Specification for fully automated biochemistry analyzer

For ~~Govt~~ Regional COVID-19 Lab at Dist Chilaw & Iranawila.

			Priority	Conformity		Remarks	Page no of technical
			C= compulsory	Yes	No		
Infrastructure	1	The unit should be a benchtop or floor standing model which is capable of producing final test results from the time of sample loading wihtout an intervention of the operator.					
	2	The unit shall operate optimally at an ambient temperature of 25°C or more and should not be at a level less than 25°C.	C				
	3	All infrastructure which is required in addition to water should be available and be clearly mentioned. The cost of such shall be indicated.	C				
	4	The unit could be operable on a power supply of 230v ± 10%, 50Hz. Online UPS with adequate kvA, power stabilizer, isolation transformer and any other ancillary unit required for functioning should be supplied and cost of such should be quoted seperately.	C				
Technical details	5	The unit shall be an open or a close system. In case of a close system there should be minimum of 15 open channels for the user to use 3rd party reagents and when such 3rd party reagent is used the unit shall produce accurate test result using any reasonably good quality reagent.					
	6	The unit should be a multi-channel system with, random access, automatic rerun, automatic reflex testing capabilities and it should be capable of performing routine chamical pathology tests on plasma, serum, urine, CSF and other body fluid samples.	C				
	7	The unit should support end point, fixed point, rates and ISE analytical measurement principles. If such operation is not possible all additional infrastructure and temperature requirement should be specifically mentioned and such requirement should be provided by the supplier without any additional cost to the user institution.	C				
	8	The unit shall have the ability to perform automatic blanking and produce the final test results without intervention by the operator.	C				

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9	The availability of anintergrated immunoassay system at least with a capability to performimg few common and demanding tests such as TSH,FT4,FT3,Troponin I,HbA1C should be mentioned					
11	The unit should support spectrophotometric, colorimetric, turbidimetric and ISE analytical measurment principles.	C				
12	The unit shall be operable in random access, batch analysis and STAT analysis modes.	C				
13	The unit shall have the ability to perform minimum of 25 tests at any given cross section of time with the facility of a 3rd or 4th reagent.					
14	The unit should have separate probes for reagents and samples.	C				
15	Each dispencer probe should have level and crash detection sensors	C				
16	Reagent probe damage due to crash detection errors should be repaired or replaced by the supplier free of charge.	C				
17	Probes should have facilities to detect clots and bubbles. In addition, there should preferably be a facility to remove clot by pressure.					
18	All probes should have long life and for probe life should be specified in the offer.	C				
19	Probes should have internal and external washing systems.	C				
20	Mixing of reactants should be done by separate stirrers					
21	The unit shall have a suitable mode of mixing the sample with the reagents while avoiding cross contamination and therefore, analyse with a separate strire, is given a preferance					
22	The unit shall have a photometer which is capable of measuring the absorbance of both end – point and kinetic assays in both UV and visible ranges starting from 320nm (or lower) to 700nm(or higher)					
23	Total Reaction Volume and Reading Volume should preferably be low as l00 µl and should not exceed 300 µl.	C				
24	It should have refrigerated reagent disk or chamber with at least 50 positions.	C				

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25	The unit should have on board reagent capacity for 40 methods and for reagent containers of different volumes (eg 15mL,30mL,120mL)in order to save the wasting, is an advantage.					
26	The unit should typically use a sample volume not exceeding 80µl in 0.5µl steps and reagent volume not exceeding 200µl in 1 µl steps.	C				
27	Either the reagent dead volume or sample dead volume should not exceed 50 µl.					
28	Cuvette and sample chamber temperature should be maintained at 37±1˚c.					
29	The unit shall have facilities to prevent evaporation of samples and reagents during the analytical run and storage.	C				
30	The unit should have the facility to monitor and graphically display the individual test reaction against the time for samples, QC and calibrators for a meaningful analysis of individual reaction to detect an analytical error. The unit should have the facility to display calibration curves or calibration response to evaluate the calibration.	C				
31	Lot to lot transition of results with regents and calibration should be minimum.					
32	The calibration of the unit shall be possible either with the calibrator supplied by the manufactures or with a 3rd party calibrator.	C				
33	The unit should have records on at least 2 sets of calibration with two different lots of calibrators at any given time.	C				
34	This unit shall be capable of providing out of control and out of calibration alerts.					
35	The unit should be able to perform serial dilutions on calibtrators and samples.	C				
36	Time should be at least 30 day calibration stability with auto or manual calibration. The analytical system and reagents must be stable enough to maintain a given calibration at least for 30 days. Preferance is given for a calibrators and reagents with higher stability. Expected duration of stability should be provided.	C				

