بسم الله الرحمن الرحيم

އުނގޫފާރު ރީޖަނަލް ހޮސްޕިޓަލް

ރ. އުނގޫފާރު، ދިވެހިރާއްޖެ

UNGOOFAARU REGIONAL HOSPITAL

Raa. Ungoofaaru , Republic of Maldives

TECHNICAL SPECIFICATION FOR MEDICAL EQUIPMENT

Equipment: FULLY AUTOMATED HEMATOLOGY ANALYZER (Quantity- 01)

OBJECTIVE

A hematology analyzer is a sophisticated piece of equipment used in medical laboratories to count and analyze various components of blood. These components include red blood cells, white blood cells, and platelets. The analyzer provides critical information for diagnosing and monitoring a range of conditions, from anemia and infections to blood cancers.

SPECIFICATIONS

1. The instrument should be fully automated fluorescence flow cytometry/ flow cytometry / Optical scatter based 5-part differential hematology analyzer offering automatic start-up, shutdown and sample-analysis.
2. The instrument should have random access discrete analysis modes for CBC, CBC + DIFFERENTIAL.
3. The instrument should have minimum 24 PARAMETERS reported:
   WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, NEUT%, LYMPH%, MONO%, EOS%, BASO%, NEUT#, LYMPH#, MONO#, EOS#, BASO#, PDW, ALY%, ALY#, IG/LIC%, IG/LIC#, MPV, PCT, P-LCR, TWO HISTOGRAMS – RBC, PLT and ONE SCATTERGRAMS.
4. The instrument should have through put of minimum 60 or more samples per hour in both the discrete analysis modes.
5. The sample aspiration volume for the complete differential blood count should not be more than 200 µl.
6. The instrument should have the following analysis modes, Manual – open / closed cap piercing (CP) capability to aspirate from closed tubes.
7. The instrument should have Hydrodynamic focusing / impedance / Laser / Light scattering method for RBC/ PLT channel.
8. The instrument should have Cyanide free colorimetric for the hemoglobin measurement
9. Instrument should have integrated barcode reader.
10. The instrument should have COMPREHENSIVE INFORMATION PROCESSING SYSTEM with:

a. User-friendly software.

b. 100000 sample data with histogram and scattergrams storage.

c. 99 QC files each with 300 points for QC can be stored

11. Should undertake calibration of the equipment as per the standards available
12. System should be compatible for lab information system & should be interfaced on HL7 / ASTM Protocol. Should have bidirectional capability. The interface cable for LIS integration should be part of standard accessories
13. Laser printer shall be provided along with the machine
14. Rate for reagents shall be fixed for 5 years from the date of price bid opening.

Quality Standard

- Manufacturing should be compliant with ISO 13485, and ISO 9001:2008/2015
- Should be compliant with European CE Class IIA or US FDA
- Equipment must meet electrical safety specifications of IEC 61010-1.

Additional requirements:

→ All equipment should specify qualifications for design, installation, operation and performance.

→ Validation and calibration reports should have traceability to applicable international standards

→ Warranty for 5 years and CMC/AMC for Three years with spare parts availability.

→ The brand, rating, model, description, specifications, price quantity of each item should be furnished separately.

→ Necessary catalogues, technical write up in English, should be attached with the offer both in hard and electronic copies.

→ Performance, efficiency, other factors as applicable should be furnished.

→ Demonstration and continued comprehensive training for user/biomedical staff and support services till expertise with the system.

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