SPECIFICATION OF FULLY AUTOMATED MYCOBACTERIUM CULTURE, DIFFERENTIATION & DST 1ST & 2ND LINE SYSTEM (MGIT SYSTEM)

1. System should be capable to perform rapid culture, differentiation and sensitivity testing for Mycobacterium tuberculosis.
2. System working principle should be based on non-invasive sensitive fluorescent technology. No bottle puncturing during sample analysis.
3. System should be capable to perform tests to differentiate typical and atypical mycobacterium within 3-4 days' time.
4. System should have continuous incubation, monitoring and detection facility with specific algorithm for analyzing slow growth patterns of Mycobacterium.
5. System should be able to process minimum 15 fresh samples per day with standard international protocol.
6. System should have more than 900 sample positions with compact space- saving design with User friendly operation keys.
7. System should be able to process both respiratory & non-respiratory samples.
8. Company should have its own ready to use digestion and decontamination kit for better sample procession and reduced contamination rate.
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10. System should have continuous online automatic quality control check coupled with BARCODE Scanner.
11. 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.)
12. Both First Line Drug Kit/ Media and its protocol should be FDA cleared and approved.
13. System should have a validated protocol to perform 1st Line Drug Sensitivity Testing.
14. System should be able to perform second line drug sensitivity testing and should have a validated protocol to perform 2nd Line Drug Sensitivity Testing.
15. System should have its own validated kit for rapid differentiation between MTBC and MOTT.
16. 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.

Prof. Avinash Agrawal
MD, IDEC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

17. System should be capable of automatic report generation for the interpretation of Drug Sensitivity testing results.
18. System should be supplemented with Ready Made Pyrazinamide Drug Media for standardized result.
19. Company should have its own factory certified drug kit for 1st Lane Drug Sensitivity Testing for 5 drugs along with Pyrazinamide Drug Media.
20. Should have provision of failure software up-gradation.
21. System should be supplied along with on line UPS with 30 minutes back-up.
22. System should be approved by Central TB Division.
23. System should be WHO approved.
24. 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-
    a) Work station
    b) Detailed Patient Data Incorporation
    c) Specimen Demographics
    d) Centralized Order Management for Microbiology testing
    e) Improved workflow
    f) Multiple Platform Connectivity
    g) Detailed Data Review – Patient, Specimen, Test & Isolate levels
    h) Unlimited Microbiology Data Storage Capacity
    i) Incorporation of Patient Therapies
    j) Full Transaction Logging
    k) Direct on-line Technical Support

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FCCM, FICCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP(USA)
Head, Department of Critical Care,
King George's Medical University, UP, Lko.

15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any

Prof. Ashish Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, L

CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, U.P., Lko.