بسم الله الرحمن الرحيم

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ANNEX 1:

Automated Bacterial Identification & Sensitivity System Specifications

1. Scope of Work

The successful bidder will be required to:

a. Supply an Automated Bacterial Identification & Sensitivity System that meets the criteria specified in this document.
b. Ensure the system's compliance with local and international standards and provide all necessary documentation and certifications.
c. Provide installation, calibration, validation (IQ, OQ, PQ), and equipment commissioning.
d. Offer training for laboratory personnel on the operation, maintenance, and quality control of the analyzer, and provide operational SOPs and MSDS.
e. Provide ongoing technical support, maintenance services, and regular software updates.
f. Supply necessary consumables and reagents required for the operation of the analyzer.
g. Ensure warranty and service agreements cover all components and spare replacement.

2. General Description

The system should be a diagnostic platform intended for microbial identification (ID) and antimicrobial susceptibility testing (AST) of both Gram-positive and Gram-negative bacteria. The system should also be a walk away analyzer suitable for mid volume laboratories, with automated sample incubation, processing and interpretation of results.

3. Technical Specifications

3.1. Minimum Identification and Detection Capabilities

- **Bacterial Identification**: The analyzer should be capable of identifying a broad spectrum of Gram-positive and Gram-negative bacteria.

- **MRSA , ESBL, & Detection**: The analyzer should be capable of detecting Methicillin-resistant Staphylococcus aureus (MRSA), Extended Spectrum Beta-Lactamases (ESBL), within the standard GP/GN workflow.

- **Fungal ID/Antifungal Sensitivity Test**:

3.2. Minimum Antimicrobial Sensitivity Testing

- **ABST for Bacteria**: The analyzer must be capable of performing Antibiotic Susceptibility Testing (ABST) for a wide range of clinically significant bacteria, including both Gram-positive and Gram-negative organisms.

- **Fungal Antimicrobial Sensitivity Testing**: Should be available

Microbe Panel	Identification	Antimicrobial Susceptibility
Gram-negative bacteria	✓	✓
Gram-positive bacteria	✓	✓
ESBL	✓	
MRSA	✓	
Fungus	✓	✓

3.3. Optional Identification & Antimicrobial Sensitivity Testing (Non-Mandatory / Additive Scope)

The supplier may optionally offer additional specialized Identification (ID) and Antimicrobial Susceptibility Testing (AST) panels, kits, or modules beyond the mandatory requirements specified under Sections 3.1 and 3.2.

• Optional offerings may include, but are not limited to:

- Vancomycin-resistant Staphylococcus aureus (VRSA)
- Vancomycin-resistant Enterococci (VRE)
- Carbapenem-resistant Enterobacteriaceae (CRE)
- Carbapenemase-producing organisms (CPO)
- Multidrug-resistant organisms (MDRO)
- Specialized fungal identification and antifungal susceptibility panels
- Other advanced or specialized resistance detection panels

• All optional items under this section:

- Shall not form part of the mandatory technical compliance evaluation
- Shall not contribute to technical scoring or bid ranking
- Must be quoted separately in the financial bid form
- Shall remain available for procurement during the contract period if required by the purchaser

• The purchaser reserves the right to procure these optional items based on future service expansion, clinical demand, or budget availability.

• Suppliers are encouraged to provide detailed pricing, menu specifications, and intended clinical applications for all optional panels offered.

4. System Components

- **Core Functionalities**: The system should include fully automated sample incubation, sample reading, and result interpretation.
- **Sample Inoculum Preparation System**: If sample preparation & standardization are not integrated, the following accessories must be supplied:

1. McFarland Densitometer
2. Liquid McFarland Standard set
3. Dispenser bottle (1-5 ml)
4. Single-channel pipettes (50-100 µl, 100-500 µl)
5. Multi-channel pipette
6. Other manufacturer devices for sample inoculum preparation and dispensing are applicable.

