

ANNEX 2

Fully Automated Blood Bank Immunohematology Analyzer

Quantity: 01

Technical Specifications:

- Should be fully automated walk away system capable of performing ABO/Rh Typing, Cross matching, D (IgM +AHG), Antibody Screening, Direct Antiglobulin test, antibody identification, red cell phenotyping and antibody titration, Weak D testing, QC testing.
- Should have continuous random access & STAT facility for emergency testing.
- Should have facility for red cell suspension preparation.
- Should accommodate standard sample tubes and pediatric sample tubes.
- Should be able to handle different sample types, centrifuged whole blood, serum, plasma, red cell suspension, & packed RBC.
- Should have facilities for barcode identification of both reagents and samples.
- Should be able to read cassette / cards bar codes.
- System should have integrated Centrifuging, Incubating, Reading and required Pipetting system.
- The measuring principles should be CAT (Column agglutination technology).
- System should be floor or table-top model.
- Should have at-least 20 slots to centrifuge.
- Easy to use Touch screen interface should be available.
- Prefixed centrifuge time: 10 minutes at speed 700-1500 RPM.
- Should maintain incubation temperature of 37 °C with required incubation time.
- Should have capacity to incubate not less than 20 cards/cassettes.
- Incubation time should be programmable based on laboratory protocols.
- Results viewing and processing software should be available.
- Barcode reader for sample programming and compatible printer should be supplied.
- The system should have LIS connection and other communication and exporting facility.

Roles & responsibilities of successful bidder:

- Reagent cost for AEH should be lower than the existing rates in the market. Prices of complete test menu shall be provided with bid.
- Supplier shall deliver the necessary consumables to AEH within 45 days of order placement
- Apart from reagents the vendor has to quote the cost of all consumables, calibrators, sample cups, disposable tips, wash solutions with their pack size, required for running the instrument in the price bid.
- The frequency of calibration for parameters should be limited only to lot changes.
- Shall provide start-up kit, calibrators, consumables required for training of the Staff/Technician/Doctors at the time of Installation, Start-up, Dry run at no extra cost
- The supplier will install the machine free of cost and will take care of regular services, maintenance, repair in order to ensure the proper functioning of the equipment for contracted period. AEH will not bear any costs for repair of equipment's as long as the reagent purchase is continued.
- The Supplier must quote the cost of complete set of all routine tests including start up and shut down consumption of reagents required by the system.
- Cost of the reagents will be quoted by the vendor along with cost of controls and calibrators.
- Cost of the consumables like sample cups, disposable tips, wash solution etc. will be quoted by the vendor. The vendor should mention pack size as per number of the tests for all test parameters.
- The Supplier will have to submit detailed rate chart of all packs of reagents, controls, calibrators and consumables with applicable GST rates which should tally with the rate quoted for all test parameters. Reagent prices cannot be revised within first 5 years of contract period.
- The workload for some new test parameters may increase/decrease as per requirement of the hospital and rates are to be quoted accordingly.
- Any expired and un-used reagents shall be replaced by supplier. Invalid test results due to mechanical failure will not be charged by the firm and in such case the firm has to replace those tests and kits as well.
- Selected company/firm must supply all appropriate and adequate ancillary equipment's required for making the system fully functional including suitable UPS with 2 Hour backup with full sample load and stabilizing system, water purification system (if required), refrigerators (to store kits), desktop computer, barcode printers, LIS interface, bar Code reader, laser printer (print speed \geq 40 pages/minute), paper, as per instrument requirement
- Service engineer and application specialist for attending trouble shooting and breakdown should attend calls within 4 hrs. Shall be available on Viber/ WhatsApp.
- Supplier shall ensure that a breakdown period of the machine must not exceed for more than 48 hours and back up option in case of equipment breakdown. Common spares shall be kept at Addu City. And rare spares shall also be available at Male City, and shall be dispatched same day in case of a requirement.

- To provide an EQAS on a half yearly basis provided by any ISO/IEC 17043: 2010 accredited agency.
- Fast moving spares shall be kept at Addu City. And recommended spares shall also be available at Male City, and shall be dispatched same day in case of a requirement.
- Selected company must provide a complete protocol for validation of the system in relation to Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) as per standard protocol.
- Should provide connection to Hospital & LIS system in bidirectional format & successful implementation of interface before commencement of user training. The successful bidder will bear all additional cost for interfacing fees & hardware required for interfacing with Hospital LIS/HIS.
- Shall specify preinstallation requirements (electrical, HVAC, compressed Air) Please specify required air pressure, water requirement, RO, distilled water with its pressure and flow rate per hour. If any of the above is essential. If RO is required successful bidder has to supply FOC along with equipment.