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37	The unit should have onboad reagent inventory indicators and facility to calculate remaining reagent volume for possible number of tests for remaning onboard reagents. The unit shall preferably have a reagent critical level indicators. It should be possible to calculate the number of tests with the remaining volume of reagents.	C				
38	The unit shall have facilities to detect liquid levels to alert the operator prior to analysis samples and reagents which are carring volumes less than the minimum required amount.	C				
39	The unit should be capable of providing flag indicators for out of reference range results, level of haemolysis, lipaemia (turbidity) and bilirubinaemia preferable at uses defined limits. Such signal should be displayed over the monitor and should appear in result print outs.	C				
40	The unit should have an internal quality control programme with graphical representation of QC performance on charts and tabulated format. Supplier should have an external quality control program, preferably with a facility to release evaluated results within 24 to 48 hours duration. In the absence of such EQC program to supplier, local agent should be able to facilitate to obtain EQA program from a 3rd party, preferably FOC	C				
41	The unit shall have facility to use third party internal quality control material on user's discussion.	C				
42	The unit should have adequate hazard preventive measures within the unit. There should be malfunction, malperformance, power loss and fire detection indicator systems. The suppliers technical staff should ensure the optimum level of function of such systems and indicators in all times of operations within warranty and service agreement period.	C				

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43	The system should have appropriate biosafety precautions and userfriendly waste handling system in order to prevent any spillage and to avoid contamination with the biological and chemical waste generated inside the analyser. Preferebly a closed system to dispose waste without manual handling is a cumpulsory requirement	C				
44	There should be a self-monitoring system to monitor the degree of wear and tear of replaceable parts for the user to be alert before reaching the critical limit of them.					
45	The unit shall have continuous cuvette loading facilities and sample loading facilities without interruption to the ongoing testing process or the test run.	C				
46	The unit shall be operable with distilled water or deionized water when the unit is operable with distilled water the water consumption should not exceed 8L/H. If a special type of water is needed (eg de-ionized) a separate water plant to genarate the required type of water should be supplied free of charge with the unit and the supplier should provide a maintenance agreement including labour and spare part cost for a minimum of five years.	C				
47	The unit shall support minimum 50 sample positions with continuous loading.	C				
48	The unit shall have facilities to load samples, reagents and reaction cuvettes continuously, without interrupting the testing process which is in operation at any given time.	C				
49	The unit should support bar code reading facility for positive sample identification.	C				
50	The unit shall be supplied with an in built barcode reader for QC, calibrator and reagent identification	C				
51	The unit should have the facility for continuous loading of STAT samples without interrupting the routine run. Minimum of 20 STAT sample positions for very urgent samples should be present.	C				

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52	If an inbuilt computer system is not provided with the unit, supplier should provide a brand new computer with latest configuration. (Minimum- Core i5 fifth generation processor, 1TB hard disk, 8GB RAM, DVD Drive, 4 USB 3.0 ports, 20 inch LED colour monitor with lisenced windows operating system.) Bidder should provide such system free of charge. The unit should have minimum 1TB external or internal storage capacity for storing all raw performance data including patients, QC calibration, Reagent usage and results.	C					
53	There should be an interface system compatible to HL-7 with bidirectional LIS. Routine and STAT test requisition should be possible with patient dermographic data downloading from host/LIS. The supplier should provide a HL - 7 compatible interface free of charge with the unit. Availability of a suitable LIS free of charge with the unit is preferable.	C					
54	The unit should be capable of performing routine biochemical tests such as, Glucose, AST, ALT, ALP, gamma-GT, albumin, total protein, total bilirubin, direct bilirubin, creatinine, blood urea, calcium, magnesium, phosphate, cholesterol, triglycerides, HDL, direct LDL, paracetamol, salicylates, CRP, micro albumin, urine/CSF protein, rheumatoid factor, sodium, potassium, chloride, lithium,Total CO2 ,Lactate, iron, TIBC, CK, CK-MB,LDH,Lipase and UA. The unit should have sample pre dilution capability so that serum plasma, urine and CSF can be directly analyzed with no requirement for manual dilution.	C					
55	The unit should preferably have the facility to analyze ADA, acetaminophen (paracetomol), lactate and ammonia in blood or serum samples.						
56	The unit shall be capable of autodiluting samples up to 1:200 when performing protein and creatinine for urine.						
57	The unit should be supplied with an inbult ISE unit.	C					
58	The ISE unit must be capable of testing Sodium, Potassium,Chloride and preferably be capable of testing ionized calcium and lithium.	C					

