

Fully Automated Bio-chemistry Analyzer		Bidders Remark
Purchaser's Technical Specifications		
Fully Automated Bio-chemistry Analyzer		
Manufacturer		
Brand		
Type / Model		
General Specifications		
System Type	Bench Top, Discrete, Fully automated, Random Access Clinical Chemistry Analyzer for analysis of Serum, Urine, CSF, Plasma, Hemolysate and others	
Throughput	200 Tests per hour for photometric tests with an option to attach 4 channel ISE module (Na/K/Cl/Li) for up to 350 Test/hour throughput with ISE.	
Programmable Parameters	System should have no limit for programmable Test parameter and Calculated parameters	
Calibration Curves	<ul style="list-style-type: none"> • K-Factor, Linear (one point, two point and multipoint), Logit-log, Spline, Exponential, Polynomial • Multipoint curves for up to 10 points • One point correction to multi-point calibration line is provided • Automatic Dilution Line Created 	
Probe for Aspiration	<ul style="list-style-type: none"> • Single Probe for Reagent and Sample • Probe with level sensor • Vertical obstruction detection feature to prevent crash • Outside and Inside preheated de-ionized water 	
On Board Refrigeration	<ul style="list-style-type: none"> • Should have on board reagent cooling with refrigeration unit for maintaining the reagent at 8-12°C • System should have facility to keep the refrigeration unit ON while the instrument is turned OFF 	
On Board Washing	<ul style="list-style-type: none"> • System should have washing unit for the proper washing of reaction cuvettes. • The washing should be minimum 8 step washing • Inbuilt cuvette overflow protection system 	
Inventory Management	<ul style="list-style-type: none"> • System should provide the residual volume of Onboard reagents • Software must have the feature to provide possible number of tests from each reagent bottle on board 	
Quality Control	<ul style="list-style-type: none"> • Facility to run 3 level quality control • Within day and day to day X-Mean and X-Range diagram • Mean, SD, %CV, R should be calculated for each parameter 	
Sample Processing		
Sample tray	<ul style="list-style-type: none"> • Minimum 35 positions for samples, Calibrator and Q.C • Facility to place STAT sample anywhere on the sample tray • STAT samples should be able to run even by interruption during analysis 	
Sample Container	<ul style="list-style-type: none"> • Should be able to place Blood Collection Tubes directly. • Blood collection tube of 5 ml, 7 ml and 10ml or Micro cups 500ul or 2ml Sample Cups • Dead Volume should be: <ul style="list-style-type: none"> ≤ 400ul for 5ml/7ml Sample tubes ≤ 130ul for 2ml Sample cup ≤ 80ul for Micro Cup ≤ 700ul for 10ML Sample Tubes 	

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Sample Volume	Sample volume programmable 2-70ul with possibility of volume adjustment in incremental of 0.1uL.	
Sample Dilution and Rerun	<ul style="list-style-type: none"> • Dilution ration programmable from 2 to 100 times • Auto Dilution by Instrument once programmed for the parameter • Auto Dilution for repeat run programmable • Facility to program repeat run by direct increase/decrease of volume • Auto rerun according to abnormal result or out of range etc. 	
Sample Identification	<ul style="list-style-type: none"> ▪ Barcode reader must be provided for sample ID recording ▪ Position ID through software ▪ Position ID for STAT sample 	
Reagent Unit		
Reagent Tray	<ul style="list-style-type: none"> ▪ Turn Table type reagent tray ▪ Supplier must provide one additional reagent tray ▪ Common Reagent tray for R1 and R2 ▪ Minimum 45 reagent positions for R1/R2 ▪ Must have reagent tray cover for protection of reagents. ▪ Dead Volume of reagent should be: <ul style="list-style-type: none"> ≤ 2mL for R1 ≤ 1.5mL for R2 	
Reagent Identification	<ul style="list-style-type: none"> ▪ With Barcode ▪ With Position ID 	
Reagent Volume	Reagent 1 (R1) should be programmable between 50 – 300ul and Reagent 2 (R2) between 10-300ul; adjustable in 1 ul incremental step	
Onboard Reagent Inventory Management	System Software should have Reagent Inventory Information features via RFID like pack size, lots no, expiry etc.	
Reaction Unit		
Reaction Tray	<ul style="list-style-type: none"> ▪ Turn table type rotating reaction tray ▪ Minimum 45 Hard Glass Reusable reaction cuvettes ▪ Reaction tray must be temperature controlled ▪ Reaction temperature $37 \pm 0.2^{\circ}\text{C}$ by dry incubation ▪ Minimum 180uL reaction volume ▪ Cuvette Integrity Check to eliminate testing in bad cuvettes ▪ Individual cuvette must be replaceable and not multiple cuvettes or whole set of cuvettes. 	
Reaction Solution Mixer	System should have minimum 3 speed variable mixer for proper mixing of reaction solution.	
Water Consumption	Less than or equal to 7Ltrs/hour	
Optical System		
Light Source	Halogen lamp	
Wavelength	<ul style="list-style-type: none"> ▪ Minimum 8 wavelengths: 340, 405, 505, 546, 578, 600, 660 & 700nm through filter selection ▪ One or Two wavelength chemistries can be performed 	
O.D. Range	0 - 2.5	
Detector	Silicon Photo-diode	
Software Features		
Process Control	<ul style="list-style-type: none"> ▪ Should have facility to show the In Progress, Completed test analysis ▪ Should have facility for reagent blank and sample blank correction ▪ Reaction curve must be graphically displayed in real time 	
Report Generation	<ul style="list-style-type: none"> • Report generation: Patient wise, Test wise, Date wise, Location wise, Abnormal result wise, Doctor name wise 	