5. Technology & Analytical Parameters

5.1. Technologies Accepted

- Shall utilize any internationally validated methodology for microbial Identification (ID) and Antimicrobial Susceptibility Testing (AST), including but not limited to biochemical, morpho kinetic, fluorescence-based, broth microdilution, colorimetric, or turbidimetric techniques, or any other validated technologies not specifically listed herein

5.2. Analytical Parameters

- **Identification Accuracy**: Must enable identification up to the species level with high accuracy.

6. Testing Base

- **Disposable Testing Base**: Testing should be conducted using disposable sealed pouches, barcoded cards, panels, broths, or strips with prefilled reagents for consistent and reliable results. Inbuilt automated reagent dispensing or separate reagent dispenser is applicable.

7. Test Capacity & Types

7.1. Capacity

- The system must accommodate ID & AST for 15-30 samples.

7.2. Panel Types

- Must support Bacterial Identification (ID) and Antimicrobial Susceptibility Testing (AST) through either separate panels or combined ID & AST panels, depending on system design. Where separate panels are used, flexibility in panel selection should be maintained. Where the instrument utilizes combined ID & AST kits, suppliers must provide separate CPT pricing for such combined panels to ensure transparent and equitable financial evaluation. The analyzer must support antibiotic panels with distinct combinations of antibiotics, customized for various bacterial groups. These should include but are not limited to, Gram-negative panels, Gram-positive panels, fastidious organism panels, and Enterobacteriaceae panels. Each panel should be specifically designed to ensure accurate antimicrobial susceptibility testing for the targeted bacterial species.

- The analyzer must support antibiotic panels that include a diverse range of antibiotic classes, such as cephalosporins, macrolides, aminoglycosides, fluoroquinolones, and carbapenems. These panels should be tailored for various bacterial groups, including Gram-negative, Gram-positive, fastidious organisms, and Enterobacteriaceae. A minimum of 30 different types of antibiotics should be available across these panels to ensure comprehensive antimicrobial susceptibility testing.

- The system should offer a variety of panels (ID & AST) separately, allowing users flexibility in selection to reduce costs.

8. Database & Reference Phenotypes

- **System Database**: The system database should contain at least 1000 reference phenotypes to ensure comprehensive identification capabilities, and also should be upgradable to include the most recent data.

9. Barcode Integration

- **Barcode Scanning**: The system must include integrated or separate barcode scanning device for easy identification of samples and test devices (panels / cards / strips etc) and reagents.

10. Software Capabilities

10.1. Workflow Management

- The software should provide comprehensive workflow management, from sample entry to result reporting.

10.2. Data Storage

- Must include robust data storage capabilities for archiving and retrieving test results.

10.3. Quality Control

- The system should manage test quality control by industry standards.

10.4. Connectivity

- Must offer real-time connectivity with Laboratory Information Systems (LIS) for seamless data integration.

10.5. Reviewing & Reporting

- Should facilitate quick and easy review and reporting of results.

10.6. Guideline Compliance

- Must identify and report test results according to NCCLS/CLSI guidelines.

10.7. Alert System

- The software should have the ability to alert users to any unusual resistance patterns or critical results.

11. Reagent and Consumable Requirements

- If additional reagents are required, vendors should provide detailed information on costs, preparation time, and usage guidelines.

12. Incubation & Processing Time

12.1. Onboard Incubation

- The system should include an onboard incubation component for microorganism growth and analysis.

12.2. Processing Time

- Test processing should be completed within 24 hours, ensuring timely results.

13. Compliance & Certifications

- The system and its components must comply with international standards and local regulations, including CE or FDA approval.

14. Standards and Electrical Requirements

- **Power requirement**: 250V, 50Hz
- **Conformity to electrical standards**: IEC 61010-1, IEC 61010-2-081, IEC 61010-2-101 or BIS equivalent
- If the system requires a water purification system, the supplier has to provide one.

