QUOTATION

No. GMCHM/Medical Store/Quote/4524/2025.
Office of the Dean Office of the Dean, Govt. Medical College & Hospital, Miraj. Date: - 02/06/2025 07

To.

Sub: - QUOTATION FOR SUPPLY OF DIAGNOSTIK KITS

The sealed quotation/rates are invited for the following items for the use of this hospital in envelope system on the official letter head of the firm and the quotation rates will be valid for period of 6 months.

The quotation should be sealed and addressed to The DEAN, Govt. Medical College & Hospital, Miraj. And must be super scribing on the envelop as 'QUOTATION FOR SUPPLY OF MEDICINES' DUE ON 11.7.25

The last date of receiving the quotation is 11.7.25 before 4.00 p.m.

Quotations will be opened on 11.7.25 at 5.00 P.M. At Dean's Chamber GMCH Miraj. Note that representatives of firms applying for Quotation should be present at the time of opening the quotation.

The Dean, GMCH Miraj. reserves the right to enhance or reduce the quantity or to decide not to purchase any quotation item or to accept any quotation in full or in part or to reject any or all items without assigning any

1. Quotation should be quoted on official letter head of the firm with signature and stamp of firm.

2. Photocopy of PAN card, Bank passbook (first page), AADHAR card of company holder, original cancelled cheque required for CMP and to be submitted.

3. Copy of valid FDA 20B & 21B drug license of the bidder (supplier). The supplier should have valid FDA Drug license as on the date of bid opening.

4. Valid WHO GMP certificate and WHO GMP Product list or COPP for quoted Items.

5. WHO-GMP Certificate of the manufacturer should be provided by the bidder. Preference will be given to bidders providing manufacturer's WHO GMP certificate.

6. GST No. certificate of the supplier. Last 3 months returns copy.

7. The bidder should not be blacklisted / deregistered by any government institution / organization during the last 3 years for supplying substandard medicines/other items.

8. Non conviction Certificate issued from concern FDA for Manufacture/Distributor Valid for this Year should be provided.

9. For Consumables: ISO 13485 (International Organization for Standardization), ISO 17025, ISO 45001, ISO 14001, GMP (Good Manufacturing Practices) / Schedule M, Quality Management System (QMS) for Medical Devices, Central Drugs Standard Control Organization (CDSCO) approved MD License.

10. The bidder should give the undertaking stating that all document furnished by them are true and only they are responsible for any discrepancy or untrue nature of the document submitted.

11. Authorization letter of original manufacturer stating that supplier is authorized dealer.

12. National Accreditation Board for Testing and Calibration Laboratories (NABL test report) Compulsory.

13. It is Compulsory for The Supplier to attach Batch wise test analysis report for each drug as well as Manufacturers package insert /prescription information. An undertaking regarding the supply of test report should be given by the Supplier at the time of filing Quotation itself.

14. It is required to submit an undertaking clearly mentioning that the bidder has no conflict of interest with

the concerned Purchasing authority & that only a single Quotation is being submitted.

15. Rates should be quoted for Per Piece/Item/Tablet/Bottle/Vial/Test

You are requested to furnish your "NET RATES" only for 'DOOR DELIVERY BASIS' (i.e. their rates should be all inclusive of all taxes and duties and transportation). The Material will be accepted only as per specifications and in good condition. No advance payment will be made. The goods should reach at hospital on priority basis.

Technical evaluation: - Technical evaluation of the documents will be done by Technical evaluation team on the day of bid opening.

In case there is query/discrepancy regarding any of the documents provided by the bidder (Supplier/Manufacturer/Distributors), a two day period will be allowed to the concerned bidder to submit correction documents (they will be informed by email), If the bidder fails to supply documents within this time frame, their quotation will be treated as invalid. The Quotation filling bidder should present all original documents of photo copies attached with quotation as and when demanded by the institution.

Supply:-

- 1. If chosen as L1 it is mandatory for supplier to accept purchase order from the institute and supply within 15 days from receipt of order by email. They should confirm the same by email.
- 2. All the order quantity should be supplied by the bidder at one time at the medical store GMCH Miraj. in their original manufacturing package as door step delivery in the quoted rate.
- 3. The material will be accepted only as per specification and in good condition. The goods should reach this Hospital urgently on working days between 10am to 4pm.
- 4. The bidder on successful supply of medical/ surgical consumable should present three invoice copies stamped original/ duplicate/ triplicate without any error addressed to the Dean, GMCH Miraj.

Payment:-

No advance payment will be made. After successful supply of medicine and submission of bills in the complete format payment will be done as soon as possible subject to availability of government funds.

Quotation List

Sr No.	Name Of Diagnostic kit	Processor.
1)	HIV Whole Blood Finger Prick / Duel Test	Printed and the last

Govt. Medical Collage & Hospital Miraj.

State Reference Laboratory & Integrated Counseling and Testing Center

Department of Microbiology, Government Medical College Pandharpur Road, Miraj – 416410, Maharashtra, India

Technical Specifications of HIV Test kits for detection of Antibodies against HIV

1. HIV test kit should have following principle: Immunochromatography (lateral flow)

- 2. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
- 3. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
- 4. Adequate documents detailing the Principle component, detail of antigen for antibody detection of HIV 1 & 2, bio safety precautions to be undertaken, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
- 5. The product insert should have the pictorial representation of the test methodology.
- 6. The kit should have approval of the statuary authority from the country of origin.
- 7. Imported and Indigenous kits should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017 .
- 8. The time required for performing the test should not be more than 30 minutes.
- 9. The kits should have a shelf life of 24months and at least $5/6^{th}$ of the minimum shelf life must remain at the time of receipt by the consignee.
- 10. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the Principle of lateral flow.
- 11. The assay should have sensitivity of 100% and specificity of >98%.
- 12. The manufacturer should ensure that:
- a. The test kit should be packed such that there is a provision to conduct the single test at a time.
- b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20 % of the test (10% negative & 10% positive controls)
- c. The pack size of HIV rapid test kits should be not more than 50 tests per kit (Any pack size)
- 13. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport of the kits at 2 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Head & Professor, Dept of Microbiology, GMC, Miraj