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	<ul style="list-style-type: none"> • Lists: Abnormal values list, Re-calculated results list, Repeat run list • Selective Backup of following data is possible: Consumables, Patient, Patient with Results, Test Parameters, Calibration, Error Log, System parameters • Full Backup 	
Result Check and Control	<ul style="list-style-type: none"> • Reference range check by age, gender, sample type • Panic limit check • Reaction linearity check • Reaction mixture absorbance checks • Antigen excess/ prozone check (by reaction time course analysis method) 	
Alarms	<ul style="list-style-type: none"> • Types of alarms: Erroneous operation, mechanical malfunction of analyzer, data processor hardware error, erroneous test results • Alarm level: Notice, temporary halt of analysis, suspension of analysis, system stop 	
System Check	Mechanical movements and functional performance can be checked through diagnostic menu	
User Access	<ul style="list-style-type: none"> • Password provided to reject an access to selected menus • Access rights for multiple users 	
Operation Unit (PC)	<ul style="list-style-type: none"> • PC: Windows machine, IBM compatible, OS: Windows 10 or compatible with machine software, CPU: I3 or I5, RAM: 4 GB or above, Hard disk: 500 GB more, Console: 15 inch color monitor. 	
System Interface	<ul style="list-style-type: none"> • Analyzer – PC: USB bi-directional • USB connectivity through USB 	
Accessories spares and Consumables		
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
	Supplier must provide start up reagent kits. The start kit must include One Kit Pack for each of Glucose, LFT, RFT, all required wash or buffer solutions etc.	
	Manufacture Company should have own manufactured brand reagent, Calibrator and Control with CE certified	
Operating Environment		
	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.	
	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
Standards and Safety Requirements		
	Must submit ISO13485:2003/AC:2007 Certificate for Medical Devices AND the product must be USFDA approved with CE certified.	
	Supplier must attach user list of the quoted model	
User Training	Must provide user training (including how to use and maintain the equipment).	
Warranty	Comprehensive warranty for 1 years after acceptance.	
Maintenance Service During Warranty Period	During the warranty period supplier must ensure corrective / breakdown maintenance whenever required.	
Installation and Commissioning	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.	

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Documentation	User (Operating) manual in English Service (Technical / Maintenance) manual in English List of important spare parts and accessories with their part number and costing. Certificate of calibration and inspection from factory.	
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Detailed Technical Specification for Fluorescence Immunoassay Analyzer

S.N	Purchaser's Technical Specification	Bidder's Compliant Sheet		
	Fluorescence Immunoassay Analyzer	Yes /NO	Page No in Catalog	Remarks
	Manufacturer:			
	Brand:			
	Type / Model:			
	Country of Origin:			
1	Description of Function			
1.1	FIA machine to measure various type of immunoassay present in whole blood, serum, plasma and urine.			
2	System Configuration			
2.1	FIA Machine with built in printer and standard complete accessories.			
3	Technical Specifications			
3.1	Sample type: Whole blood, serum, plasma, urine			
3.2	Shall have FIA measurement system.			
3.3	Specific test parameters like HbA1c, full range CRP, FT3, FT4, TSH, mALB, D- Dimmer, Vitamin D, Vit B12 IgE, AMH should be available.			
3.4	Sample Volume: Approx. 5ul			
3.5	Should be microprocessor-based system.			
3.6	Should have LCD color touch screen.			
3.7	Should process the fast result within minimum. 10 minutes.			
3.8	All in one cartridge for single test.			
3.9	Fully Automatic one step operation.			
3.10	Data Storage of at least 5,000 Tests.			
3.11	Auto identification of test by barcode on reagent cartridge.			
3.12	Should have zero carryover.			
4	Operating Environment			
4.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.			
4.2	Power supply: 220 – 240VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3m in length.			
5	Standards and Safety Requirements			
5.1	Must submit ISO13485:2003/AC:2007 for Medical Devices.			
5.2	Must submit CE, NGSP or USFDA approved product certificate.			
6	User Training			
6.1	Must provide user training (including how to use and maintain the			
7	Warranty			
7.1	Comprehensive warranty for 2 years after acceptance.			
8	Maintenance Service During Warranty Period			
8.1	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.			

