ANNEX 1

Fully Automated Glycohemoglobin Testing Analyzer

Quantity: 01

SECTION A

SPECIFICATIONS

The instruments must meet or exceed the following requirements:

1. A Compact, brand new, Bench Top, Fully Automated, High Performance Liquid Chromatography (HPLC) Glycohemoglobin Analyzer for HbA1c and HbA2 estimation.
2. The system should be equipped with an automated barcode reader facility.
3. The system should have automated cap-piercing of primary tubes and direct dilution of samples without manual intervention.
4. The system shall be equipped with sample mixing technology by inversion of tube.
5. The system should be NGSP (National Glycohemoglobin Standardization Program) Certified, IFCC (International Federation of Clinical Chemistry) standardized.
6. No sample pre-treatment should be required. Diluted and Undiluted sample run mode should be available.
7. Vendor should provide bi-directional LIS/HIMS interfacing and sample bar code reader should be compatible with local LIS/HIMS.
8. The system should have an in-built printer for reports.
9. Analyzed data should be printable as graphical presentation.
10. Machine should perform ≥ 15 tests per hour.
11. System should detect Hb variants that affect A1c interpretation. Type of automation: fully automatic
12. Assay menu:

- Hb Variants detection: HbE, Hbc, HbS, HbD, HbF
- HbA1c (whole blood)
- HbA2

13. System should have STAT sample capability.
14. System should be able to analyze both HbA1c and HbA2 in a single mode.
15. The system should have feature to load samples using racks with a minimum sample loading

capacity of at least 40 samples with continuous loading facility.

16. HPLC system shall be supplied with complete ready to use kit with Buffers or relevant reagents with inventory management system to view the level of buffers; columns, primers, calibrators & sample vials etc.
17. The HPLC system should have better precision, CV less than 2.5%.
18. The calibration should be based on 2-point calibration or advanced for higher accuracy.
19. System should not have any interference from HbF up to 20% and any other hemoglobin derivatives.
20. System should not use primers before each run of batches and minimal reagent consumption during automated maintenance schedule.
21. Operating system: Windows or compatible
22. It should have a sufficient data storage of at least 500 samples and a remote data access feature when connected to LAN or Intranet.
23. The system must have a software for real time viewing of the analysis of the sample.
24. Should have Quality assurance system with calibration.
25. QC Management: QC (2 levels) should be available & supplied along with reagents.
26. The instrument should be supplied with appropriate capacity of UPS with minimum 120 minutes backup.
27. The supplier should provide the servicing/ maintenance/ replacement of UPS and the batteries.
28. Company should provide licensed copy of software of the quoted equipment. Software up gradation should be provided by the company free of cost, throughout lifetime of the equipment.
29. System should have 2 x RS 232 bidirectional interface and in-built modern for remote service diagnostics / tele services as well as standard pc ports, USB, Ethernet.
30. For external storage or Exporting data, USB ports should be available.
31. Power supply: 230 V +/- 10% 50 Hz +/ 3%.
32. Operating Environment: Temp: 15oC- 30oC. Relative Humidity 15- 80%.
33. Please Specify the Standard Information required from Vendor, Principal Manufacturers, and Post Sale Service Facilities (Service network in Maldives), Availability of Spares in the quotation.
34. **Reagent System: Single Unit strips, device or cups. (One test one Reagent System).**
35. The frequency of calibration for parameters should be limited only to lot changes.
36. Sample Volume: 10- 200uL
37. Foot Print: Small
38. The pack size of reagents should range from 20 to 200.

39. Analyzer Type: random and batch analysis
40. The reagents should be ready to use.
41. All supplied reagents should have a minimum shelf life of 6 months.

Standards and 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:

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

Year of Manufacture:

- 2021 or later

Distributorship:

- Must submit a letter authorizing submission of tender for this project from manufacturer.
- Suppliers shall have a valid authorized distributer license or reseller license for the country/region at the beginning of agreement or signing of contract.

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.

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.

