

Amendment No. 02

Sub: Amendment to the referred tender enquiry

Ref.: Tender Enquiry No. HITES/PCD/PMSSY-IV/24/PATH/2022-23 dated 05-Aug-2022 and Its Amendment No 01 dated 09-Sep-2021.

Following changes are being incorporated in the above referred Tender Enquiry Document.

SECTION VII
TECHNICAL SPECIFICATIONS

| Sch. No. 01 Electronic Blood Cell Counter with Six Part Differential | | |
|---|--|--|
| Tender spec Para | TENDER SPECIFICATION | READ AS |
| 1 | Should provide complete blood cell counting including 5 part WBC differential with capability of doing Retics and NRBC enumeration | Should provide complete blood cell counting including 5 part WBC differential with capability of doing Retics and NRBC enumeration |
| 2 | Must be upgradable to attach with fully automated slide-maker & slide stainer in future | Must be upgradable to attach with fully automated slide-maker & slide stainer in future with option to integrate with similar units in future. |
| 3 | Should have discrete mode to save the cost of reagents CBC CBC+Diff Retic CBC+Diff+nRBC CBC+Diff+Retic+Nrbc | Should have discrete mode to save the cost of reagents CBC+Diff CBC+Diff+Retic |
| 5 | Must analyse leucocytes in their native state through laser based scatter analysis | Must analyse leucocytes in their native state through laser or lamp based scatter analysis |
| 14 | Database capacity of at least 20,000 sets of results and graphics | Database capacity of at least 10,000 sets of results and graphics |
| 22 | Must be able to select CBC, CBC and Diff and Reticulocyte testing mode | Deleted |
| 29 | At least 20 Quality control Files which store 100 runs each XB analysis | At least 20 Quality control Files which store 100 runs each |
| 32 | Should have inbuilt autoloader cum mixer with capability of loading min 90 samples at any time | Should have inbuilt autoloader cum mixer with capability of loading min 50 samples at any time |
| 37 | System should be European CE with notified body number or USFDA approved product | Should be BIS or European CE IVD or USFDA certified |
| | Cost for 1000 Test with all reagent, should be supplied with separate rate provided, rate will be calculated for L1 Ranking. And price will be freezed for three years (50 samples per day for calculation). | The bidder shall supply the startup kits (after installation & validation of equipment) consisting of diagnostics/reagent kits, accessory reagents, calibrators, controls etc. along with the equipment. Startup kits for all parameters (as mentioned in Appendix 1) comprising of total 500 tests to be supplied. 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). |

| Sch. No. 01 Electronic Blood Cell Counter with Six Part Differential | | |
|--|----------------------|---|
| Tender spec Para | TENDER SPECIFICATION | READ AS |
| | | <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> <p>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.</p> |

| APPENDIX 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" | Unit Price per Pack incl. taxes (ii) | Total Price (i) x (ii) |
| 1 | CBC + Diff | 82,500 | | | | | | | |
| 2 | CBC+DIFF+NRBC | 33,000 | | | | | | | |
| 3 | CBC + RETIC/ CBC+DIFF+NRBC+ RETIC | 33,000 | | | | | | | |
| 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 | | | | | | | | |
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| | Quality controls | | | | | | |
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| | Additives | | | | | | |
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| | Cleaners | | | | | | |
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| | Any other Consumables | | | | | | |
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| | Important Note: Price quoted here will be added with equipment price for ranking purpose. Bidders should quote in price bid only. | | | | | | |
| | 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 | | | | | | |

| Sch. No. 02 Fully Automated Coagulation Analyzer | | |
|---|--|--|
| Tender spec Para | TENDER SPECIFICATION | READ AS |
| 10 | The analyzer should have facility for keeping at least 40 reagents on board | The analyzer should have facility for keeping at least 30 reagents on board |
| 12 | The reagent rack should be cooled at 10° C or lower for maximum stability of on board reagents | The reagent rack should be cooled at 20° C or lower for maximum stability of on board reagents |
| 18 | Should have at least 500 cuvettes onboard capacity | Should have at least 400 cuvettes onboard capacity |
| 24 | Should have European CE or US FDA certification or BIS approved | Should be BIS or European CE IVD or USFDA certified |
| 26 | To be supplied with Branded computer system with at least Core i7 processor, 8GB RAM, 1TB HDD, DVD R/R, 21" or better LED Monitor, Genuine Windows 10 or more, A4 size laser printer and appropriate bar code reader. Or Inbuilt system capable of integrating LIS and connecting printers | To be supplied with latest and branded computer system compatible with machine and with A4 Laser Printer, appropriate barcode reader and system should be capable of integrating with LIS. OR Inbuilt system capable of integrating LIS and connecting printers |
| | | 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 |

| Sch. No. 02 Fully Automated Coagulation Analyzer | | |
|---|-----------------------------|--|
| Tender spec Para | TENDER SPECIFICATION | READ AS |
| | | <p>quoted model.</p> <p>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.</p> |

| Sch. No. 03 Automated Urine Analyser | | |
|---|--|--|
| Tender spec Para | TENDER SPECIFICATION | READ AS |
| 4 | Instrument Strip Feeder should have Storage of 300 test strips | Instrument Strip Feeder should have Storage of 200 test strips |
| 12 | Software should be User friendly with programmable QC Files for Sediment and Chemistry. Instrument throughput should be minimum 270 samples / hour (chemistry) & 80 samples / hour (sediment analysis). | Software should be User friendly with programmable QC Files for Sediment and Chemistry. Instrument throughput should be minimum 240 samples / hour (chemistry) & 80 samples / hour (sediment analysis). |
| 13 | Instrument should be capable of analysis in Automated Sampler Mode with capacity of 80 sample tubes and Internal Barcode for Sample Identification. | Instrument should be capable of analysis in Automated Sampler Mode with capacity of 50 sample tubes and Internal Barcode for Sample Identification. |
| 16 | The system should have separate body fluid mode | Deleted |
| 17 | In body fluid mode the system should provide all required parameters like RBC, WBC, Epithelial Cells (EC), Mononuclear Leucocytes, Polymorphonuclear Leucocytes, Total Nucleated Cells (TNC) & Bacteria. | Deleted |
| 18 | Body fluid sample volume requirement should be 0.5 -2ml | Deleted |
| | | <p>Added Para:</p> <p>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> <p>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.</p> |

Note:

- i. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- ii. All other contents of the tender enquiry including terms & conditions remain unaltered.
- iii. **For Tender IDs 2022_HLL_125774_1, 2022_HLL_125774_2 & 2022_HLL_125774_3 only:**
TC compliance sheet v1.0 and Price bid format v1.0 is being uploaded on CPP Portal for necessary actions of interested Bidders.
- iv. EMD should be valid up to 225 days or more from the date of submission mentioned above.