

## TECHNICAL SPECIFICATIONS FOR FULLY AUTOMATED BIO-CHEMISTRY ANALYSER

1. Fully automated random access clinical chemistry analyzer based on the principles –absorbance photometry, turbidimetry, fluorescence polarimetry for TDMs, Drug abuse testing like cocaine, ethanol etc. and ISE with STAT capability.
  2. Instrument should be equipped with Diffraction grating spectrophotometer with wavelengths accuracy 300-800nm for mono and bi-chromatic measurements.
  3. Test Throughput: 400 tests /hour with ISE.
  4. Analysis time should be not more than 10 minutes / test.
  5. Sample types: Serum, plasma, urine, whole blood and CSF.
  6. Sample input: Continuous loading of at least 100 sample positions on board.
  7. Instrument should have on board Refrigeration facility, Reagent stability on board should not be less than 60 days.
  8. There should be at least 40 reagent positions on board and Reagents should be ready to use.
  9. System should have facility for on-board programs for 150 -175 different test parameters
  10. System should use on-board washing facility with onboard reusable cuvettes to prevent any carry over contamination to have reliable patient results. Water consumption per hour shall not be more than 15 liters/ hour.
  11. Instrument should be able to perform tests like LFT, RFT, Blood Glucose levels, uric acid calcium, magnesium, CKMB, amylase, lipase etc.
  12. System can be used for testing special parameters like Liver function test, HbA1c, Lactate, hs-CRP, Myoglobin, D-Dimer, Prealbumin, Ferritin, IgA, IgM, IgG, ASO, Rheumatoid Factor, MPA and electrolytes (Na, K, Cl and Li), TDM and DAT's.
  13. In built Quality Control Program-Levy Jennings Graph etc. should be available
  14. Auto QC, pooled QC positions and Control positions should be refrigerated. There should be Options for online QC with inter lab comparison free of cost. Instrument should have a provision for QC flags.
- Calibration should be done on-site with a traceable calibrator.
15. Inventory display should be on screen for operator info.
  16. Sample Volume should be 1- 30 ul in 0.1 ul steps



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17. Machine should have the following options for Sample container: Direct tube sampling, primary tubes 5-10ml, sample cup, micro cup and cup on tube.
  18. Calibration of reagents should be lot to lot hence saving calibration costs.
  19. Information on tests per reagent kits should be available on screen.
  20. Machine should have Liquid sensing probes and Sample clot detection facility, Lipaemia, Haemolysis and Icterus analysis, probe crash protection (integrated level sensor) and System should have high sensitive pressure sensors to detect any incorrect pipetting even at 2 ul sample volume. For detection of these errors there should be proper alarm system.
  21. System should have facility for calculated parameters.
  22. On board sample and calibrator dilution should be available for urine and other specimens with provision for Automatic rerun (2-100 times)
  23. There should be Separate containers for biohazard.
  24. There should be latest **Pentium 4** computer attached with external printer and having standard size touch screen color monitor for programming the tests and entering the tests data. System should have latest user friendly windows based software and Anti-virus security .
  25. Computer interface should be RS 232 C and easy connectivity with Hospital LIS. System should have single user interface for easy programming and control.
  26. machine should support Bidirectional Hospital LIS (HMIS)
  27. MACHINE SHOULD have BIS/ISO US/FDA Certified System.
  28. STAT positions for analysis of high priority samples, at least 25 STAT sample positions.
  29. There should be Automated reflex and repeat testing facility
  30. System should use latest ultrasonic technology or a latest technology to mix the samples and reagents to have complete uniformity with no or minimal carryover risk of reagent/ sample
  31. Light source should be halogen lamp with lamp save feature.
  32. System should have onboard data storage for 10,000 samples and quality control data for 2500 samples @100 tests/sample.
  33. There should be inbuilt Bar code scanner.
  34. Equipment must be supplied with 5 year comprehensive warranty for the equipment as well as for its accessories i.e. RO plant, UPS, Computer & its software with updating if required, and Printer.
  35. Firm should quote AMC and CMC rates after the expiry of warranty period.



Machine and its accessories installation at Divisional Railway Hospital Bangalore will be sole responsibility of the firm and should be free of cost.

37. Firm must provide Practical training of the machine and its accessories to available Lab staff /Doctors till they get proper competency to run the machine.

38. Firm must indicate the location of service centre; Firm should have a service engineer based at Bangalore. They must ensure Service & Breakdown calls to attend within 24 hours with minimum downtime.

39. Facility to perform Tele services to ensure prompt maintenance/servicing with minimum downtime.

40. If the firm is not offering 5 years warranty, then firm should quote CMC for the next 5 years, year wise and this will be considered for financial evaluation of the bid

41. UPS – company should provide UPS with minimum of 1 hour backup compatible with the analyzer, capacity according to the requirement of random-access auto-analyzer to work on input of 180 V-270 V

42. RO Plant: MILLIPORE OR SIMILAR MAKE should be provided along with machine.

Suitable Reverse osmosis water plant for water requirement which shall be— Bacteria Free, Deionized water, capacity of RO Plant should be more than requirement of main system.

The maintenance and various consumables required for the same will be the responsibility of the auto analyser firm.

