)	Total basic cost (in Rs)	Rate of Tax/GS T (in %)	Tax/GST per item (in Rs)	Total Tax/GS T(in Rs)	Total amount (in Rs)
	Automated TB culture and drug sensitivity detection system		65,00,000	NA	NA	NA	NA	65,00,000
	2,500222							

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Dr. Alisha Aggarwal प्राह्मयन-आचार्य सहायन-आचार्य सहायन-आचार्य सहायन-आचार्य सहायन-आचार्य सहायन-अन्ति विज्ञान विभाग Department of Microbiology आंदाल भारतीय आयुर्तिज्ञान संस्थान, विजयपुर जम्मू-१८४१२ आधित भारतीय आयुर्तिज्ञान संस्थान, विजयपुर जम्मू-१८४१२ आधित आयोजिक आधीरातीय आयुर्तिज्ञान संस्थान, विजयपुर जम्मू-१८४१२ आधित आयोजिक आधीरातीय आयोजिक अधीरातीय आयोजिक आधीरातीय आधीरातीय आयोजिक आधीरातीय आधीरातीय आधीरातीय आधीरातीय आयोजिक आधीरातीय आध t Professor | विज्ञान विभाग nont of Microbiology |रतीय आयुर्विज्ञान संस्थान, विजयपुर जम्मू-१८४१२० |किकार्यक of Mactical Sciences, Visavour, Jammu



#### ALL INDIA INSTITUTE OF MEDICAL SCIENCES, VIJAYPUR, JAMMU- 184120

## DEPARTMENT OF MICROBIOLOGY

#### APPENDIX A

# <u>Proposal for purchase of Automated Tuberculosis (TB) culture and Drug sensitivity</u> detection system

#### **Background**

The Department of Microbiology at AIIMS Jammu aims to strengthen its diagnostic capabilities, particularly for Mycobacterium tuberculosis (MTB), a critical pathogen responsible for tuberculosis (TB), a major public health threat in India. Early detection and drug susceptibility testing (DST) are crucial for effective treatment and management. Current solid culture methods for MTB have limitations in speed, sensitivity, and recovery of viable organisms. Liquid culture systems represent a significant advancement in TB diagnostics and patient care.

#### Justification for Automated TB culture:

- Increased Sensitivity and Speed: The automated liquid culture system provides
  more sensitive and rapid detection of MTB compared to traditional solid cultures.
  This reduces the time for mycobacterial growth detection from weeks to just 7-14
  days, enabling quicker diagnosis and treatment.
- Improved Drug Susceptibility Testing: Accurate DST is essential for managing TB, especially in cases of multi-drug resistant (MDR) and extensively drug-resistant (XDR) strains. The automated system facilitates DST, allowing prompt identification of drug-resistant strains and guiding appropriate treatment regimens.
- Automated System with High Throughput: As the system is automated, it allows
  continuous monitoring, standardization, and reduced human error. It is ideal for highthroughput settings, where a high volume of samples can be processed efficiently, an
  important aspect given the potential TB burden in the region.
- Enhanced Patient Care and Infection Control: Faster and accurate TB diagnostics reduce delays in initiating treatment, improving patient outcomes and reducing the risk of transmission within healthcare settings and the community.

डॉ. अलाशा अंग्रवाल Dr. Alisha Aggarwal सहारका-आवार्य

Department of Microbiology Fair Floor, Academic Block, Vijaypur, Jan

Department of Microbiology अधिल भारतीय आयुर्विज्ञान संस्थान, विजयपुर जम्मू-१८४१२० All India institute of Medical Sciences, Vijaypur, Jammu-184120

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हाँ मनीच रंजा। **Manish Ransan** Assistant Professor

सुरम् जीव विज्ञान विषाग Department of Microbiology अवित्त भारतीय आयोगन संस्थान, विजयपुर सम्मू-१८४१२० अवित्त भारतीय आयोगन संस्थान, विजयपुर सम्मू-१८४१२०



