ANDHRA PRADESH STATE MEDICAL SERVICES & INFRASTRUCTURE DEVELOPMENT CORPORATION

(AN ENTERPRISE OF GOVT. OF A.P.)

Plot No.9, Survey No.49, IT Park, Mangalagiri, Guntur District – 522 503.

No: 01/2020-21/IFQ/HCV Test kits/Dt:16-11-2020

INVITATION FOR QUOTATIONS (IFQ): ANTI HEPATITIS C VIRUS ANTIBODY TESTS (RAPID AND ELISA)

TO			
M/s_	 	 	

Sub: APMSIDC inviting quotations for procurement and supply of Anti Hepatitis C Virus Antibody Tests(Rapid and Elisa Tests)-Reg

Ref: Lr.Rc.No.754lDME/NVHCP/2O2O Dt: O9-11-2O2O

- 1. Competitive quotations are invited by the undersigned for the following
 - ANTI HEPATITIS C VIRUS ANTIBODY TEST (RAPID) 7800 Tests.
 - ANTI HEPATITIS C VIRUS ANTIBODY TEST (ELISA)- 900 Tests.

Quantities mentioned in this document are TENTATIVE. Quantity may increase or decrease as per the requirement of the indented department and sole discretion of the IFQ authorities.

2. Quoted Price:

- a. The quotation shall be submitted in the name of The Managing Director, APMSIDC.
- b. All duties, taxes and other levies payable by the tenderer (including GST) shall be included in the item rate.
- c. The rates quoted for each item shall be fixed for the duration of the contract and shall not be subject to any adjustment.
- d. Corrections if any shall be made by crossing out, initialing, dating and rewriting. e. Cable or Facsimile quotations are not acceptable.
- f. The rates quoted shall be inclusive of supply of the items at various warehouses across Andhra Pradesh.
- 3. Each tenderer must submit only **one** quotation.

4. Validity of quotations:

a. The quoted rates shall remain valid for a period not less than 30 days from the date of issue of NOA.

APMSIDC-DRUGS WING

5. Evaluation of quotations:

The Purchaser will evaluate and compare the quotations determined to be substantially responsive i.e., which are properly signed, and confirm to the terms and conditions and specifications in the following manner:

- a. The evaluation will be done including all taxes. If the tenderer has not included the taxes in his quotation for the item rate, and has also not indicated the rate of taxes applicable, the quoted rate will be treated as though it is inclusive of taxes and no extra payment for taxes will be made.
- b. The Drug/Miscellaneous/Item for which no rates have been quoted would be treated as Zero and considered as not bidding for that product.

6. Contract:

- a. Payment shall be made after the quality assurance report from the in house/ empanelled labs after the delivery of the goods and their acceptance.
- b. Notwithstanding the above, the Purchaser reserves the right to accept or reject any quotations and to cancel the quotation process and reject all quotations at any time prior to issuing supply order.
- c. Bid inviting authority reserves the right to award a part of the order quantity to L2, L3.... if they match L1 price to ensure early supplies or in case L1 fails to supply the goods as per the delivery schedule mandated in this IFQ.

7. Supply period

The supply shall be completed within 10 Days from the date of issue of supply order. Otherwise the supply order remains cancelled.

a. If The supplier fails to supply within the stipulated period the legal action will be initiated.

8. Terms and Condition

- A) Contract to be signed.
- B) Submit copies of previous Purchase order/work order/supply order received from any state/union territory/ corporation/Government Institutions for the Quoted Item.
- C) Manufacturing import license By Concerned Authorities should be submitted.

- D) Dealer Should Submit Authorization letter from Manufacturer/Importer.
- E) GST Registration of the Firm.
- F) Brochures, Certificates and Manuals.
- G) Delay supply: Order will be cancelled.
- H) 5% of order value to be submitted as security Deposit in the form of DD.
- I) Bidder should specify the quantity available at their disposal. The firm should declare the Delivery schedule for the Entire quantity.
- J) The supply shall be mandatorily accompanied by in-house- analytical certificate.
- K) Shelf life of the product shall not be less than 80% of the total stipulated Shelf life at the time of delivery.
- L) Supply details should be compulsorily entered in the supplier module of eAushadhi software (user name and password will be given by APMSIDC) the same entries will be considered for quality monitoring and billing.
- M) The stock of supply having date of expiry should be replaced with fresh stock from the latest batch about which the Manufacturer shall be informed around 3 months before the date of expiry.
- N) If a batch / batches of Drug are declared as **NOT OF STANDARD QUALITY** the Firm shall supply fresh stocks of standard quality of Drug equivalent to the entire quantity of the batch supplied earlier irrespective of quantity available in the stock, within 30 days from the date of receipt of the communication.

