SPECIFICATIONS FOR AUTOMATED BIOCHEMISTRY ANALYSER

S. no.	Areas	Specifications
1.	**Equipment:**	1. Newfullyautomated, random accessimmunoassaysystem 2. The complete system should be the latest on the production line and mustnotbe refurbished 3. TheequipmentandallreagentsshouldbeEuropeanCE-IVD/USFDA/CDSCO/BIS approved. 4. Suppliermustprovideoriginaldocumentaryproofofthedateandplaceof manufacturingof equipmentat the timeofsupply. 5. Anynecessaryupgradation in equipment requiredin futurewill be 6. thesupplier'sresponsibility.
2.	**TestSpecimen**:	1. Shouldprocess Serum,Plasma, Urine,CSFand other bodyfluids
3.	**AssayMode**:	1. ShouldbebasedonElectrochemiluminescence/Chemiluminescence
4.	**Throughput**	1. Shouldbe a minimumof 200tests/hour
5.	**On boardAssay-capacity**	1. Shouldbea minimumof 25reagentpositions
6.	**Reagent**:	1. Reagentpacksshouldbereadytousewithautomaticonboard reagentmixing 2. Onboardreagentstabilityofa minimumof 4weekswithcalibrationstabilityof a minimum of 4 weeksshould bethere.
7.	**Operational part**:	1. Singlepointdataentryandresultviewingwiththe windows-basedoperatingsystem havinga widetouch screen monitor 2. Continuousprintingfacilityofpatientresults, QCand calibrationdetailsshould beavailable. 3. Optionoftakingback-up ofpatientresultsandQCreportsonexternalservicesand USBdevices shouldbepossible 4. Onboardreagentinventorywithautomatictrackingandnotificationof remaining tests, onboard stability and expiration, calibration andstorageconditions foreach packshould bethere. 5. Refrigerated reagent compartment/disk with temperature 4-10°C andhumiditycontrol should beavailable.
8.	**Sampleh andling**	1. Shouldhaveaccess to samples duringoperation. 2. Samplesmixingshouldbestirrer-less 3. Shouldhaveseparateprobes forsamplesandreagents.
9.	**SampleCo ntainer**	1. Equipmentshouldbeabletowork withalltypes ofsamplecontainersincludingstandard primarytubes(both vacuum andnon-vacuum tubes),samplecups,microcups andcupsonthe tube.
10.	**Samplec apacity**	1. Minimum100onboardsampleloadingcapacityatatimewitha continuousloadingfacilityshould beavailable.

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11.	**Stat Facility**	1. Stat prioritization should be available on the system without interrupting the routine run.
12.	**Reaction cuvettes**	1. Should be of the disposable type
13.	**Assay requirement:**	1. Should have onboard sample auto dilution at least up to 1000 times. 2. Should have Clot detection, bubble detection and low sample detection facility 3. Should have a lot-to-lot calibration for each assay. 4. Reaction time should be within 10 – 60 minutes 5. System should have automatic re-run and automatic reflex testing 6. Should have facility for continuous random access, including loading 7. and unloading of reagents, other consumables and samples without stopping the analyzer.
14.	**Calibration and Quality Control**	1. Random access calibration should be possible. 2. Provision of inbuilt QC monitoring system by LJ plots and Westgard and Configurable QC-based rules should be available. 3. User-defined Auto QC and Auto calibration ordering should be possible.
15.	**Information Technology**	1. It is the responsibility of the vendor to integrate the software of the equipment with the existing HIS of the hospital for interfacing the results, free of cost. 2. The software should have the capacity for data management and auto validation. 3. HIS port, Ethernet port and USB port should be available along with the equipment 4. Real-time monitoring of QC violations, auto-verification and turn-around time for samples should be available. 5. Onboard sample data storage capacity should be a minimum of 25,000 patient results.
16.	**Equipment requirements**	1. Should be able to work with Voltage: 200-240 V and Frequency 47-60 Hz 2. Appropriate battery backup should be arranged and maintained by the bidder at no extra cost. 3. If required for the equipment, a suitable water plant should be arranged and maintained by the bidder at no extra cost. 4. Floor drain kit should be set up by the bidder to route waste directly to a floor drain
17.	**Test-Reagent:**	1. The firm has to quote the cost per reportable test (CPRT) for the investigations along with specifications (sensitivity and linearity) mentioned in table 1 which will be frozen for three years. 2. The firm is requested to give the CPRT for the investigations available other than those in the table with the minimum number feasible for the OPEX model as well as the cost of the kit and calibrator if the statistics are below the minimum number and the rates will be frozen for 3 years.

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		3. The firm should maintain enough reagent stock for uninterrupted services in their analytical refrigerator with a data logger within the lab as per NABL guidelines.

		4. All controls, calibrators, wash reagents, assay diluents, disposablesample probe tips, reaction cuvettes and other consumables necessaryfor the investigationsmentioned inTable 1should be provided freeofcost forthe period ofOPEX purchase. 5. Any consumables not mentioned above but essential for performingthe investigationsmentionedinTable1shallhavetobesuppliedfreeofcost forthe entireworkload duringthe validityofthe contract.
18.	**Siteprepara tionandInst allation:**	1. The vendor should inspect the site before installation and prepare thesiteforinstallation andproper functioningoftheequipmentround theclock,freeofcost. 2. Bidderwillberesponsibleforinstallation,commissioningandtrialruns providing free trial kits for all tests along with respectivecalibrator and control. 3. Thefirmshouldprovide onekitperparameter atnocostfortrial andtrainingpurposes. 4. Equipment being installed should be validated in-house anddocumentsforIQ/OQ/PQhastobeprovidedtotheInstitute
19.	**Maintenance**	• 3 years of complete maintenance including supporting systems likeUPS,watersystems,computer, printerandperipherals likeACatnoextracost to theInstitute.
20.	**QC**	1. ThreelevelsofinternalQCshouldbeprovidedbythebidderfromanFDA-approvedthird-partymanufacturer. 2. NABLstandard willadherefor runningQCs andthe numberofQCswill be paid as perCPRT. 3. OnfailureofQC, theCPRT fortroubleshooting will bebornebythefirm.
21.	**Standby/Backu p equipment**	• A unit from the same manufacturer with a throughput equivalent tothat of main equipment should be provided as standby equipment,freeof cost. CPRTwill remain thesame for thisequipment also.

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.

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4. Other necessary certifications, if any, will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e.,

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Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.

17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.

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23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

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