Standards and Electrical Requirements:

- USFDA, CE approved 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

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue (Soft & hard copy).
- Details of equipment's and procedures required for local calibration and routine maintenance to be supplied and advance 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 expected to be resolved within 48 hrs.
- Common spares parts shall be readily available with supplier at any given time.
- User/Technical/ Maintenance manuals with detailed circuit/schematic diagrams 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, spares, calibrators used in breakdown service, preventive maintenances & calibrations shall be provided by supplier.
- Should provide reagents, Quality Control, Calibrators, tips cuvettes and ancillary reagents to perform the tests (mentioned in table: 2).

- Shall have to vacate the hospital space within 30 days of expiry/termination of contract.
- Shall carry out repeat investigations in case of erroneous observations due to quality control issue without any additional cost.
- Provide Standard Operating Procedures (SOPs) for functionality of equipment, processing and testing of samples.
- To provide necessary hands on training to Laboratory Technicians and other technical staff for handling the equipment's.
- To provide comprehensive maintenance of the all the equipment's under this contract during period of contract.
- Material safety data sheets for all reagents should be supplied during bid submission.
- The supplier shall bear the costs incurred for both software & hardware in LIS bidirectional integration with HIS/LIS (HINAI).

Key Operators & Technical Training and Validations Requirements:

- Onsite Application and Operator training for users by authorized **application specialist ONLY**.
- Technical training for in house Engineers should be provided by the Authorized trainers or engineers.
- Equipment calibration & validation should be performed at the time of installation.
- The agency should provide all training materials and documents.
- Shall provide International Training/Conference for 2 persons in laboratory/clinical medicine/support staff in a neighboring country each year of contract.
- Training for staff should be provided on site by company using their own reagents. Each training should be conducted by certified /authorized company approved persons. A training completion certificate shall be issued with each training. Training shall include a theoretical and practical aspects of the equipment and application. And periodic refresher training shall be conducted once annually.

Consumables & Reagents & Cost per Test:

- The shelf life of reagents and consumables should be given in reagent and consumables list provided.
- Details of consumables, pack sizes & prices of consumables to be quoted as per the format below 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 3 Table:1. Please see example in Table below.
- If a consumable is required periodically should be specified.
- ***Unit Cost per Test should be calculated and provided. Details of derivation/Calculation of Cost Per test should be provided separately. Any hidden costs like, equipment priming, washing/disinfection, other regular consumables, should be included in the Cost Per Test calculation.***
- **Usage and consumptions ratio of consumables should be supported by manufacturers documentation for verification purpose. This document is mandatory.**
- **Cost Per Test for hematology cell counter and (slide maker and Stainer) shall be made separately made. Please consider slide make and Stainer as one equipment for CPT calculation purpose.**

Table 1:0

S.No.	Generic Description of consumable	Name of Reagents/ consumables, etc.	Pack Size (Test /pack)	Cost of Reagents pack Size (MVR.)	CPT (Including washer, diluents, controls, Calibrators, QCs, Tips, Trays, Waste Liners, & any other consumables, disposables)	Net Cost Per Test Including GST
Example:	Agglutination Card/Cassette					
1	Suspension solution					
2						
3						
4						
5						
6						
7						
8						

NOTE:

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

Cost Evaluation:

- **Cost will be evaluated based on *unit cost per test*. And the lowest cost per test proposed will be given the highest marks. Rest will be based on pro rata ratio.**

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.

Distributorship:

- Suppliers shall have a valid authorized distributor license or reseller license for the country/region at the beginning of agreement or signing of contract.
- A distributorship or licensorship certification is not 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.

Samples:

- At the time of bid opening bidders may provide with samples of consumables and reagents. Diluents, buffers and wash solutions which are bulky need not be submitted a sample. Test kits for both parameters also not mandatory. One test kit from any test parameter would suffice.
- Sample submission is NOT mandatory.

AEH Responsibilities:

- AEH shall provide a place to install the equipment's.
- To conduct awareness among AEH staff on equipment use and functions.
- To ensure users are operating equipment as per manufacturers recommendations and advice.
- To prepare and share with supplier AEH 4 months consumables requirements required to provide services.
- To prepare and share annual forecast of reagents & consumables with supplier.
- AEH will purchase machine related consumables from the supplier Only.
- AEH can decide to change the location of the machine within AEH or to any other health facility under AEH.

Tentative Annual Requirement:

Table: 2

Serial No	Name of test	Estimated Annual tests
1	Blood Grouping	3500
2	Cross Matching	1500

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

Country of origin:

USA, Canada, UK, Austria, Belgium, Denmark, Finland, Germany, France, Hungary, Ireland, Spain, Japan and Australia.

Year of Manufacture:

2021 or later

Rental period:

- The rental period will be for an initial term of 5 years.