# ANNEX - 01

## Automated Microbiology Analyzer (Identification & Antibiotic sensitivity) Specifications

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| **Description:** | The system should be totally automated for sample loading, incubation, sample standardization & interpretation of results. |
| **Analytical Parameters:** | Identification up to species level. Direct growth based up to MIC level |
| **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. |
| **Bar Code** | The system must have a bar code scanning device for Test cards/Cartridges/Medium and or panel identification. |
| **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. |
| **Sample dispensing** | Database of reference phenotypes will be an **added advantage.**<br>The software must have the following capabilities: -<br>• Workflow management.<br>• Data storage.<br>• Test quality control management.<br>• Real-time connectivity with LIS.<br>• Quick and easy reviewing and reporting<br>• Identify test results as per NCCLS guidelines. |
| **Additional reagents** | If additional reagent costs are required, please supply details including cost and preparation time. |
| **Incubator** | On board incubation chamber |
| **Test Processing Time** | Within 5 to 18 hours. |
| **Type of Panels** | It shall have different panels (ID & AST) separately to give user more flexibility on selection and save on cost. |
| **Panels For** | ID & AST of Gram-negative cocci/bacilli, Gram Positive cocci/bacilli and Yeast. |
| **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.<br>Power requirement:250V, 50Hz.<br>Conformity to electrical standards: IEC 61010-1, IEC 61010-2-081, IEC 61010-2-101 or BIS equivalent |

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| | Shall provide suitable capacity UPS along with machine. |
| **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.<br><br>Operator's manual and Service manual should be provided.<br><br>All access codes to service mode shall be provided.<br><br>Manufacturer's standard warranty with documents should be available.<br><br>Manufacturer website information to be provided if specifications needed to be verified.<br><br>Manufacturer's standard warranty with documents should be available.<br><br>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 distributer license or reseller license for the country/region at the beginning of agreement or on signing of contract.<br><br>A distributorship or licensor-ship certification is mandatory at the time of bid submission. |
| **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. |
| **Additional Remarks or Requirements** | Complete product details to be enclosed with the original brochure or catalogue (Soft & hard copy).<br><br>Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.<br><br>Quotation with details of all equipment price should be given. |

At minimum it should have facilities for identification & antimicrobial susceptibility of the following clinically significant microbes;

| **Microbe** | **Identification** | **Antimicrobial Susceptibility** |
|---|---|---|
| Gram-negative bacteria | Yes | Yes |
| Gram positive bacteria | Yes | Yes |
| Yeast | Yes | Yes |
| Anaerobes | Yes | Optional |
| ESBL | Yes | Yes |
| MRSA | Yes | Yes |
| Neisseria & Haemophiles | Yes | Optional |

**Tentative Annual Requirement:**

| **Serial No** | **Name of test** | **Estimated Annual Tests** |
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| **1** | No of identification Tests | 6805 |
| **2** | No of Antibiotic Sensitivity | 4625 |

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

# Automated Blood Culture System Specifications

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| **Description:** | System should be fully automated, upgradable, walk-away, continuous monitoring and random-access system, which does continuous agitation for optimized recovery of organisms.<br><br>System detection should be based on advanced sensitive fluorescent technology. |
| **Sample capacity:** | Minimum 40 sample positions and can be upgraded on site up to 160 samples as and when required. |
| **Technical Specification:** | System must support lab quality control requirement for automated analytics of blood volumes monitoring<br><br>System should have facility to generate automated reports ready to be analyzed and sent to be various departments<br><br>System should have more than 16 algorithms to monitor growth patterns in case of Positive samples<br><br>System process enhanced visual indicators both inside and outside the instrument in the form of different colored LEDS to indicate exact station status –available, ongoing, positive, and negative & anonymous.<br><br>System should support special resin-based media for Antibiotic Neutralization for optimized recovery from various patients those are under treatment. Antibiotic neutralization device must have a proven record of neutralization even for last resort antibiotics like carbapenems at Trough, Mid and Peak levels in the Blood specimen, proof source to be submitted<br><br>Instrument is having the facility to enter patient details and can scan the sample accession number using bar code reader (Feature: Accession Barcoding)<br><br>System allows the user to load bottles anywhere in the system, without any software intervention in order to get the bottles loaded in the instrument round the clock.<br><br>System should support special media for processing Pediatric Samples and Low volume sterile body fluid samples.<br><br>System should support special media for optimal recovery of yeast, fungi and mycobacterium from Blood samples.<br><br>Instrument positive bottle supports with rapid and accurate gram stain results without any hindrance like charcoal stains in microscopic background<br><br>Special supplement for enhanced recovery from low volume sterile body fluid and special bottle for low volume pediatric samples will be added advantage. |

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| | Media bottles are fully compatible with vacutainer holders without the need for a special adapter to improve blood collection workflow and safety.<br><br>System should be capable of bi-directional interfacing with LIS/HIS (Laboratory/Hospital Information System).<br><br>System should automatically calculate and provide TTD (Time to time detection) and Time in protocol (Time in protocol).<br><br>System should take reading at every 10 Minute intervals. |
| **Standards and Electrical Requirements** | USFDA, CE and or ISO certifications or relevant standards certification.<br><br>Power requirement:250V, 50Hz.<br><br>Conformity to electrical standards: IEC 61010-1, IEC 61010-2-081, IEC 61010-2-101 or BIS equivalent<br><br>Shall provide suitable capacity UPS along with machine. |
| **Distributorship** | Suppliers shall have a valid authorized distributer license or reseller license for the country/region at the beginning of agreement or on signing of contract.<br><br>A distributorship or licensor-ship certification is mandatory at the time of bid submission. |
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| **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. |