TECHNICAL SPECIFICATION FOR MEDICAL EQUIPMENT

Equipment: Fully Automated Urine Analyzer (Quantity- 01)

OBJECTIVE

Automated urinalysis can be used for urinary tract screening and for diagnosing and monitoring a broad variety of nephrological and urological conditions; newer applications show promising results for early detection of urothelial cancer.

The Analyzer provides automated reading of the urinalysis tests include:

- Leukocyte
- Nitrite
- Protein
- Blood
- Glucose
- Ketone
- Bilirubin
- Urobilinogen
- pH
- Specific Gravity
- Creatinine
- Protein-to-Creatinine Ratio
- Albumin
- Albumin-to-Creatinine Ratio (ACR)
- hCG Pregnancy Test

SPECIFICATIONS

1. The analyzer should be compact benchtop, fully automated integrated urine analyzer, integrating urine chemistry and urine sediment analysis.

2. Chemistry parameters required to be provided should be glucose, protein, blood, bilirubin, urobilinogen, ph, ketones, nitrate, leukocyte, creatinine & albumin.

3. Additional instrument parameters should have specific gravity, turbidity & color.

4. The analyzer should be based on fluorescence flowcytometry/ Digital flowcytometry for accurate measurement of urine parameters such as RBC, WBC, epithelial cells, cast and bacteria.

5. The instrument should provide scattergrams and histograms or actual images for easy interpretation.

6. The analyzer should provide additional RBC information, UTI information and conductivity.

7. The analyzer should have user friendly software with cross check function.

8. The analyzer should have a throughput 100 samples / hour (chemistry) & 50 samples / hour (sediment analysis).

9. The equipment should have a storage of 200 test strips at a time with continuous loading for true walkaway analysis.

10. The equipment should be capable of analysis in both manual and sampler mode.

11. Sampler should have the capacity of 60 sample tubes and internal barcode for sample identification

12. Controls should be available for both chemistry and sediment analysis

13. Data storage of 10000 samples including graphics & multiple qc files, with 300 data points each should be available.

14. The equipment should have interface for output to printer or transmitted to LIS / HIS and it would the responsibility of the supplier to do the interfacing.

OPERATION

User Interface: Touchscreen

Computer Interface: Uni-directional via Serial Port (RS232)

Data Entry: Onboard touchscreen

Temperature range: 18 to 30ºC (64 to 86ºF)

Humidity range: 18-80% Relative Humidity, non-condensing

Calibration: Automatic, self-calibrating

Memory: Data Storage up to 10,000 samples

POWER REQUIREMENTS

Electrical Rating: 100V - 240V AC, 50-60 Hz (with in-line lead)

Battery operation: Recommended

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.
- Should provide electronic and hard copies of User Manual (English), Service manual (English) and Complete construction details with respect to material specification, thickness, finish etc.
- Should provide a set of equipment's for calibration (e.g., Thermometer) and routine Preventive Maintenance as per manufacturer documentation in service/technical manual. Should provide Log book with instructions for daily, weekly, monthly and

quarterly maintenance checklist. The job description of the hospital engineer/technician and company service engineer should be clearly spelled out.