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.
- Material safety data sheets for all reagents should be supplied during bid submission

SECTION B:

1. Supplier Responsibilities:

1.1. Reagent cost for AEH should be lower than existing rates in the market or lower. Prices of complete test menu shall be provided with bid.

1.2. Supplier shall deliver the necessary consumables to AEH within 45 days of order placement

1.3. Apart from reagents the vendor has to quote the cost of all consumables, calibrators and Quality controls required for running the instrument in the bid price.

1.4. The frequency of calibration for parameters should be limited only to lot changes.

1.5. 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

1.6. 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.

1.7. 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.

1.8. Cost of the reagents will be quoted by the vendor along with cost of controls and calibrators.

1.9. 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.

1.10. 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.

1.11. The workload for some new test parameters may increase/decrease as per requirement of the hospital and rates are to be quoted accordingly.

1.12. 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.

1.13. 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

1.14. Service engineer and application specialist for attending trouble shooting and breakdown should attend calls within 4 hrs. Shall be available on Viber/WhatsApp.

1.15. Supplier shall ensure that a breakdown period of the machine must not exceed for more than 48 hours and keep ready a backup 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. If 3 instances where breakdown period exceeds 48hrs occurs hospital shall claim the performance guarantee.

1.16. To provide an EQAS on a half yearly basis provided by any ISO/IEC 17043: 2010 accredited agency.

1.17. 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.

1.18. Shall have to vacate the hospital space within 30 days of expiry/termination of contract.
1.19. Shall carry out repeat investigations in case of erroneous observations due to quality control issue without any additional cost.
1.20. Provide comprehensive maintenance of the all the equipment's under this contract during period of contract.
1.21. Consumables & reagents, spares, calibrators used in breakdown service, preventive maintenances & calibrations shall be provided by supplier.
1.22. Should provide reagents, Quality Control, Calibrators and ancillary reagents to perform the tests (mentioned in table: 1 of Annex 3).
1.23. Common spares parts shall be readily available with supplier at any given time.

2. Deliverables:

2.1. 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.
2.2. 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.
2.3. List of important spares and accessories, with their part numbers to be supplied to the buyer at the time of supplying the equipment.
2.4. User/Technical/ Maintenance manuals to be supplied in English in hard and soft copy
2.5. Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.
2.6. Should provide reagents, Quality Control, Calibrators, tips cuvettes and ancillary reagents to perform the tests (mentioned in table: 2).
2.7. Provide Standard Operating Procedures (SOPs) for functionality of equipment, processing and testing of samples.
2.8. 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.
2.9. List of important spares and accessories, with their part numbers to be supplied to the buyer at the time of supplying the equipment.
2.10. Installation and demonstration of equipment and training to be provided after completing supplies before acceptance.

3. Key Operators & technical Training and Validations Requirements:

3.1. Provide necessary hands-on training to Laboratory Technicians and other technical staff for handling the equipment's.

3.2. Onsite Application and Operator training for users by authorized application specialist ONLY.

3.3. Technical training for in house Engineers should be provided by the Authorized trainers or engineers.

3.4. Equipment calibration & validation should be performed at the time of installation.

3.5. The agency should provide all training materials and documents.

3.6. Shall provide International Training/Conference for 2 persons in laboratory/clinical medicine in a neighboring country each year of contract.

3.7. 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.

4. AEH Responsibilities:

4.1. AEH shall provide a place to install the equipment.

4.2. To conduct awareness among AEH staff on equipment use and functions.

4.3. To ensure users are operating equipment as per manufacturers recommendations and advice.

4.4. To prepare and share with supplier AEH 4 months consumables requirements required to provide services.

4.5. AEH will purchase machine related consumables **exclusively** from the supplier.

4.6. AEH can decide to change the location of the machine within AEH or to any other health facility under AEH.

5. Tentative Annual Requirement:

Table: 2

Serial No	Name of test	Estimated Annual tests
1	HbA1c	8000
2	HbA2	250

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

6. Rental period:

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

SECTION C:

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.**

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:	HbA1c program kit					
1	HbA2 program kit					
2						
3						
4						
5						
6						
7						
8						
9						
10						

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.**