

All-India Institute of Medical Sciences
Ansari Nagar, New Delhi-29
(RESEARCH SECTION)

Ref. No. 10/Prop/CCRF/AIIMS/2018-19/St.

Dated: 05.03.2019

Subject: Purchase of MGIT 960 Culture System for the Deptt. of CCRF, AIIMS, New Delhi-29 on proprietary basis- Inviting comments thereon.

The request has been received from Assoc. Dean (RS), Member Secretary, Deptt. of CCRF, AIIMS to purchase the subject item from M/s Becton Dickinson India Pvt.Ltd.(Mfg. by M/s Becton Dickinson and Company, USA) on proprietary basis. The proposal submitted by M/s Vision Diagnostic (I) Pvt. Ltd. and Departmental PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference **No. 10/Prop/CCRF/AIIMS/2018-19/St.**

The comments should be received by office of Stores Officer (RS), Research Section at AIIMS on or before **20/03/2019 upto 12:00 p.m.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

STORES OFFICER (RS)

Encl: Related documents enclosed.

1. PAC Certificate enclosed.

2. Performa Invoice

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110 029

PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1. Item/Type/Model No. required along with specifications. *Automated Mycobacterial culture system MGIT-960*
2. Is the item a spare part, attachment or accessory for an existing equipment. *Full equipment*
3. Name of Manufacturer/supplier of the item proposed by the indenter. *BD*
4. Are they sole manufacturers/sold distributors of the item. *Yes*
5. Is there any other item with similar/ equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding Officer should bring out comparative functional advantages/obsolescence/ effectiveness of the recommended item from those offered by other. *NO*
6. What were the efforts made to locate alternative source of supply or use other substitutes. *Tender was put already.*
7. Why open/limited tender can't be resorted to, for locating alternative source. *Tender was put but not a single alternate company applied for it.*
8. Are the proprietary items certifying that the rates are reasonable or not. *Yes*
9. Any other justifications for procuring item from single source. *Non invasive, Based on fluorescence technology, automated culture system TB. No one else has same technical specification. can perform firstline & second line DST.*

Kiran
Signature of Indenter
(Demanding Officer)

Dr. Kiran Kalia, MD
Senior Professor
Department of Microbiology

RMK
COUNTERSIGNED
(Head of the Department)

Technical Specifications of MGIT 960 Culture System-02 Nos.:

1. System should be capable to perform rapid culture, differentiation and sensitivity testing for Mycobacterium tuberculosis.
2. System should be based on true non-radiometric, Non-invasive technology, ensuring no bottle puncturing during sample analysis.
3. System-working principle should be based on sensitive fluorescent technology.
4. System should have more than 900 sample positions with compact space saving design with user friendly operation keys.
5. System should continuous incubation, monitoring and detection facility with the specific algorithm for analyzing growth of mycobacteria in each sample positions.
6. System should be capable of culturing typical and atypical Mycobacterium.
7. System should be able to process both respiratory & non-respiratory samples.
8. System should be provided with media bottles with reagents to make isolation media selective and enriched for better isolation.
9. System should have calibrator for quality control check.
10. System should be supplied along with ready to use lyophilized drug vial for entire range of 1st Line Drug Sensitivity testing- S, I, R, E, P with certificate of analysis from manufacturing units and First Line Drug Kit should be FDA approved.
11. System should be able to generate the interpretation of 1st Line Drug Susceptibility testing, automatically, without need of manual interpretation.
12. System should be able to perform second drug sensitivity with standard protocol.
13. System should be supplied with ready to use Pyrazinamide Test -media to avoid any false results in sensitivity testing.
14. System should be supplied with latest work-station with suitable epicenter software with bi-directional interface for LIS.
15. System should be supplied along with additional computer for data storage.
16. System should be supplied with on line UPS with maintenance free batteries with 30 minutes back up.
17. System should be approved by Central TB Division (India) for Liquid Culture Facility.
18. The supplier should provide comprehensive training to users on operation of the instrument, software and application support onsite as per specifications.
19. Certificates of Installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) should be provided.
20. Instruments are approved to CE (Europe) and UL/CSA standards.

General Clauses

1. Only Principal companies or Authorized Distributors from Principal companies should quote. Quotations from non-authorized distributors will not be entertained. Features in the quotations should be substantiated with proper principal company catalogue.
2. Should operate under a Quality Management System which complies with the requirements of ISO 9001:2008 for design, manufacture and services.
3. Should be CE (Europe) UL/IMC/CSA certified.
4. Copies of all certificates e.g. Quality Standard certificate, Proprietary Item/Parts Technology, Principal company/ Authorized Distributorship should be attached with the quotations.
5. In-House Service Engineers from Principal company/ or authorized agents should be available in India on one day notice basis in case of emergency (this will apply for that equipment wherein the clause is not built in to the specification).
6. Complaint points should be given (in the sheet) in order of the specifications serial order. Complaint points should be highlighted in the company catalogue with page number.
7. Must include: User's list with telephone numbers and email address.
8. Vendor should submit an undertaking from manufacture about the responsibility of maintenance in case of merger or acquisition.
9. Rate list of spares should be provided.
10. A performance certificate from at least 2 users should be provided.

