No GMCH-Micro/OU...1241
Dated ...10.07.2019

GOVERNMENT MEDICAL COLLEGE HOSPITAL, CHANDIGARH
Department of Microbiology

Subject: **Purchase of Automated Blood Sterile /Body Fluids and Mycobacterial and Detection System and Automated Microbial Identification & Antibiotics Susceptibility Testing System for the Department of Microbiology.**

An Automated Blood Sterile/ Body Fluids and Mycobacterial and Detection System and Automated Microbial Identification & Antibiotics Susceptibility Testing System (a proprietary item) manufactured by M/s Biomerieux India Pvt. Ltd., A32, Mohan Cooperative Industrial Estate, Mathura Road, New Delhi-110044 is to be purchased for the Department of Microbiology, Govt. Medical College Hospital, Chandigarh. Specifications and parameters of the same have also been uploaded on the website of GMCH, Chandigarh. Objections, if any by the firms may be communicated to the following officers within one month of issuance of this notice otherwise it will be presumed that there is no objection for the said purchase.

10/7/2019

Dated : 10.07.2019

(Dr. Jagdish Chander)
Professor & Head

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ANNEXURE-A

Technical Specifications for Automated Blood / Sterile Body fluid and Mycobacterial culture system

1. Fully automated system capable of blood, body fluid and mycobacteria testing in the same instrument with minimum 240 positions.
2. System should be capable enough to culture mycobacterium tuberculosis in the same unit, in case if it is required i.e one system is capable enough to culture blood specimen, sterile body fluid and mycobacterium tuberculosis.
3. System should work on the reliable colorimetric principle of detection based on CO_2 sensor to indicate growth of organisms.
4. System should have LIS compatibility.
5. Every cell should have its own optics and detection device.
6. System should have built in calibration check.
7. System should have screen monitor.
8. System should be capable of exporting data to zip drive for long term storage.
9. System should have facility of analyzing delayed entry specimens with the routine bottles.
10. System should have a capability for continuous monitoring of samples for growth of organism in each cell.
11. System should have continuous agitation to provide facility for optimal growth for the organisms.
12. System should have special type of culture bottles to neutralize antibiotic effect.
13. System should also be capable for detecting yeast and other fastidious organisms.
14. System should support use of plastic bottles for safety and ease of disposal.
15. System should have additional capability for mycobacterial culture from respiratory, non-respiratory and blood specimens.
16. System should have modular design and additional detecting module can be added in future as per requirement.
17. System should have FDA clearance for microbial quality control testing of leucocyte reduced apheresis platelets.

1. **Description of Function**
   i. Micro organism, culture is required to be done on blood & body fluid a sample is inoculated into liquid media and is incubated in a controlled environment for 1 to 7 days.
2. **Operational Requirements**
   i. Fully automated system capable to culture micro organisms
3. **Technical Specifications**
   i. Should work on non - radiometric technology
   ii. Systems should have, inbuilt calibration check, touch screen monitor. Should have LIS compatibility
   iii. Should have modular design which is upgradeable and should be FDA approved
   iv. Should be able to monitor the growth of organisms continuously in each cell. The media bottles should have the capacity to neutralize antibiotics
   v. System should be capable of exporting data to the data management system for long-term storage, and should have the facility to analyze delayed specimens with the routine bottles.
   vi. Should be able to grow aerobes, anaerobes & fungi.
   vii. Should include data management system and software to analyze and store the data.
   viii. Should have the capability for continuous monitoring of samples for growth of organisms in each cell & have the capacity to generate hard copy of each growth kinetics.
   ix. Easy to use software for patient information, entry and storage. Long term data storage facility, tracing patient by name, I.D. Hospital registration number.
   x. Should have inbuilt incubator with facility for decontamination.
   xi. Company should quote their latest system available in India for Blood/Body fluids and mycobacteria culture in same unit.
4. **System configuration Accessories, spares and consumables**
   i. System as specified
   ii. All consumables required for installation and standardization of system to be given free of cost.
5. **Environmental factors**
   i. The unit shall be capable of being stored continuously in ambient temperature of 10-30 deg C and relative humidity of 10-90 %
   ii. The unit shall be capable of operating continuously in ambient temperature of 10-30 deg C and relative humidity of 10-90%
6. **Power Supply**
   i. Power input to be 220-240 VAC, 50Hz fitted with Indian plug
   ii. Resettable over current breaker shall be fitted for protection
   iii. Suitable UPS with maintenance free batteries for minimum Three (one)-hour back-up should be supplied with the system.