15. Data Security & Connectivity

15.1. Connectivity

- The system should allow seamless integration with hospital/laboratory networks and support remote monitoring capabilities where applicable.
- **HIS/LIS Interface**: Support HL7 or Ethernet
- Should be possible for Network Integration with LIS.

16. Country of Origin

- Open

17. Supplier responsibilities

- Complete product details to be enclosed with the original brochure or catalogue (Soft & hard copy).
- Details of equipment and procedures required for routine calibration and periodic maintenance to be supplied, and advanced maintenance task documentation also to be furnished.
- List of important spares and accessories, with their part numbers, to be supplied to the buyer at the time of supplying the equipment.
- Installation and demonstration of equipment and training to be provided after completing supplies before acceptance.

- Breakdowns are expected to be resolved within 48 hours.
- Common spare parts shall be readily available with the supplier at any given time.
- User/Technical/Maintenance manuals to be supplied in English in hard and soft copy.
- Details of the standard accessories, additional accessories, optional items, consumables, and minimum supplies to be stated clearly.
- Consumables & reagents, calibrators used in breakdown service, preventive maintenance & calibrations shall be provided by the supplier. This should be calculated and additionally provided later FOC.
- Shall have to evacuate equipment from the hospital space within 45 days of expiry/termination of contract.
- Shall carry out repeat investigations in case of erroneous observations due to quality control issues without any additional cost.
- Provide Standard Operating Procedures (SOPs) for the functionality of equipment, processing, and testing of samples.
- Provide necessary hands-on training to Laboratory Technicians and other technical staff for handling the equipment.
- To provide comprehensive maintenance (CMC) of all the equipment under this contract during the period of the contract without additional charge.
- Material safety data sheets for all reagents should be supplied.

18. Calibration & Quality Control

- The system must have monitoring of all aspects of instrument performance.
- Submissions must include details of the QC material proposed and any associated costs.
- Proposals must specify the recommended frequency of QC.
- Details of QC handling programs on the equipment must be given and must show SD, CV, and mean results (if applicable).
- The onboard storage capacity of QC data must be given and must be extractable in an appropriate format (if applicable).
- QC results must be clearly indicated with appropriate status flags against defined results (e.g., out of limit results or unusual resistance patterns should be flagged (if applicable).
- The QC batch numbers, targets, results, and an onboard comment facility must be available for storage suitable for accreditation purposes (if applicable).
- Price of control strains should be provided for QC (separate from CPT).
- Calibration frequency should be mentioned.

19. Consumables & Reagents

- The shelf life of reagents and consumables should be given in the reagent and consumables list provided.
- Suppliers must state how sample and reagent deterioration is minimized while on board. The maximum viability of reagents on board must be (If applicable).
- State storage requirements for one month and six-weekly supplies of reagents and consumables, including space required at room temperature or refrigerated. State temperature limits for both.

- State-guaranteed minimum shelf life of products provided.
- Provide details of standard and emergency orders for reagents and the lead time for both groups.

20. Software Updates

- The vendor must provide regular software updates to maintain compatibility with new technologies and industry standards.

ANNEX 2

1. Supplier Responsibilities

1.1 **Installation and Maintenance**

- The supplier will install the machine free of cost and will take care of regular services, maintenance, and repair to ensure the proper functioning of the equipment for the contracted period. AEH will not bear any costs for repair of equipment as long as the reagent purchase is continued.
- The machine and all its accessories will remain the property of the supplier.

1.2 **Consumables and Start-Up Kit**

- The supplier shall deliver the necessary consumables/reagents to AEH within 45 days of order placement.
- All reagents and consumables required for training and demonstration of the instrument for Staff/Laboratory Technologists/Doctors at the time of Installation, Start-up, and Dry run will be provided at no extra cost.

1.3 **Test Results and Replacement**

- Invalid test results due to mechanical failure will not be charged by the supplier. In such cases, the supplier must replace those tests and kits.