S.No	Item Name	Manufacturer /Make	Default Pack Size	MRP per Pack	Landed Price per Pack (incl GST/Taxes /All/Transport if any)	Landed Price per Test
					LANDED PRICE=	
1					{QUOTED PRICE +GST AMOUNT(GST%)}	

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9. FALL CLAUSES

- a) The price quoted shall not in any case exceed the maximum wholesale ceiling price (bulk), if any, fixed by the Govt. of India / NppA / State Government or the Whole Sale price fixed by the bidder for General Market.
- b) The Bidder shall mention such MRP rates in the quotation sheet against each item quoted. The rate quoted for the Drug supplied under this Contract, in no event shall be more than the lowest price quoted at which the contractor sells his products of identical description to any other persons, State, Union territory, corporation, Board, university, Trust, Local authority, company or any others including his own dealer, distributor, stockiest, agent during the period of the currency of contract.
- c) If at any time during the period of contract, the contractor reduces the sale price of such products to any other persons, State, Union territory, corporation, Board, university, Trust, Local authority, company or any others including his own dealer, distributor, stockiest, agent during the period of the currency of rate contract at a price lower than the price quoted in this contract, he shall forthwith notify such reduction or sale to The Managing Director, APMSIDC. The price payable under this contract shall correspondingly be reduced to the same extent as was sold to such others, under no circumstances the rate quoted shall be higher than the price notified under Drug Price Control Order issued from time to time.
- d) Failure to notify the Purchaser to pass on such benefits due to decrease in existing tax structure (Wherever applicable) Exemption accorded shall entail disqualification of the Contractor and forfeiture of the Security Deposit due if any and the firm will be Blacklisted.
- e) The order stands cancelled after the expiration of delivery period, and if the extension is not granted with or without liquidated damages. Apart from risk/alternate purchase action, the Bidder shall also suffer forfeiture of the Security Deposit and shall invite other penal action like blacklisting/Debarring disqualification from participating in present and future bids of Bid Inviting Authority/ordering authority.
- f) It shall be the responsibility of the supplier for any shortage/damage at the time of receipt at the designated places.

APMSIDC-DRUGS WING

- 10) Last date and time of receipt of quotations On or Before 18-11-2020 04.00 PM
- 11) eMail Id: apmsidc.gm@gmail.com with subject as Sub: Quotation for HCV Kits Dt 16-11-2020-Reg
- **12)** The managing director is authorized to alter conditions in exceptional cases.

MANAGING DIRECTOR, APMSIDC

Note: Specification of the Items given below:

Specification for HCV RAPID TEST KIT:

- 4) Anti-HCV Antibody (Rapid Test)
- Should utilize recombinant and /or synthetic peptide antigens for core, NS3, NS4 and NS5.
- 2. The assay should detect total anti HCV antibodies
- 3. Should be compatible with plasma and serum both.
- Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
- 5. The kit should have approval of the statutory authority from the country of origin
- 6. In case of imported kits it should be registered and licensed by the DCG(I)
- In case of indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
- The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
- 9. The total procedure time shall not be more than 30 minutes.
- 10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit.
- The assay should have sensitivity more than or equal to 99% and specificity of more than
 or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC(65)
 dated 12/7/2017
- 12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

- The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8° C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
- 2. The pack size should not be more than 50 tests wherein each test is individually packed.
- 3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters.
- The kit will be evaluated on the above parameters by the centers approved by the program

Specification for HCV ELISA TEST KIT:

Hepatitis C Virus

Anti-HCV Antibody Kits (ELISA)

- Microplate ELISA coated with recombinant/synthetic peptide antigens for core, NS3, NS4 and NS5.
- 2. The assay should detect total anti HCV antibodies.
- 3. Should be compatible with plasma and serum both.
- Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
- 5. The kit should have approval of the statutory authority from the country of origin
- In case of imported kits it should be registered and licensed by the DCG(I).
- 7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) and Medical Device Rule 2017
- The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port
 of discharge of consignees.
- All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
- The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature

General Specifications

- The manufacturer /authorized agent should ensure maintenance of cold thain during storage and transport of kits at 2-8°C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
- The kit size should be 96 tests/kit(in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with ELISA reader and washer.
- 3. 4 kits should be supplied along with the procurement lot of which two kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and two kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
- 4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Anti-HCV Antibody Kits (ELISA)