## SPECIFICATIONS OF FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER (HIGH SPEED)

- 1. It should be Fully Automated, Fully-Open Random Access Biochemistry Analyzer with STAT testing capability.
- 2. The Instrument should be capable of all routine and special biochemical tests including Specific Proteins, Therapeutic Drug Monitoring, Drug of Abuse, and Immunoturbidimetric Assays serum, plasma, urine, CSF etc.
- 3. Throughput of machine should not be less than 800 Photometric tests/hour and about 1200 tests/hour with ISE.
- 4. It should have ISE for electrolytes Sodium, Potassium and Chloride.
- 5. It should be able to perform test of HbA1c using and coagulateed whole blood.
- 6. Reaction Cuvettes should be at least 150 permanent cuvettes For permanent cuvettes the cleaning should be with at least 7 or more steps.
- 7. It must have Low water requirement of not more than 30 Litres/hour even during full load use. It must have alarm for fluid levels.
- 8. Sample dispenser probe must have level and crash sensors. Should have both internal and external washing facility for the probe. Liquid level detection, clot, collision and bubble detection must be present. Removal of Clot by pressure facility. Facility of Repeat washing the probes & cuvettes as per user requirements.
- 9. It should show alert whenever sample is turbid, icteric, lipemic or hemolysed.
- Total Reactions Volume and Reading Volume should be low about 120μl or 150μl for most chemistries and maximum 450μl.
- 11. Must be programmable for all test menus and state of art work stations.
- 12. Must have Self Diagnostic Tests with Error Messages and Online Display.
- 13. It should have Diffraction Grating Photometric Detection with 12 or more wavelength selections in the spectral range 340nm to 800 nm. The wavelengths 405nm, 450nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm should be selectable Wavelength Precision ±2nm. Linear Range 0 3 Abs.
- Light source Halogen/Xenon lamp should be covered under warranty and should have minimum life of 1000 hours.
- 15. Assay Types should be End-point, Kinetic, Fixed rate, Monochromatic, Bi-chromatic, ISE, Turbidimetric and Homogenous.
- 16. It must have Provision of barcode reader.
- 17. Equipment should be supplied with compatible External water treatment system Compatible On-line UPS for entire machine with one hour backup and 3 ton A.C. with Stabilizer.
- 18. Must be programmable for all test menus and have state of art work station. It should have capability for predilution and automatic repeat of the diluted sample. Automatic repeat for reduced or increased volume of sample.
- 19. Must have continuous loading of samples with on board capacity of at least 75 samples.
- 20. Cuvette temprature should be maintained at  $37 \pm 0.1$  C
- 21. Mixing of reactants should be done by stirres. It should have at least 80 positions for various reagents in cooled reagent compartment.
- 22. It should have good Real-time QC programme with L-J graph for NABL activities. Printout of QC charts and reports. Data Management should be in Real-time with monthly QC DATA LOGS, Automatic plotting of Levy-Jennings charts and Alarms when control results are out of range.
- 23. It should have Automatic printout of Patient Reports and full Patient Demographic.
- 24. Connectivity Connect with bidirectional LIS/HIS system: Extensive data management software, compatible & programmable windows based comprehensive data processing and management system. Graphical user interface software, LIMS Capability, Complete backup of data base for calibration control and patient sample results.
- 25. Reagents probes must have liquid level sensor and crash detection. Should have internal and external washing facility for probes. All probes should have long lift of at least 24 months and covered in warranty otherwise free replacement during every breakdown if 24 months life is not obtained each time even during future replacements.
- 26. If should have two separate probes for reagents and separate probe for samples. Must typically use between 2-15 μl sample in 0.1 μl steps and 20-300 μl reagents in 1 μl steps. For paediatric samples minimum dead volume of sample cup not more than 50μl.
- 27. It should support Sample Tubes of various standard sizes.
- 28. It should be able to take blank cuvette reading for each run.
- It should have a dedicated program for precision study. Vendor must provide QC software to manage QC data
  of the laboratory as per NABH/NABL requirements.
- 30. Should have pre and post dilution of samples and rerun capacity of out of range samples.

- 31. Calibrations should be automatic by 1, 2 point linear method and non-linear method. Calibration by Factor, Point to Point, spline & exponential type be available. Several types of calibration curves should be obtained by using multiple calibrators per test. Calibrator tracking and control with repeat facility be available. Should be able to perform serial dilutions of Calibrator.
- 32. The Operating System should be system compatible, Windows based Software.
- 33. It should have capability of: Reaction process monitoring, Cross-contamination pervention, Unclean cup memory & skipping, Patient information memoty, Automatic, Audit report, Report statistics, Reference range inputs, Automatic dormancy and start up, Report Printing, Report formats in user-defined mode.
- 34. It should have Reagent Inventory Calculation of remaining reagnet volume and number of tests available. Alerts for reagents shortage to ensure continuous analysis by Reagnet refill message and monitoring.
- 35. It should have the compatible PC.
- 36. Complete service manual & circuit diagrams, operating manual must be provided.
- 37. Comprehensive and full training of all users by supplier for operating equipment and trouble free maintenance at installation point.
- 38. System should be supplied with all necessary pre requisites, start-up kits, QC and calibrators, free reagents and consumables for testing and calibration.
- 39. Vendor must have 3 year standing in India and have done installations of same machine in any Govt./Semi Govt./Reputed NABL accredited Lab. and provide the user list with address and telephone contacts.
- 40. Vendor must give written assurance & undertakings that they have an Instrument specialist who will attend to any machine related problems within 24 hours.
- 41. The system should be quoted with standard one year guarantee and AMC/CMC for next three years should be quoted after guarantee period.
- 42. Demonstration of functionality should be arranged at jaipur.
- 43. Service back up should be available within 24 hours after which penalty of Rs. 5000 will be imposed for each passing day. Company should have Jaipur based engineer.
- 44. System should be FDA & CE approved.

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