ANNEX 01

TECHNICAL SPECIFICATION FOR MEDICAL EQUIPMENT

Equipment: FULLY AUTOMATED COAGULATION ANALYZER (Quantity- 01)

OBJECTIVE

A fully automated coagulation analyzer, which have optical detection technology and the reagent system with new features. It is great as a primary analyzer for routine hemostasis testing in low-volume hemostasis laboratories.

SPECIFICATIONS

1. The equipment should be a random-access system.
2. The instrument should be able to provide simultaneous measurement of Clotting, Chromomeric and Immunological assays.
3. Principle based on change in viscosity by electromagnetic clot detection system with steel ball oscillation or multi wave length scanning and sample liquid-sensing technology.
4. Technology should be insensitive to LIPEMIC, COLOURED, HEMOLYSED plasma and turbid reagent.
5. It is able to calculate low levels of factor VIII and weak clot.
6. The instrument should be able to use primary sample tube.
7. The instrument should be capable of continuous sample & reagent loading during the run.
8. The instrument should be able to add, delete, rerun tests during the run.
9. Availability of 30 programmed and up to 60 Test methodologies should be provided.
10. Minimum 96 sample positions with all STAT facility should be provided.
11. Refrigerated reagent positions of a minimum of 30 all at 15c should be available·
12. Instrument should have in-built Barcode reader for positive identification of sample and reagents i.e., name, stability, volume, position etc.

13. Instrument should be able to detect automatically positive sample and reagent positions.
14. Possibility of Auto Rerun and Auto re-dilution of samples should be available.
15. Positive sample and reagents level detection should be provided.
16. Instrument should have online sample reagents monitoring.
17. Instrument should have data storage capacity of 600 patient includes 12 results per patient.
18. Multi batch Q.C. Capacity on levy- Jennings graphs should be available in the system.
19. Flexibility to rerun, add a test or delete a test, handling of stat sample at any time should be provided.
20. Automatic dilution for sample and calibrators should be possible.
21. Provision for bi-directional LIS connectivity should be available.
22. Minimum test menu available should include PT, APTT, Fibrinogen, TT, LA, All Factors, ATIII, Heparin, PC, PS, PLG, AP, APCR, DDI, FDP, FM, vWf.

OPERATION

Software components and user interfaces

Touch screen – Required

Operating system- Minimum Windows 7

Data storage- Up to 50,000 test results

Online User Assistance/ Remote Solutions - Required

Connectivity- Both HIS/LIS

Utility specifications

Power consumption minimalize up to 1000 VA

Water consumption should be less than 6 L/hour (maximum)

Noise emission <60 dB

Heat dissipation less than 1000 W (maximum)

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 2 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.

****