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# JAMMU-184120

# Technical Specifications of the automated TB culture System

- System should be capable to perform rapid culture, differentiation and sensitivity testing for Mycobacterium tuberculosis.
- System working principle should be based on non-invasive sensitive fluorescent technology.
- System should have continuous incubation, monitoring and detection facility with specific algorithm for analyse slow growth patterns of Mycobacterium.
- System should be able to process minimum 5 fresh samples per day with standard international protocol.
- System should have more than 900 sample positions with compact space-saving design with User-friendly operation keys.
- System should be able to process both respiratory & non-respiratory samples.
- System should have BARCODE Scanner.
- System should not have any sharp at the time sample inoculation to avoid any needle stick injury to user. (To avoid infectious disease transmission to the user, like HIV, HCV, HBV, etc.)
- Both First Line Drug Kit/ Media and its protocol should be FDA cleared and approved.
- System should have a validated protocol to perform 1st Line Drug Sensitivity Testing
- System should be able to perform second drug sensitivity testing and should have a validated protocol to perform 2<sup>nd</sup> Line Drug Sensitivity Testing
- System should have its own validated kit form rapid differentiation between MTBc and MOTT within 15 minutes.
- System should be supplied with ready to use lyophilized drug vials for entire range of 1st Line Drug Sensitivity testing i.e. S,I,R,E,P.

System should be capable of automatic report generation for the interpretation of Drug Sensitivity testing results.

> डॉ. अलीग्न अग्रवाल Dr. Alisha Aggarwal विविध-आहार्र

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- System should be supplemented with Ready Made Pyrazinamide Drug media for standardized result.
- Company should have its own factory certified drug kit for 1st Line Drug Sensitivity Testing for 5 drugs along with Pyrazinamide Drug Media
- Should have provision of future software up-gradation.
- System should be supplied along with on line UPS with 30 minutes back-up.
- System should be approved by Central TB Division.
- System should be supplied with high end database management system which can integrated to Hospital/Lab information system for bi-directional information flow for patient data and information on drug sensitivity patterns with following features-
  - Work-station
  - **Detailed Patient Data Incorporation**
  - Specimen Demographics
  - Centralized Order Management for Microbiology testing
  - Improved workflow
  - Multiple (instrument) Connectivity
  - Detailed Data Review-Patient, Specimen, Test & Isolate levels
  - Unlimited Microbiology Data Storage Capacity
  - **Full Transaction Logging**
  - Direct On-line Technical Support

Warranty for 5 years 02 CTwo) years + 08 yx CMC fox

The system should be US FDA approved and compliance with ISO 9001 and ISO 13485 standards

#### **Budget Estimation**

The estimated budget for the liquid culture system is approximately 65 lakhs

#### Conclusion

The adoption of the liquid culture system at AIIMS Jammu will ensure high-quality, timely, and accurate diagnostics for tuberculosis. It will significantly impact patient care, especially for MDR and XDR-TB cases, aligning with national and global TB eradication goals

Department of Microbiology, 2nd Floor, Academic Block, Vijaypur, Jammu 1841 20 प्रभा जाव प्रसार Microbiology Jaypur, Jammu Department of Microbiology गुक्रमुण, नुस्थान अधित भारतीय आयुर्वजान संस्थान, विजयपुर जम्मू-१८४१२० अधित भारतीय आयुर्वजान संस्थान, विजयपुर जम्मू-१८४१२०



Beccon, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA

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

bd.com

### PROPRIETARY CERTIFICATE

To Whom it May Concern:

We hereby declare that the below listed instruments are a registered trademark of Becton, Dickinson and Company. All trademarks mentioned below are proprietary items under international intellectual property rights.

SKU NO.	Product Description	Intended Use
441743	BD Bactec MGIT 320 System	The BD BACTEC™ MGIT™ 320/960 System is designed for the automated rapid detection of mycobacteria from clinical specimens (except blood and urine). In addition to detection of mycobacteria, the BD BACTEC™ MGIT™ Antimicrobial/Drug Susceptibility Testing (AST or DST) system is a rapid qualitative procedure for susceptibility testing of Mycobacterium tuberculosis, from culture, to streptomycin, isoniazid, rifampin, ethambiol, and pyrazinamide.
445870	BD Bactec MGIT 960 System	The BD BACTEC™ MGIT™ 320/960 System is designed for the automated rapid detection of mycobacteria from clinical specimens (except blood and urine). In addition to detection of mycobacteria, the BD BACTEC™ MGIT™ Antimicrobial/Drug Susceptibility Testing (AST or DST) system is a rapid qualitative procedure for susceptibility testing of Mycobacterium tuberculosis, from culture, to streptomycin, isoniazid, rifampin, ethambutol, and pyrazinamide.