CMC

- Warranty: The 5 years warranty should be all inclusive.
- 5 years CMC (6th-10th years) after completion of the 5 years warranty period with spares and labor. The price of CMC will be added to cost of the equipment for calculating L. I.
- Penalty Clause: Direct presence in India with strong after sales technical and service support and must ensure that all faults are rectified with in one week, failing which would lead to extension of warranty by twice the period of downtime. The warranty should be all inclusive.

Justification for procurement of Automated mycobacterial culture system (MGIT 960) on proprietary basis (No.2)

The Bacteriology/TB lab in BSL-3 facility requires Automated Mycobacterial culture system (MGIT 960) which is a standalone instrument for Mycobacterium tuberculosis culture with various functions.

It has the capability to cater a variety of functions required for rapid culture, diagnostic applications and anti-tubercular drug susceptibility testing for first line and second line drugs. These qualities are required for patient care and research.

This system is based on true non-radiometric, Non-invasive technology, ensuring no bottle puncturing during sample analysis and its working principle based on sensitive fluorescent technology. System have 960 sample positions with compact space saving design with user friendly operation keys. This equipment is capable of culturing typical and atypical Mycobacterium and able to process both respiratory & non-respiratory samples. The system is capable to perform rapid culture, differentiation and sensitivity testing for Mycobacterium tuberculosis. It also provides 1st Line Drug Susceptibility testing, automatically, without need of manual interpretation and System is able to perform second drug sensitivity with standard protocol.

To the best of our knowledge, BD Mycobacterium Growth Indicator Tube (MGIT 960) Automated mycobacterial culture system is the only standalone system that fulfills all our requirements in a single equipment.



Becton, Dickinson and Company
7 Liverton 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 Equipment's 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 |
|---------|---|---|
| 441386 | BD BACTEC™ FX Instrument - Bottom Unit | The BD BACTEC™ FX Instrument is designed for the rapid detection of bacteria and fungi in clinical specimens. |
| 441385 | BD BACTEC™ FX Instrument - Top Unit | Samples drawn from patients are injected directly into BACTEC culture vials, which are placed into instrument for incubation and testing. |
| 445870 | BD BACTEC™ MGIT™ 960 Mycobacterial Detection System | The BD BACTEC™ MGIT™ instrument is an in vitro diagnostic instrument designed and optimized for rapid detection of mycobacteria from clinical specimens (except blood and urine). |
| 441743 | BD BACTEC™ MGIT™ 320 Mycobacterial Detection System | |
| 448100 | BD Phoenix™ Automated Microbiology System | The BD Phoenix™ Automated Microbiology System is intended for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically significant bacteria. The Phoenix system provides rapid results for most aerobic and facultative anaerobic Gram-positive bacteria as well as most aerobic and facultative anaerobic Gram-negative bacteria of human origin. The BD Phoenix system is also intended for the rapid identification of yeast and yeast-like organisms. |
| 440478 | BD ProbeTec™ ET Instrument | The BD ProbeTec™ ET System, when used with the BD ProbeTec ET amplified nucleic acid probe assay(s), is intended for use in the in vitro detection of targeted organisms from specimens as identified in the assay specific reagent package inserts. |
| 441091 | BD Viper™ Instrument | The BD Viper™ System when used with the BD ProbeTec amplified nucleic acid probe assay(s) is intended for in vitro detection of targeted organisms from specimens as identified in the assay-specific reagent package insert(s). |



Becton, Dickinson and Company
7 Linstead Circle
Sparks, MD 21152
USA
Tel: 410-216-4000
Fax: 410-216-4188
bd.com

The above mentioned instruments 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,

Carol E. Ledford
Carol E. Ledford
International Regulatory Affairs Manager

March 21, 2017
Date

Jennifer A. Cramer
03/21/17

Jennifer A. Cramer
Notary Public, Maryland
Baltimore County
My Commission Expires:
October 19, 2019

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Unifex (Unifex.com)

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BD & Bn Floor, Signature Tower B
SouthCity 3, Gurgaon-122 001
Haryana, India
Tel: (91) 124 2843386
Fax: (91) 124 2383224/5/6
www.bd.com/india
CIN: U74900DL1900PT0264117



05 Nov. 2018

TO WHOME IT MAY CONCERN

It is hereby confirmed that the instrument Modal MGIT 960, is a sole propriety item of BD.

