Republic of the Philippines
Department of Health
CARAGA REGIONAL HOSPITAL

TECHNICAL SPECIFICATION

PROCUREMENT OF ONE (1) UNIT FULLY AUTOMATED URINE ANALYZER
IB NO. 2023 - 04 - 26 (16)

1	FULLY AUTOMATED URINE ANALYZER	1 UNIT @ PHP 1,400,000.00	TOTAL: PHP 1,400,000.00
		Total Approved Budget for the Contract	PHP 1,400,000.00

	PURPOSE OF USE		
		DESCRIPTION	A fully automated urine analyzer machine intended for the in-vitro quantitative, qualitative and/or semi-quantitative determination of urine chemical analysis of at least 15 parameters or more, urine color, transparency/turbidity, and microscopic examinations of at least 20 or more parameters of urine sediments.
		Clinical or other purpose	Such machine should have the ability to perform urine analysis, both chemical and microscopic examinations in order to provide related information to the requesting physicians and to aid them in the clinical management of their patients.
		Clinical department/ward	Department of Pathology
		Overview of functional requirements	*Brand New Fully Automated Urine Analyzer with flat Flow Cytometer and with digital technology. With high precision aspiration and provides user with precise data lowering the risk of both false positive and negative results .*

			Urine fully-automated analyzer capable of providing accurate and reliable test results of urine specimens within two (2) minutes per sample, with the ability to auto-dilution procedures for abnormal urine samples, classifies all sediment readings, produces quality readings of chemical parameters, provides graphical representations of quality control test results, with built-in storage of test results, built-in inventory of reagents and/or supplies, flags abnormalities or irregularities as applicable, internal and external barcode reader, and other important capabilities.
	TECHNICAL CHARACTERISTICS		
		Sample type	Urine
		Sample Volume	3.0 ml to 5ml
		Principle	Flow Imaging Technology/Flow Cytometry (Formed Elements), Photoelectric Colorimetry (Chemistry)
		Test Items	**Formed elements :** 20 or more sediment parameters (such as WBC, WBC in clumps, RBC, NRBC, Epithelial Cells, Renal Cells, CASTS (specific), Crystals (specific), Yeasts, Mucus, Sperm, etc) **Chemistry:** 15-parameters or more (pH, Specific Gravity, Urobilinogin, Bilirubin, Protein, Glucose, Ketone, Blood, Leukocytes, Nitrite, Microalbumin, Creatinine, & etc) Physical: Color & Turbidity
		Throughput	Hybrid Mode: 120tests or more /hour of microscopy and urine chemistry analysis
		Communication	**Connected to LIS/HIS of the laboratory** (the winning supplier will shoulder the connectivity cost for the LIS)
			Internal & External Barcode Scanner (with built-in barcode reader)
		Memory Capacity	At least 100,000 tests
			With 3 – 5 counting chamber

		User adjustable/other technical specs	Has 98% to 99% detection rate at concentration of 5cells/ul
			Has loading capacity of more than 40 samples
			Strips capacity of 100-200 strips
			With random access for STAT requests
			Has a comprehensive port of results with images and diagnosis
			With accuracy and repeatability Measurement up 95% and 7 % respectively
			Routine Reagent: 3 or less
	PHYSICAL/CHEMICAL CHARACTERISTICS		
		Components	To be protected against fluid ingress from above source
			Machie cover can be opened for repair and maintenance
		Raw Materials	High standard quality materials
	UTILITY REQUIREMENTS		
		Power Supply	Electrical sources requirements: Voltage 110-240V; 1 phase
			Protection against over-voltage and over-current line conditions
			Online UPS (Heavy Duty)
	ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
		Accessories	External Barcode Scanner
			Complete Set of Desktop Computer with 3 in 1 continuous printer with UPS and AVR (Core Intel I5 to I7 8th Genereation and Up, 250 GB SSD, 500 GB-1 TB HDD, 8GB RAM)

			4000 sample Tubes for analysis
			At least 10 sample racks (as applicable)
			Heavy Duty online UPS (for the machine), extension wires (if necessary)
		Consumable / Reagents	Not more than 3 types reagents
			Supplier will provide reagents and supplies good for 4,000 tests and corresponding quality control samples needed to accomplish the test specified and other start up reagents needed
			Complete set of Calibrators and other consumables needed.
			Control (Normal and Pathologic) for chemistry and sediments
	TRAINING, INSTALLATION AND UTILIZATION		
		Pre-installation requirements	Supplier to perform installation, safety and operation checks before hand over
		Requirements for commissioning	Engineer and/or representative from Biomed of CRH and MedTechs to affirm completion of installation
		Training of user/s	Training of MedTechs in operation and basic maintenance shall be provided.
			Must train personnel particularly from Biomed of CRH for the troubleshooting, basic maintenance and repair of the machine
			Training must be conducted by the company employed technician.
		User care	To demonstrate the proper cleaning and disinfection with provision of printed cards or tags beside the unit
			Cleaning Instruction
		Place of installation	Pathology / Laboratory Department
	WARRANTY AND MAINTENANCE		

		Warranty	2 years for parts and labor
			2 years preventive maintenance and calibration
			Machine calibration must be performed every 6 months and/or when the need arises, and provides Certificate of Calibration and Traceability within the warranty period.
			Supplier shall provide Warranty Certificate
	DOCUMENTATION		
		Documentation requirements	· User, technical and maintenance manuals to be supplied in English language. (hard and soft copy)
			· Provide certificate of Calibration upon delivery/installation.
			· List to be provided of equipment and procedures required for local calibration and routine maintenance
			· List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
			· Certificate of Product Registration and/or its equivalent
			· Material Safety and Data Sheet (Reagents)
			Operator's Manual, Work Instructions and other Reference/s (hard and soft copy)
	SAFETY AND STANDARDS		
		Regulatory Approval / Certification	Environmental-friendly with proper waste management
			ISO 13485, FDA, CE. ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU)

		Internationally Standards	ISO 14971:2007 Medical devices -- Application of risk management to medical devices
			ISO 17025 - the international standard for laboratory competence
			Compliance to ISO 13485-Quality Management System
		Regional / Local Standards	Pass FDA Regulatory requirement, Product Registration Certified
		Other Requirements	Technician/Engineer assigned must be employed by the company for at least 1 year
			Supplier must have technical support / Service Center within Mindanao Area with support facilities and trained personnel.
			Supplier must ensure that the transfer of learning on the technicalities of their equipment is effectively done before leaving it to the end user.
		COMPLETION OF DELIVERY AND INSTALLATION	ITEM SHALL BE DELIVERED WITHIN 45 CALENDAR DAYS FROM RECEIPT OF NOTICE TO PROCEED, INCLUDING ITS INSTALLATION
		TERM OF PAYMENT	Payment shall be processed right after complete delivery, commissioning, testing, installation and compliance with all necessary documents in according to audit rules and regulations.
		Validity of the Contract / Contract Termination	Without prejudice to the provision of applicable laws, rules and guidelines, the Contract shall be automatically terminated under the following conditions:
			a. When the total item / s in the contract is fully consummated; or
			b. For any justifiable reason ground where the contract will not redound to the benefit of the government or there is violation of the contract.

		General Conditions	All other rules governing contract implementation and termination under RA 9184 and its IRR, and relevant procurement policies shall be applicable.