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

For Becton, Dickinson and Company

Sincerely,

Carole E. Ledford

Senior Manager, International Regulatory Affairs

Albruary 16, 2023

डॉ. स्वीर १००१ रक्तावर Dr. Manish रक्तावर सामावर्ग Assistan Professor एम केता दिवारी Verbatmont of McCobiology Unique सामाव्यक्षात्र संस्थान, ह्यानम् अस्त्र १९४९०० अनेवर्ग सामाव्यक्षात्र अस्त्रवेशन स्थान,

# ALL INDIA INSTITUTE OF MEDICAL SCIENCES, VIJAYPUR, JAMMU- 184120



(A Central Autonomous Body under PMSSY, MoH&FW, Government of India)

Annexure III

# UNDERTAKING REGARDING TECHNICAL SPECIFICATIONS

To whom it may concern,

This is to certify that the specifications provided herein for the procurement of items/equipment/instruments/consumables are formulated in a broad-based manner and are general with respect to the requirements of the department/institute. These specifications are not tailored to suit any particular firm, brand, or manufacturer

We, the undersigned, hereby undertake that:

- The specifications provided have been developed to meet the actual and essential needs of the department/institute without any bias towards a specific firm or brand.
- No brand names, catalogue numbers, or specific manufacturer details have been included in the specifications except where unavoidable due to technical necessity. In such cases, the specifications clearly state that alternatives meeting equivalent standards will also be acceptable.
- In the case of the Proprietary Article item, the "Proprietary Article Certificate" (PAC) has been signed and submitted along with the Technical Specification after doing market survey/research.
- 4 The specifications have been carefully reviewed to ensure compliance vitter procurement regulations and standards.
- 5. Any deviations from standard specifications or additional parameters have been only recorded and justified.

This undertaking is issued with full authority from our department and is binding upon all relevant stakeholders.

Manish Ranjan and stamp of authorized person)

भूमित प्रस्तिप आपूर्वितान संस्थान, विजयपुर क्यू १८४१२० भूमे ladia Institute of Madical Sciences, Vijeypur, Jammy-184120

### AL L INDIA INSTITUTE OF MEDICAL SCIENCES, VIJAYPUR, JAMMU- 184120



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Annexure IV

## PROPRIETORY ARTICLE CERTIFICATE FROM THE USER DEPARTMENT

(i) Item/Type/Model No. required along with specifications.

: Automated TB liquid & Drug Sensitivity System : -NA-

(ii) If the item is a spare part attachment or accessory for an existing equipment.

(iii) Name of the manufacturer/Supplier of the item proposed

: Becton, Dickinson and Company

Are they sole manufacturers/distributors of the (iv) item?

Yes

(v) Is there any other item with similar/equivalent specifications available in the market to meet the job requirement envisaged? If the answer is ves, why the same can't be procured. The demanding officer should bring comparative functional advantages /cost-effectiveness of the recommended item from those offered by others.

- NA -

What were the efforts made to locate (vi) alternative sources of supply or use other substitutes?

: Yes, no other alternative available

Why open/limited tender can't he resort to for (vii) locating an alternative source?

: I tem is PAC; to the best of our Kuntedge. Ho All na jor Institutions/ INIs have trus Instrument.

Are the proprietary items certifying that the (viii) rates are reasonable or not?

Is there any other justification for procuring (ix)items from a single source?

- 1) It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/ equivalent specifications which can fulfil the vital requirements of end user.
- 2) It is certified that the purchase is proposed to be made on proprietary usage basis because any other material / equivalent/ instrument chemical etc. if used will lead to deviation and affect the integrity/ accuracy, validity or analysis of the assignment / patient care.

with date and stamp of authorised person)