

ANNEX 1

Automated Microbiology Analyzer (Identification & Antibiotic sensitivity) Specifications

Description:

1. The system should be totally automated for sample loading, incubation, sample standardization & interpretation of results.
2. Analytical Parameters: identification up to species level. Direct growth based up to MIC level.
3. Panel capacity: The system must have the capacity to accommodate a minimum of 15 panels (ID & AST) at any time. The system must have separate cards for Identification and Susceptibility testing.
4. Bar Code: The system must have a bar code scanning device for Test cards/Cartridges/Medium and or panel identification.
5. Testing base: Should be on disposable sealed bar coded, cards, panels, strips with prefilled reagents, without additional requirements for adding reagents manually after incubation. Automated addition of reagents within analyzer is acceptable.
6. Sample dispensing: Shall be automatic without any manual step of inoculum dispensing.
7. The System should have database of reference phenotypes.
8. The software must have the following capabilities: -
 - 8.1. Workflow management.
 - 8.2. Data storage.
 - 8.3. Test quality control management.
 - 8.4. Real-time connectivity with LIS.
 - 8.5. Quick and easy reviewing and reporting
 - 8.6. Identify test results as per NCCLS guidelines.
9. The system software: Must have the ability to alert to any unusual resistance pattern.
10. Additional reagents: If additional reagent costs are required, please supply details including cost and preparation time.
11. Incubator: On board incubation chamber.
12. Test Processing Time: Within 5 to 18 hours.
13. At minimum it should have facilities for identification & antimicrobial susceptibility of the following clinically significant microbes;

Microbe	Identification	Antimicrobial Susceptibility
Gram-negative bacteria	✓	✓
Gram positive bacteria	✓	✓
Yeast	✓	✓
Anaerobes	✓	-
ESBL	✓	✓
MRSA	✓	✓
Neisseria & Haemophiles	✓	-

14. Type of Panels: It shall have different panels (ID & AST) separately to give user more flexibility on selection and save on cost.
15. Panels For: ID & AST of Gram-negative cocci/bacilli, Gram Positive cocci/bacilli and Yeast.
16. Printer: Inbuilt or External. If both options available both shall be provided.

Standards and Electrical Requirements:

- USFDA, CE and or ISO certifications or relevant standards certification.
- Power requirement:250V, 50Hz.
- Conformity to electrical standards: IEC 61010-1, IEC 61010-2-081, IEC 61010-2-101 or BIS equivalent

Country of origin:

- Open

User Training:

- **International Training:** A one-time user training for one laboratory technologist shall be provided at an International Research Institute or Hospital laboratory with a volume of minimum 10 test per day. The length of the training shall be 14 days not counting travel and holidays. All cost of training to be provided by supplier.

Warranty & Service:

- The company should have service engineers who should be available 24/7 on phone & at site within 48 hours of reporting an error.
- Operator's manual and Service manual should be provided.
- All access codes to service mode shall be provided.
- Manufacturer's standard warranty with documents should be available.
- Manufacturer website information to be provided if specifications needed to be verified.
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- The supplier shall provide annual comprehensive maintenance of the supplied equipment as per manufacturers recommendation. And shall provide a maintenance report every 6 months.

Distributorship:

- Suppliers shall have a valid authorized distributor license or reseller license for the country/region at the beginning of agreement or on signing of contract.
- A distributorship or licensor-ship certification is not mandatory at the time of BID submission, however is mandatory to start selling reagents.

Demonstration:

- All prospective bidders shall demonstrate the unit online before technical evaluation. This should include detailed explanation about reagents and consumables, operation, other accessories utilizations. And also, a short video how the equipment works.

System Configuration Accessories:

- All consumables required for system installation & configuration shall be provided free of cost.

Samples:

- At the time of bid opening all bidders shall provide with samples of consumables and reagents. Diluents, cleaners, wash solutions which are corrosive or belong to dangerous goods category need not require to submit a sample. Test kits for all parameters also not mandatory. One sample test kit from any two-test parameter would suffice. In this case one ID and AST kit is adequate.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue (Soft & hard copy).

- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.
- Quotation with Details of all equipment price should be given.

Tentative Annual Requirement:

Serial No	Name of test	Estimated Annual Tests
1	No of identification Tests	4057
2	No of Antibiotic Sensitivity Tests	2560

- Please note this is an estimated number which can either increase or decrease based on availability of patients.