1.4 **Minimum Shelf Life of Reagents and Consumables**

- All reagents and consumables (when applicable) should have a minimum expiry of 8-12 months.

1.5 **Ancillary Equipment**

- The supplier must supply all appropriate and adequate ancillary equipment required for making the system fully functional, including:
    - Suitable UPS with 2-hour backup
    - Full sample load and stabilizing system
    - Water purification system (if required)
    - Desktop computer
    - LIS interface support
    - Barcode reader (if not included with the instrument)
    - Laser printer (print speed ≥ 40 pages/minute)
    - Paper, as per instrument requirement. Provide cost price.

1.6 **Service and Support**

- A service engineer and application specialist must attend troubleshooting and breakdown calls within 4 hours (online) and be available on Viber/WhatsApp.
- The supplier must ensure that the breakdown period of the machine does not exceed 48 hours and provide a backup option in case the equipment is not repairable. If the breakdown period exceeds 48 hours more than three times during the contract term, AEH has the right to terminate the contract.
- The supplier must describe the daily, weekly, and monthly maintenance procedures.
- The quantity, frequency, and duration of preventative maintenance visits per annum must be stated, and a schedule of works must be provided after installation.

1.7 **Spare Parts Availability**

- Fast-moving spares shall be kept at Addu City. Rare spares shall also be available at Male City and shall be dispatched the same day in case of a requirement.
- The supplier must provide comprehensive maintenance of all the equipment under this contract during the contract period.
- An assurance must be provided that the proposed equipment will be supported, and spares will be available for a minimum of five years.

1.8 **Contract Termination**

- The supplier shall remove the equipment from the hospital space within 45 days of the expiry/termination of the contract.

1.9 **Quality Control**

- The supplier must carry out repeat investigations in case of erroneous observations due to quality control issues without any additional cost.
- Installation, demonstration of equipment, and training must be provided after completing supplies to ensure the system is acceptable for AEH before payments are made.

1.10 **Training**

- The supplier must provide training to logistics and procurement staff on reagent ordering and storage.
- Necessary hands-on training must be provided to Laboratory Technologists and other technical staff for handling the equipment.
- The supplier must provide all deliverables and the training listed in Sections 2 and 3 of this Annex 2, respectively.

2. Maintenance & Support

2.1 **Troubleshooting and Breakdown Response**

- The service engineer and application specialist must attend troubleshooting and breakdown calls within 24 hours-48 hours onsite and be available on Viber/WhatsApp.
- Failure to fulfill a response or attend a call will result in the issuance of a service dissatisfaction report to the vendor.

2.2 **Breakdown Management**

- The supplier must ensure that the breakdown period of the machine does not exceed 48 hours and provide a backup option if the equipment is not repairable.

ANNEX 3

1. Costs of Consumables & Reagents

1.1 **Reagent Costs**

- Reagent costs for AEH should be comparable with or lower than existing market rates. The prices of the complete test menu shall be provided with the bid.

1.2 **Consumables Costs**

- Apart from reagents, the vendor must quote the cost of all consumables, calibrators, broths, diluents, sample cups, disposable tips, disposal covers, or biohazard bags, and wash solutions, printer rolls, (whichever is relevant for the instrument) with their pack size, required for running the instrument separately in the price bid.

1.4 **Reagent Costs**

- The cost of reagents, and consumables will be quoted by the vendor.

1.5 **Consumables Costs and Pack Size**

- The cost of consumables like sample cups, disposable tips, and wash solution will be quoted by the vendor. The vendor should mention the pack size as per the number of tests for all test parameters.

1.6 **Rate Chart Submission**

- The supplier must submit a detailed rate chart of all packs of reagents, calibrators, and consumables with applicable GST rates, which should tally with the rate quoted for all test parameters. Reagent prices cannot be revised within the first five years of the contract period.

2. Cost per Test

2.1 **Unit Cost per Test**

- The unit cost per test should be calculated and provided in the Bid Form. Details of the derivation/calculation of the cost per test should be stated clearly. Any hidden costs, such as equipment priming, washing/disinfection, and other regular consumables, should be included in the cost per test calculation.

