

Amendment No. 02

Sub: Amendment to the referred tender enquiry

Ref.: Tender Enquiry Document HITES/PCD/PMSSY-IV/22/BIOC/2022-23 dated 01-07-2022 and Amendment No. 01 dated 22-Jul-2022

Following changes are being incorporated in the tender:

SECTION IV
TECHNICAL SPECIFICATION

Item No 1 Chemiluminescence Immunoassay Analyser		
Tender spec Para	TENDER SPECIFICATION	READ AS
10	Facility for onboard dilution and reflex dilution for high and abnormal samples	Facility for onboard dilution and reflex/auto dilution for high and abnormal samples
18	Capability of bar-coded stored master curve with two point calibration	Capability of stored master curve with two/six point calibration
25	Should be European CE with 4 digit notified body no. or USFDA or BIS certified	Should be BIS or European CE IVD or USFDA certified
		<p>Added Para: The bidder shall supply the start-up kits (after installation & validation of equipment) consisting of diagnostics/reagent kits, accessory reagents, calibrators, controls etc along with the equipment. Start-up kits for all parameters (as mentioned in Appendix 1) comprising of total 200 tests to be supplied.</p> <p>For every diagnostic/reagent kit, number of tests/pack and pack size in ml, needs to be specified. The bidder should quote unit prices for all the possible reagents /consumables on their equipment separately as per Appendix 1 and price will be frozen during the warranty period (for 5 years).</p>
		<p>Added Para: Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.</p>

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		In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract, if applicable.
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Item No 2 Vertical Gel Electrophoresis System		
1	The system should runs two 10 x 10cm gels or one gel when used with blocking plate; accommodates 8 x 10cm gels utilizing the provided adapter	The system should run two Cassette/ Gel , size of at least 10 x 8cm gels or one gel when used with blocking plate
7.a	Double Sided Vertical System, 8-10 x 10cm gel system, 150mL to 300mL buffer volume	Double Sided Vertical System atleast 8-10 x 7-10cm gel system, 300-700 ml buffer volume
7.b	Length (Metric) Gel; 8 to 10cm	Length (Metric) Gel; 7 to 10cm
7.c	Width (Metric) Gel; 10cm	Width (Metric) Gel; 8 to10cm
7.d	Volume (Metric) Lower Buffer Chamber Max; 300ml	Volume (Metric) total Buffer Chamber 300 - 700 ml
7.e	Volume (Metric) Lower Buffer Chamber Min; 150ml	Deleted
7.f	Volume (Metric) Upper Buffer Chamber; 150ml	Deleted
9	The system should comply with following power supply ranges; Voltage 230V, max. Voltage 300V, max. Current 400 mA, Hertz 50/60 Hz, 03 sets of input jacks, display voltage or current & timer 0 to 999min.	The system should comply with following power supply ranges; Voltage 10-300V, Current 400 mA , Hertz 50/60 Hz, minimum 03 sets of input jacks, display voltage or current & timer 0 to 999min. System should have constant voltage or constant current option.
12	Should have European CE or US FDA certification or BIS approved.	Manufacturer should have ISO 13485 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body
13	The calibration, IQ, OQ and PQ of the instrument should be	Deleted

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	performed at the time of installation and certificates should be provided	
		Added para : Should be supplied with following accessories: compatible Tank & lid with power cables, electrode assembly, Tapping free casting stand for minimum 2 gels, five 10- well combs of 1.0mm thickness, and five sets of glass plates with bounded 1.0mm spacers.

APPENDIX 1 for Sch. 1									
Section I - Reagent cost									
Sl. No	List of Parameters	(A)	Reagent Pack Details						
		No. of tests (approximate load over 5 years being factored for bid ranking only)	Reagent Pack - make/brand	Pack Catalogue No.	No. of tests/pack	Pack size in ml	Total No. of Reagent packs to be used for No. of tests in column "A" (i)	Unit Price per Pack incl. taxes (ii)	Total Price (i) x (ii)
1	Troponin (T/I)	35000							
2	Myoglobin	17500							
3	CK-MB	17500							
4	TSH	175000							
5	Free T3	87500							
6	Free T4	87500							
7	PTH	35000							
8	Vitamin D	70000							
9	Folate	52500							
10	Vitamin B 12	35000							
11	Ferritin	35000							
12	Transferrin	35000							
13	Total PSA	52500							
14	Free PSA	52500							
15	CEA	52500							
16	AFP	52500							
17	CA 125	35000							

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18	CA 19-9	35000							
19	FSH	35000							
20	LH	35000							
21	Cortisol	52500							
22	Testosterone	17500							
23	Prolactin	52500							
24	Progesterone	35000							
25	Estradiol	35000							
26	HIV Combo	52500							
27	HBS Ag	52500							
28	HSV-1	35000							
29	HSV- 2	35000							
30	Rubella IgG	52500							
31	Rubella IgM	52500							
32	Beta HCG	70000							
33	PCT	52500							
34	NT Pro BNP	35000							
35	CPK	35000							
36	Serum Iron	35000							
37	TIBC/UIBC	35000							

Section II - Consumable cost (other than reagents)							
Items/ Pack Details							
Sl. No.	Type of Consumable (Bidder may add additional rows)	Details of Tests / Analyzers/ Equipment, etc. the consumable is being used for	Make/ brand	Catalogue No.	(E) Total No. of Consumable item/ packs to be used for cumulative no. of tests as detailed in column "A" of Section 'I'	Unit Price per pack incl. taxes (iii)	Total Price (iii) x (E)
	Calibrators						
	Quality controls						

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	Additives						
	Cleaners						
	Any other Consumables						
	Important Note:						
	Any reagent or any consumable required for performing tests, calibration, quality control, cleaning the lab system, etc. as per quantities detailed in column "A" of Section-I, if not quoted in section-I and section 'II' of APPENDIX 1 shall be provided free of cost by the bidder during the validity of the contract. This appendix should be submitted with Price Bid						

Note:

- i. All other contents of the tender enquiry including terms & conditions remain unaltered.
- ii. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- iii. TC compliance sheet v1.0 and Price bid format v1.0 is being uploaded on CPP Portal for necessary actions of interested Bidders.