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9	Installation and Commissioning			
9.1	Supplier must accomplish proper installation and commissioning of the equipment on site.			
10	Documentation			
10.1	The bidder should submit a valid authorization from the manufacturer			
10.2	The bidder should submit the original brochure or e-copy.			
10.3	User (Operating)/ Service (Technical / Maintenance) manual in English			

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	Purchaser's Specifications Patient Monitor, 5 parameter		
	Name of Bidder		
	Manufacturer		
	Brand		
	Type / Model		
	Country of Origin		
	Description of Function		
1	It should be suitable for usage in Emergency, Operation Room and ICU Capable of monitoring ECG, SPO2, Non Invasive Blood Pressure (NIBP), Respiration Rate and Temperature.		
2	It shall operate on AC power supply as well as built-in battery		
3	Five parameter Patient Monitor, portable with complete accessories		
4	Monitor must be able to monitor ECG, Respiration, SpO2, NIBP and Temperature as a standard parameter.		
5	At least 15" high resolution TFT display with LED backlight with touch screen.		
6	Display waveform: simultaneously display of at least 14 waveforms along with related numerical parameters on single screen.		
7	Monitor must have Lithium ion Battery. More than 3 hour battery Backup.		
8	Should have Adult, Pediatric and neonatal measurement mode.		
9	Shall have Protection system against defibrillator discharge.		
10	Shall have at least 72-hour ECG waveform data storage and recall with more than 2000 hour data trends, graphics and tabular view.		
11	2000 groups event, ARR and SpO2 storage		
12	The monitor should be able to configure automatically for new parameters as they are connected.		
13	Should have alarm indicators with different alarm tones and visible alarm lights indicators for different issues.		
14	The key volume, alarm volume and beat volume should be adjustable according to clinical practices and/or preferences.		
15	Shall have Integrated 3 channel thermal Printer to record the events.		
16	Connection and interface: Should have network capability to connect central monitoring system.		
17	Clinicians should be able to "freeze" applications at the bedside and have access to real-time ECG monitoring and other information at the same time.		
18	<u>NIB Measuring range:</u> Systolic pressure: 40mmHg~275mmHg Diastolic pressure: 10mmHg~210mmHg Mean arterial pressure: 20mmHg~230mmHg PR measuring range: 0 to 250 bpm. Accuracy +/-2%		
19	<u>ECG</u> HR measuring range: 15bpm~350bpm HR measuring accuracy: $\pm 1\%$ or $\pm 2\text{bpm}$		
20	<u>TEMP</u> Measuring range : 21.0°C~50.0°C Measuring accuracy: $\pm 0.2^\circ\text{C}$ for range from 25.0°C~45.0°C		
21	<u>RESP</u> RR measuring range: 0rpm ~120rpm RR measuring accuracy: $\pm 5\%$ or $\pm 2\text{rpm}$		
	Accessories, spares and consumables		
a	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.		
b	NIBP reusable cuffs with hose of 3 various sizes (neonate, pediatric and adult) – 1 no. each. • Spo2 Probe with extension set, various size (Neonate, Pediatric and Adult) • 1 no each .• ECG:- 3/5 lead ECG cable		

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	• wire- 1 set• TEMP:- Skin temperature probe- 1 set		
Operating Environment			
22	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug.		
	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.		
Standards and Safety Requirements			
23	Must submit ISO13485:2003/AC:2007 for Medical Devices AND		
24	Must Submit CE (93/42 EEC) Directive certificate and USFDA approved product certificate.		
25	Shall meet IEC 61010-2-081 safety requirements for electrical equipment.		
User Training			
26	Must provide user training (including how to use and maintain the equipment).		
27	Warranty for 2 years.		
28	Maintenance Service During Warranty Period		
29	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.		
Installation and Commissioning			
30	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail		

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