	Specification for Chemiluminescence Analyzer (CLIA)		
	Chemiluminescence Analyzer (CLIA)	Bidder's Compliance Sheet	
	Purchaser's Specifications (f/y-082/83)	Yes/No	Bidders Offer, deviation if any/ Remarks
1	**Chemiluminescence Immunoassay Analyser**		
2	**Manufacturer**		
3	**Brand**		
4	**Type / Model**		
5	**Country of Origin**		
6	**Description of Function**		
	A diagnostic equipment based on the highly specific interaction between an antibody and an antigen. Chemiluminescence Immunoassay analyser is used to perform serological and immunological tests to detect or measure specific proteins or other substances through their properties as antigens or antibodies.		
7	**Operational Requirements**		
	Fully automated analyser, benchtop analyzer to perform the immunoassays from whole blood, serum, plasma, & other body fluids.		
8	**System Configuration**		
	Chemiluminescence Immunoassay Analyser, complete unit with complete accessories, reagents.		
9	**Technical Specifications**		
a)	System shall be based on Chemiluminescence technology for measuring the assays.		
b)	System shall have batch, random or continuous random access.		
c)	System shall have provision of emergency/STAT samples		
d)	First result should come in minimum 12 min or lesser time.		
e)	Onboard reagent stability of minimum 28 days.		
f)	System shall have throughput of minimum 200 tests/hr or more and 24 hour ready to use.		
g)	Should have RFID/Barcode recogniation system for Reagent and Sample.		
h)	system should have at least 80 test can be incubate at the same time , and incubator temperation must be 37 ±0.2 °C		
i)	Reaction vessels (Cuvettee) must be made plasic disposable, Single reaction cup and should be able to load by dumping and could load maximum 500 at a time		
j)	No daily calibration required. Depends on assay parameter.calibration stability at lease 7 days to 28 days		
k)	have system to detect clot and liquid level detection.		
l)	Shall have automatic sample Dilution and Auto Reflex Testing available.		
m)	Inbuilt refrigeration system with controlled temperature for Reagent onboard at 2-8 degree celcius		
n)	Shall have minumum 60 samples can be programmed at a time.		
o)	Shall have sample volume 5-150 µL t oavoid the wastage of sample.		
p)	Shall have minumum 25 reagents can be loaded at a time		
q)	Reagent assays must be ready to use, liquid, and include calibrator and control in each reagent kit, FOC calibrator and control.		

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r)	The reagent should come with 25test pack for low test parameters and 50Test pack for routine test parameters		
s)	Shall have not more than 2-Point calibrator.		
t)	System should have probe wshing technology for sample and Reagent to prevent Carryover and should be ≤ 0.5ppm.		
u)	In built Refregeration system with Controlled Temperature and humidity for reagent storage to maintain the onboard reagents.		
v)	System should have Inventory track, flag, calibaration validate, reagent inventaory and expiry.		
w)	Shall have the features of QC management within run control program includes Levy-jennings histograms, Mean X and Westergard rules etc. to monitor the quality of result with company provided QC material.		
x)	Must have facility to collect both liquid and solid waste for better disposal.		
y)	Shall have LIS facilites.		
z)	Shlud have reservoir for substrate and automatic switching of substarte during working condition to avoin interference on working condition and should not be hold instrument to change it manullay.		
11	Shall have big touch screen inbuilt with complete computer set (Microsoft Windows Operating system, RAM 4 GB, compatible dual core or higher CPU) HDD: 100 GB or higher, with printer.		
12	**Accessories, spares and consumables**		
14.0	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).		
15	**Operating Environment**		
a)	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.		
b)	Power supply: 220 - 240 VAC, 50Hz fitted with appropriate plug. The power cable must be approx. 3 metre in length.		
16	**Standards and Safety Requirements**		
a)	Must submit ISO13485:2003/AC:2007 for Medical Devices		
b)	CE (93/42 EEC Directives) or USFDA approved.		
17	**User Training**		
a)	Must provide user training (including how to use and maintain the equipment).		
18	**Warranty**		
a)	Warranty for 2 years		
19	**Maintenance Service During Warranty Period**		
a)	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.		
20	**Installation and Commissioning**		
a)	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.		
21	**Documentation**		
a)	User (Operating) manual in English.		
b)	Service (Technical / Maintenance) manual in English.		

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