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	59	The unit shall perform at least 300 test/hour only with photometric system and at least 100 test/hour only with ISE system.An analyzer with higher capacity for both photometric and ISE is an advantage.					
	60	When random access mode is in used the unit should be capable of completing minimum of 30 samples / hour or minimum of 300 tests/hour. An analyzer with higher capacity is an advantage.					
	61	The unit shall be capable of producing calculated parameters utilizing the analyzed or fed results. Eg. LDL Cholesterol, Osmolarity, Albumin to Globulin ratio ,Corrected calcium etc.	C				
	62	Electrodes for Na, K and Cl should have a minimum lifespan of 6 months and such period should be warrented. Referance electrode should be warranted for a period of 1 year. If such a warranty can not be provided maximum period of warranty and the cost for electrode at the 5 year fixed rate should be clearly mentioned for each electrode.	C				
	63	Light source should be covered under warranty and should have minimum life of 3000 hours. If third party compatible lamps are available it should be clearly mentioned. Cost of such lamps that are offered with the unit should be compatible with the prevailing market rates.	C				
Out put capacity	64	The unit shall have a printing device having the facility of printing the patient's final report on a user defined report format or mode, quality control charts, data and screen print of the monitor.	C				
	65	The unit should have ability to define users with different levels and previlages with restrictions on altering raw data.	C				
Input	66	The unit shall be able to use the different size primary tubes instead of sample cups particularly for small volume samples.					
	67	The unit shall be able to use the primary sample tubes (75 x 12mm) or sample cups to load samples.	C				

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68	Reaction cuvettes should preferably be disposable. When semi permanent or permanent cuvettes are used there should be an efficient automatic onboard washing system with 5 or more steps to reduce carryover. Preferably there should be a seperate probe for cuvette washing. Cost of cuvettes, life time and the operational cost of onboard washing system including detergents etc should be quoted seperately.The unit should have an effective system of screening cuvette to identify those which could genarate an analytical error due to light impedence. Cost of the cuvette should be quoted with the bid. If auto laundry system is available, a lifetime warranty to the system should be given with the unit.					
69	Preferably, the unit should have the abillity to change cuvettes on individual basis.					
70	The bidder shall submit the cost of reagents for each analyte for a period of 6 months on the basis of attached statistics herewith assuming a consumption of two levels QCs daily and use of calibrator aliquate once in three days. Procedure used in such calculation should be clearly provided. Statistics are attached to the tender document.	C				
71	The bidder shall submit the cost of consumables other than reagents including periodic maintenance kits, electrodes, cuvettes, cost of washing system (detergents etc.), light source etc on the basis of given statistics for a period of six months. Procedure used in such calculation should be clearly provided. Statistics are attached to the tender document.	C				
72	The local distributor should agree to supply the reagents, quality controls, calibrators, other consumables and services on a constant fixed price for at least 5 years after successful installation of the unit and also should be in a position to supply reagent and consumables without interruption of services.	C				