BD INDIA PVT. LTD is only authorized to spares/ consumables and servicing /AMC of this instrument India.

For

BD INDIA PVT. LTD.

Abhishek Mishra
(Authorizing Signatory)

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BD & Bn Floor, Signature Tower B
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CIN: U74900DL1900PT0264117



05 Nov. 2018

TO WHOME IT MAY CONCERN

This is to certify that the rates Quoted by us to AIIMS, New Delhi. For the part no. 4405902(Power supply Module) and 440774(PCB 960 Detection Board) for BD MGIT 960 are do not exceeded the prevailing Market Rates being Charged by us from any other Govt./ Semi Govt./Other agencies for similar Services.

For

BD INDIA PVT. LTD.

Abhishek Mishra
(Authorizing Signatory)

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Unifex (Unifex.com)

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Becton Dickinson India Pvt. Ltd.
Head Office: BD & Bn Floor,
Signature Tower B, South City 3,
Gurgaon - 122001, Haryana, India
Tel: +91-124-2843386
Fax: +91-124-2383224/5/6

Regd. Office : 204, Noida House,
15, Tandon Marg, New Delhi-110001, INDIA
CIN: U74900DL1900PT0264117
bd.com

February 12, 2019

Ref: AIIMS/MGIT960/12/02/19
Validity - till 30th June' 2019

To,
The Director,
All India Institute of Medical Science, Ansari Nagar
New Delhi, INDIA

Sub-Commercial Offer for BD BACTEC™ MGIT™ 960 - Automated Mycobacterium Culture System

| Catalogue No | Product Description | Quantity | Amount (USD) |
|--------------|---|----------|--------------|
| 443870 | BD BACTEC™ MGIT™ 960 Automated Mycobacterium Culture System (TDS same as previous) with Standard Accessories & spigot | 1 Unit | 49998.00 |
| | UPS of APC suitable capacity with 30 min backup | 1 nos. | 4000.00 |
| | Total Price (FOB Hong Kong) | | 49998.00 |

Terms & Conditions:

1. Payment: 100 % advance in the form of irrevocable letter of credit.
2. Price mentioned is on FOB Hong Kong basis.
3. Customs duty (Approx 15%), Clearing & Forwarding charges needs to be borne by Institute, if applicable.
4. Delivery Terms: The equipment will be supplied within 4 - 6 weeks upon receipt of written order along with LC.
5. MGIT™ tubes / Consumables / UPS and any other required accessory will be supplied locally from India.
6. Warranty period: 1 years from the date of installation.
7. Air freight (1500 USD) & Insurance (200 USD) will be borne by Institute.

For: Becton Dickinson India Pvt Ltd
Your faithfully,



Pooja Tiwari, Sr. Area Sales Manager,
BD Life Science, Diagnostic Systems
+91- 717248479 Pooja.Tiwari@bd.com

W. Z. Zia

Receved

on

Dr. Anand

Dr. Anand



Beckon Dickinson India Pvt. Ltd.
Head Office: 5th & 6th Floor,
Signature Tower B, South City II,
Gurgaon - 122001, Haryana, India
Tel: +91 124 2942780
Fax: +91 124 2942241/5/6

Regd. Office: 25th, Tollymore House,
15, Tollymore Park, New Delhi-110001, INDIA
CN: UH49990A.1999PT004117
bd.com

Beckon Dickinson Holdings Pte Ltd.

Bank Details
Citibank NA, Singapore Branch
A/C: S-855026-026 (USD)
A/C: S-855026-002 (SGD)

Swift Code: citiingp

3 Temasek Avenue
#12-02 Centennial Tower
Singapore 039190

Terms & Condition

Terms of Payment: 100% of order value vide irrevocable Letter of Credit to be opened in favour of.

Beckon Dickinson Holdings Pte Ltd.

30, ALAN Avenue 2

SINGAPORE 039481

TEL: + 65 8610633

FAX: + 65 8601106

GST Reg No: ME-8500255-9

L/C Validity: 90 days

Port of shipment: Hongkong / Singapore / USA / Europe

Mode of shipment: By air

Country of Origin: Hongkong / Singapore / USA / Europe

Transshipment/Partial Shipment: To be Permitted in L/C

Delivery: Within 90 days from receipt of Purchase Order & Commercially clean Swift L/C at our Singapore Office

Installation & Training: By BD-India at site, nonparamentary

For Beckon Dickinson India Pvt Ltd

Peruvali Thurai, Sr. Area Sales Manager,

BD Life Science, Diagnostic Systems

+91 9712248476

peruvali.thurai@bd.com



Peruvali Thurai
Peruvali Thurai
(Dr. Peruvali)

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