2.2 **Test Quotations**

- Prospective bidders must quote for the tests specified in **3.1 , 3.2 & 3.3 Minimum Identification and Detection Capabilities** of Annex 1 separately in the Bid Form and must quote for all tests (IDs and ASTs) possible in the proposed machines in the Optional IDs and ASTs section of the Bid Form.

2.3 **Consumables Details**

- Details of consumables, pack sizes, and prices of consumables must be quoted as per the format provided in **Table 1:** If a particular consumable can be used for more than one test, the estimated number of tests or frequency of consumption should be specified in column 4 of **Table 1**: (example provided below).

2.4 **Shelf Life**

- The shelf life of reagents and consumables should be given in the reagent and consumables list provided with the brochure/catalogue.

2.5 **Periodic Consumables**

- If a consumable is required periodically, this must be specified.

2.6 **Usage and Consumption Ratio**

- The usage and consumption ratio of consumables should be supported by manufacturer's documentation for verification purposes. This document is mandatory.

Table 1: Consumables Cost Breakdown

S.No.	Generic Description of Consumable	Name of Reagents/ Consumables, etc.	Pack Size (Test/pack)	Cost of Reagents Pack Size (MVR)
Example	Amoxiclav	Augmentin Antibiotic 15mcg	5 x 50 disc/pack	150
1	Gram Neg Bacteria			
2	Gram Positive Staph			
3	G Positive panel A			
4	G Negative Panel B			

3. Cost Evaluation

3.1 **Evaluation Criteria**

3.1.1 **Unit Cost per Test**

- The lowest sum of all costs per test (tests specified in #3.1 and #3.2 of Annex 1) proposed will be given the highest marks. The rest will be based on a pro-rata ratio.

3.1.2 **Optional IDs and ASTs**

- The lowest total price of optional IDs and AST provided will be given the highest marks. The rest will be based on a pro-rata ratio.

3.2 **Consumption Discrepancy**

- If the calculation provided for consumption does not match the initially provided numbers in real use, the additional consumption of consumables shall be provided without any additional cost to the customer.

4. Documents to be Submitted with Bid Submission

Documents	Mandatory Submission (✓)
Bid Form	✓
Brochure or Catalogue	✓
Details of the standard accessories, additional accessories, optional items, consumables, and minimum supplies	✓
CE or FDA Certificate	✓

ANNEX 4:

Estimated Annual Test Volume Forecast (5-Year Projection)

The following projected annual test volumes are provided solely for bidder reference to support financial proposal preparation, reagent forecasting, and service planning. These estimates are approximate and do not represent **guaranteed procurement quantities.**

- Actual annual consumption may vary based on patient load, epidemiological trends, service expansion, and budget availability.
- Bidders must quote unit pricing for all mandatory and optional panels listed.
- Optional panels shall be separately quoted and will not form part of technical evaluation scoring.

#	**Analyzer Panel**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
1	Gram Positive Bacteria ID & AST	250	263	276	289	304
2	Gram Negative Bacteria ID & AST	850	893	937	984	1,033
3	MRSA ID & AST	250	263	276	289	304
4	ESBL ID & AST	450	473	496	521	547
5	Yeast ID & Antifungal Susceptibility	100	105	110	116	122
6	Optional – Neisseria ID & AST	10	11	11	12	12
7	Optional – Streptococcus ID & AST	50	53	55	58	61
8	Optional – Anaerobes ID & AST	30	32	33	35	36
9	Optional – Other Specialized Panels ID & AST	50	53	55	58	61

Note:

These projected quantities are intended for pricing guidance only. The purchaser reserves the right to procure based on actual operational requirements. Inclusion of optional panel pricing is mandatory for contractual flexibility; however, such optional items shall not influence technical compliance scoring or financial ranking unless otherwise specified.