43. Firm to quote only for Brand New machine, No refurbished machine

44. Measuring range of ISE electrodes for Sodium from 80 – 180 mmol/l and for Potassium it is 1.5 – 10 mmol/l.

45. System should have external Printer to take print outs of patient results and QC reports.

46. Firm should supply along with Analyser free of cost –

a. An additional Latest all in one computer – i.e. latest generation CPU with intel i7 or i9 processor, 16 to 32 GB RAM, 528GB to 1TB SSD, latest version windows 11 software and MS Office software, 23.8 to 27 inch display, having multiple ports for cable connection/ integration of LIS, supporting interfacing cables.

b. 2 Bar code generator with printer (hardware and software) with resolution 203 dpi or more to be provided by the firm free of cost.

c. System should have external double-sided Printer to take print outs of patient results and QC reports.

47. If the Reagents which are to be used for machine is proprietary (closed system) then the cost of all the reagents (all the parameters) to be committed at the time of tender (price to be committed preferably for 05 years. For every diagnostic kit, no. of tests per pack



size needs to be specified. In case of discrepancy more than 5%, company would be responsible for replenishing the reagents.

48. COST PER REPORT.

The cost per report (including laundry and cuvette, reagents, scheduled maintenance, running wake up mode and shutdown of analyser, external and internal quality controls performed) for the test range as per the annexure should be declared.

Firm should quote the amount for cost per report in Rupees which will be multiplied by Approximate yearly samples

Cost per report for different throughputs should be mentioned as given below (Approx. samples tested yearly is mentioned next to the test. The actual tests may increase or decrease as per actual requirement) :

1	Description of test	Approx. samples tested yearly	Cost per report
2	Blood Glucose	15000	
3	Blood Urea	7500	
4	Creatinine	7500	
5	Cholesterol	3500	
6	Triglycerides	3500	
7	HDL-chol	3500	
8	LDL-Chol	3500	
9	VLDL	3500	
10	Sr. Bilirubin-T	5500	
11	Sr. Bilirubin-D	5500	
12	Sr. Bilirubin-ID	5500	



13	SGOT	5500	
14	SGPT	5500	
15	ALP	5500	
16	Total Protein	5500	
17	Albumin	5500	
18	Globulin	5500	
19	A.G.Ratio	5500	
20	Na	2000	
21	K	2000	
22	Sr.Calcium	600	
23	Sr.Uric acid	1500	
24	CK-MB	100	
25	LDH	1000	
26	Chloride	2000	
27	HbA1C	2500	
28	Amylase	300	
29	Lipase	250	
30	Iron	1500	
31	Phosphorous	200	
32	GGT	5500	
	<b>Total</b>	<b>121950</b>	

49. The company shall supply the starter kits (minimum of 2000 tests each) consisting of diagnostic kits, accessory reagents, calibrators and controls with the instrument free of cost.



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50. The company shall provide a list of accessories, accessories reagents, calibrators and controls to be used. The quantity should suffice for the whole year. In case accessories, accessories reagents, calibrators and controls get exhausted before time, company shall supply additional material free of cost for a particular fiscal year during the ten year period.
51. Quality of the Test reports to correlate both Internal quality assurance programme as well as External quality assurance programme.
52. Traceability of Reagents is the sole responsibility of the firm.
53. Firm must indicate the country of origin of the machine, and submit Invoice along with shipping documents and custom clearance details along with the supply.
54. The company shall quote separately for diagnostic kits, accessories, accessories reagents, calibrators and controls in Indian rupees. For diagnostic kits, accessories, accessories reagents, calibrators and controls the price for the first year shall be quoted. The price of diagnostic kits, accessories, accessories reagents, calibrators and controls shall be frozen on rate contract basis for the period of 5 years of warranty and an additional can be extended for 2 years. The company shall quote on the following format:
- a) Equipment
  - b) Diagnostic kits (yearly price X 10 years)
  - c) Accessories and accessories reagents (yearly price X 10 years)
  - d) Calibrators and controls (yearly price X 10 years)
  - e) CMC charges (5years)
  - f) Total
55. **Supply of diagnostic kits:** Company shall supply diagnostic kits in two instalments per year. The first installation of the diagnostic kits shall be supplied within one month of installation of the instrument.
56. **Penalty:** If due to any lapse of the instrument, diagnostic kits, accessories, accessories reagents, calibrators and controls, the reports generated on a particular day are not of the required standard, the company shall be levied a penalty of Rs. 2000 per day.
57. Foreign firms if quoting, they must have minimum 5 years of experience in India directly, firm must submit performance statement along with the offer. Offer without any performance will be treated as non- responsive.
58. Minimum 300 Installations of similarly machine in any Government Hospital/ Railway hospital or any reputed Institutions must be there. Firm must submit their installation details along with the offer; without that offer will be treated as non -responsive.



59. Firm must submit minimum 20 customer satisfaction report about their performance and sales and services after installation. Without that offer will be treated as non- responsive.

60. For deciding the technically suitable lowest offer (L1) the following will be taken into consideration

- a. Machine cost
- b. Cost per report x yearly samples
- c. Comprehensive maintenance contract cost.

Chief Lab supdt./RH/SBC