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	73	With the offer bidder should submit the price, pack size and tests per pack for full range of available system reagents. The bidder should provide the cost/ test on the basis of given statistic and 5 year fixed reagent cost. Details of cost/ test calculation should also be provided.	C				
	74	Reagent/method calibrators quoted for the unit must be traceable to an Standard Reference Material.	C				
Support Service	75	Supplier should produce details of technical staff assigned for the service and maintenance of quoted equipment. The addresses of available workshop facilities within the closest proximity should be mentioned.					
	76	The supplier shall preferably provide service and maintaine free of charge during the period when the institution uses supplier recommended reagent.					
	77	The unit shall be supplied with a complete and detailed set of operation and service manuals in English.	C				
	78	The unit shall be preferably provided with an external quality control program free of charge. Such external quality control program should preferably be a daily basis one with minimum of two levels.					
	79	The unit should have conprehensive warranty for a period not less than 36 months from the date of successful installation on full parts and labour basis. Such warranty shall include service, spare parts and preventive maintenance during the period of validity. The warranty period should be calculated from the time of successful installment and not from the time of delivery to the hospital.	C				
	80	The local representative should propose a 5-year service and maintenance contract after the warranty period and the cost of such contract shall be separately indicated. This shall include details of routine/ periodic maintenance, services and parts to be replaced periodically, with the price breakdown. There should be a warrant assurance from manufacture on availability of reagents and spareparts for at least for a period of 10 years.	C				

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	81	The local agent shall preferably provide a backup system on a temporary basis, when needed as part of the service provided by the local agent.					
	82	The local agent should have factory trained technical staff operating within the region. Details of such technical staff assigned for the service and maintenance of quoted equipment should also be provided. The addresses of available workshop facilities within the closest proximity should also be mentioned.	C				
	83	The local distributor should agree upon repairing of the entire unit within 24 hours of informing about out of order situation and should provide a backup instrument if the repair takes more than 24 hours from the time of informing a break down and failing such should bear the cost associated with the investigations that would be sent to the private sectornas aresult of service interruption.	C				
	84	Periodic upgrade / update versions of software should be provided free of cost during and after the warranty period for a period of 10 years of successful commisioning of the unit.	C				
	85	When the laboratory uses machine specific reagents the local agent or the supplier should agree to provide services free of charge during the period of such use	C				
	86	The local agent should provide on-site training to the end-users (Laboratory technical and medical staff) before comminsioning of the unit and ensure competence of the laboratory staff in all aspects of operations and troubleshoots in handling the unit. The agent should also agree to provide additional training when required.	C				
	87	The supplier should cooperate with continuous education of the staff on hardware and soft ware technical aspects of the unit as it is an essential element in continuous quality improvement cycle.	C				

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Spare parts	88	A detailed proforma invoice of the equipment describing the parts and accessories offered as requested by the specifications together with their make, model, country, unit price, quantity, total price and reference numbers of accessories, spare parts and consumables with the period of warranty offered should be compulsorily provided with the offer.	C				
	89	Bidder should quote the price of full range of available spare parts, accessories and periodic maintenance kits. Price of such items should be fixed for five years term. Items that are not given in the list are assumed to be provided by suplier/ local agent free of charge.Tthe list of consumables and spare parts should be separately mentioned.	C				
	90	The unit should be in production line at present and for further 10 year.	C				
	91	Manufacturer's confirmation on availability of spare parts for at least 10 years should essentially provided with the offer.	C				
Tender documents	92	The bidder shall submit a statement of compliance (or otherwise) in respect of every clause in this specification. The bidder shall also provide printed illustrated original technical literature to substantiate conformity with such statements. Relevant page numbers of these details should be clearly mentioned against each specification in the appropriate column.	C				
	93	The local agent should provide a user referance list. When there is no such referance list supplier/local agent should provide a sample.	C				
	94	The bidder should supply a page index of tender document.	C				
	95	Preferably unit should have approval from reputed organization such as FDA, CE, IFCC.					
	96	The product must be CDDA registered & manufacturer should be ISO certified for quality, safety, standards.	C				

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Test Name	Number of tests for 6 months
1 Albumin	5000
2 Amylase	1000
4 ALT	10000
5 AST	10000
6 ALP	3000
7 Glucose	10000
8 Cholesterol	3000
9 Creatinine	15000
10 Direct Bilirubin	500
11 Total bilirubin	2000
12 Urea	15000
13 CRP	10000
14 Na	15000
15 Potassium	15000

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