7. Standards and Safety

i. Should be compliant to ISO 13485: Quality systems – Medical devices – Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities.

ii. Comprehensive training for lab staff and support services till familiarity with the system.

iii. Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450

iv. Should be FDA or CE or ISI approved product

v. Ten years warranty, 10 yrs. comprehensive AMC (CAMC) should be available with service centers in close proximity within 15 KM distance.

8. Documentation

i. Certificate of calibration and inspection from factory.

ii. Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue.

iii. List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.

iv. Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out

v. List of Important spare parts and accessories with their part number and costing.

vi. Media bottles price fixed for One year.

Technical specifications of Automated Microbial Identification & Antibiotics Susceptibility Testing System

1. The system should be totally automated for sample standardization, loading, incubating and reading the results.
2. It should be used for identification (ID) and antimicrobial susceptibility (AST) of clinically significant bacteria and yeast (ID/AST)/
3. Analytical parameters: Identification up to species level- Direct growth based (up to MIC level).
4. Testing base panel: should be on disposable sealed bar code card/ (ready to use). There should be no need to add any additional reagents after incubation.
5. Panel for: ID & AST of Gram negative, Gram positive and Yeast ID panels for anaerobes, ESBL confirmation, Neisseria, & Haemophilus.
6. It should have capacity of processing 50 or more samples at a time (IDORAST)
7. Expert system: The software should have an expert system permitting appropriate intervention for organisms with unusual resistance pattern. The system must have ability to check the quality of test results and stop for validation by Microbiologist. The system software must have the ability to alert to any unusual resistance mechanisms. The system should provide highest discrimination between species.
8. Sample dispensing: System should preferable not require any manual dispensing of inoculums to avoid human error, it should be done automatically.
9. Additional reagent: System to be compatible with cost effective test card to avoid any extra cost of additional reagents.
10. Incubator: On board incubation chamber.
11. Testing time: Ideally be on the same side (Between 5-10 hrs), which reduces time to results.
12. Printer: External printer for direct report print outs.
13. Bar code: The system should have barcode scanning facility to identify each panel type.
14. Software: Should be Windows based, user friendly.
15. Screen Key pad: The software should identify and interpret results as per CLSI guidelines.
16. Should facilitate monitoring of all functions of a microbiology laboratory and hospital acquired infection (HAI) control procedures.
17. Should have facility to design user defined alerts and options for designing drug suppression rules as per hospital internal infection control policy (Antibiotic Policy)/
18. Customized reports, nosocomial and epidemiology reports should be generated.
19. Training: onsite application training.
20. Consumables: Details of consumables, pack sizes and prices of Consumables to be quoted in the price bid fixed for next One year.
21. Ten years warranty, 10 yrs. comprehensive AMC (CAMC) should be available with service centers in close proximity within 15 KM distance.

Technical Specifications

1. **Analytical parameters**: Identification up to species level automated system for identification for Antibiotic Susceptibility of micro organisms.
2. **Testing base**: Should be on disposable sealed bar coded card (ready to use) with pre filled reagents with pre inserted transfer tube for easy automatic transfer of inoculums.
3. **Type of panels**: It should have different panels (ID & AST separately depending on the user to save cost) it should be based on advanced colorimetric principle.
4. **Panels for** : Gram negative panels, Gram positive panels, Anaerobic ID panels, ESBL confirmation panels, Neisseria & Haemophilus & Yeast panels.
5. 50 or more samples (ID or AST) at a time.
6. **Sample dispensing**: System should not require any manual dispensing of Inoculum to avoid human error, it should be done automatically.
7. **Additional reagents**: System to be compatible with cost effective test cards to avoid any extra costs of additional reagents.
8. **Incubator**: On board incubation chamber.
9. **Testing time**: Ideally be on the same day (between 5-10 hrs), which reduces time to result &turn around time.
10. **Printer**: External printer for direct report print outs.
11. **Bar Code**: Positive sample identification with the bar code on the card. (ID for AST card)
12. **Software**:

a) Should be Windows based, user friendly with key pad.
b) Should facilitate monitoring of all the functions of a Microbiology lab and infection control procedure (HAI)
c) Should have facility to design user defined alerts and option for designing drug suppression rules as per hospital internal infection control policy (Antibiotic policy)
d) Customized reports, nosocomial and epidemiology reports should also be obtained.

13 **Installation in India**: Minimum 100 installations in the country with reputed Hospitals / Organizations.