Technical Specification of Fully Automated Urine Analyzer

S.N.	Purchaser's Specifications	Bidder's Compliance Sheet		
		Yes/No	Page No. in Catalog	Remarks
	Fully Automated Urine Analyzer			
	Manufacturer:			
	Brand:			
	Type/Model:			
	Country of Origin:			
1	**Description of Functions**			
1.1	The one button operation analyzer should be compact bench top, fully automated integrated urine analyzer, integrating urine chemistry and urine sediment analysis.			
2	**Operational Requirements**			
2.1	Chemistry parameters required to be provided should be 11 items: occult blood(BLD),bilirubin (BIL),ketone body(KET),glucose(GLU),protein(PRO) ,nitrite(NIT),leukocyte(LEU),pHvalue9pH),specificgravity(SG),Urobilinogen(URO),ascorbic acid(ASC),14 items: 11 items + creatinine(CRE), calcium ion(Ca), Micro albumin(MCA) 2 ratios: MCA/CRE, cA/CRE			
2.2	Formed element detection: Automatic recognition of red blood cells, abnormal red blood cells, white blood cells, leukocytes, clear tubes, granular tubes, white blood cells, red blood cells, glomerular epithelial cells, wax tubes, fat tubes, wide tubes, mixed tubes, blood tubes, other tubes, calcium oxalate crystals, uric acid crystals, calcium phosphate crystals, magnesium ammonium phosphate crystals, bilirubin crystals, cholesterol crystals, cysteine crystals, leucine crystals. There are 37 kinds of tyrosine crystals, sulfa crystals, amorphous crystals, squamous epithelial cells, small round epithelial cells, other epithelial cells, phagocytes, clue cells, bacterial, yeasts, fat globules, and sperm. Mucous filaments, trichomonasvaginalis , etc.			
2.3	Additional formed element analysis required to be provided should be Red Blood Cell, leucocyte, cast, crystal, epithelial cell, bacteria.			
3	**System Configurations**			
3.1	The analyzer should be based on Dry chemistry test: Reflection spectrophotometry or equivalent.			
3.2	The instrument should provide scatter grams and histograms or actual images for easy interpretation.			
3.4	The analyzer should have user friendly software with cross check function.			
3.5	The analyzer should have a throughput of minimum 120 samples/ hour (chemistry) &minimum 100 samples/hour (formed element analysis) ; minimum100 samples/hour (integrated analysis mode)			
3.6	Bidder should provide technical data sheet.			
4	**Technical Specifications**			
4.1	**Analyzer :**			
a	Sample rack should have at least 10 samples tube storage positions and minimum 5 rows of sample racks can be loaded at most at one time with barcode for sample identification with automatic rotation of the test tube.			

b	The equipment should have a storage of at least 100 test strip at a time with continuous loading for true walkaway analysis without considering the direction of test strip when loading (Intelligent identification of test strip direction) on machine .			
c	The equipment should be capable of analysis in both manual and sampler mode.			
d	Control should be available for both chemistry and sediment analysis.			
e	Automatic inspection for urine color and turbidity.			
f	It must have disposable urine sediment chip for cross-contamination free & biosafety with simultaneous testing of minimum five samples at one time. Carry – over rate of formed elements ≤ 0.05% **(Reused counting chamber will not be considered)**			
h	It shall have the STAT function for the emergency test sample.			
i	It must have the minimum of 2 objective lens of Low Power Lens: 10 X and High power lens: 40 X with auto switch function.			
j	High resolution imaging should be provided with at least of 6 megapixel high resolution CCD camera.			
h	Network Connection: External RS232 and USB interfaces can be connected with hospital computer network and LIS system.			
i	On machine stability of test strip : minimum of 10 days and minimum of 1 year validity if not opened.			
5	**Accessories and Consumables**			
a)	All standard accessories / consumables / parts required for the proper operation of the above item shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer, which have not been specified in this Technical Specifications Forms.			
b)	All standard Maintenance tools and cleaning /lubrication materials where Applicable shall be included.			
6	**Operating Environment**			
a)	Power supply: 220–240VAC, 50Hz fitted with appropriate plug type D 3 pins. The power cable must be atleast3 meters in length.			
7	**Standards & Safety Requirements**			
a)	Must submit ISO9001 or ISO13485			
b)	Must submit CE or USFDA approved product certificate.			
7	**Training**			
7.1	The Supplier should conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational function so the equipment, as well as routine check and maintenance expected by users			
7.2	Certified Training to Biomedical Engineer, Lab Technician and Biomedical Technicians.			

8	**Warranty**			
8.1	The supplier company must provide Comprehensive warranty (CMC) forfive years after installation except the consumables and wear and tear parts such as Tube, Lamp.			
9	**Maintenance Service During Warranty Period**			
9.1	During warranty period supplier must ensure preventive maintenance &corrective/breakdown maintenance whenever required.			
10	**Installation and Commissioning**			
10.1	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. LIS has to be done by the supplier.			
11	**Documentation**			
11.1	User (Operating) manual in English.			
11.2	Service (Technical/Maintenance) manual in English.			
11.3	Certificate of calibration and inspection from factory.			
11.4	Bidder must submit the Technical Compliance (Yes/No) chart which is co-related with the Catalog and other documents.			
11.5	Should submit Manufacturer's Authorization Letter. Sub Authorization will not be valid.			

SUBMITTED BY

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