## **APMSIDC**

## **TENDER NO: 179**

**PROCUREMENT OF SURGICAL CONSUMABLES** 

**APMSIDC:: DRUGS WING** 

2025-26

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TENDER NO: -179/APMSIDC/MEDICINE WING/2025-26

#### TENDER FOR SUPPLY OF SURGICAL CONSUMABLES

To

# ANDHRA PRADESH MEDICAL SERVICES & INFRASTRUCTURE DEVELOPMENT CORPORATION

(Finalization of Rate Contract for Two years From the date of Price bid approval)

ANDHRA PRADESH 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. ANDHRA PRADESH

URL: <a href="http://apmsidc.ap.nic.in">http://apmsidc.ap.nic.in</a>

### ONLINE TENDER FOR THE SUPPLY OF SURGICAL CONSUMABLES

S. No	Information	Details
1	Bid Reference	179/APMSIDC/MEDICINE WING/ 2025-26
2	Date and time for downloading bid document	From 19-Dec-2025, 05:30 PM
3	Prebid Meeting/Queries	Submit your Query through email till 26-Dec-2025 before 05:00 PM to email tendersapmsidc@gmail.com with subject: Pre bid Queries for T NO 179
4	Last date and time for uploading Documents	09-Jan-2026 at 5.00 pm
5	Date and time of opening of Online technical bids	09-Jan-2026 at 5.01 pm
6	Last date and time of submission of offline documents and SAMPLES	09-Jan-2026 at 5.00 pm
7	Tender Processing Fee	The bidder shall remit processing fee ( <b>Non-Refundable Rs. 11,800</b> in online Through eprocurement site
8	Earnest Money Deposit (EMD)	The Earnest Money Deposit (EMD) in the form of Demand Draft for <b>Rs.3,00,000/-</b> in favour of Managing Director, APMSIDC, Mangalagiri, Guntur district/Online/NEFT/RTGS
9	E-mail	tendersapmsidc@gmail.com, apmsidc.gm@gmail.com
10	Contact number	General Manager- Drugs: 89786 80705 Pharmacy Officer : 91541 70485
11	APMSIDC Bank Details	Account Holder Name: The Managing Director, APMSIDC, Account No: 110224878693,IFSC Code: CNRB0013753, Bank Name: Canara Bank, Branch Name: Guntupalli, Krishna District, Andhra Pradesh.

The tender document can be downloaded free of cost from the e-Procurement Portal https://tender.apeprocurement.gov.in/ and from the website of APMSIDC www.apmsidc.ap.nic.in.

# ONLINE TENDER FOR THE SUPPLY OF SURGICAL CONSUMABLES TO APMSIDC

APMSIDC is responsible for procurement and supply of all essential Medicines & Surgical Consumables to the Government Health facilities of A.P., to ensure availability of medicines on free of cost. The main functions of the Corporation are Construction & Maintenance of Hospital Buildings. Further, the Procurement and distribution of Drugs, Surgical& Consumable and Equipment is also entrusted to this Corporation by the Government (Medical and Health Department). The Corporation is functioning on No Profit and No Loss basis.

**Purchaser/Tender Inviting Authority** – Managing Director, APMSIDC, Mangalagiri-522503, Guntur District, Andhra Pradesh(hereinafter referred as Tender Inviting Authority unless the context otherwise requires).

**Purchaser/Tender Accepting Authority** – Managing Director, APMSIDC, (hereinafter referred as APMSIDC unless the context otherwise requires).

Tender Inviting Authority invites Tender for the supply of Surgical Consumables to APMSIDC.

#### A. GENERAL CONDITIONS:

- 1) (a) At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a clarification requested by a prospective Tenderer, may modify the condition in Tender documents by an amendment uploading on website on <a href="majority.cip.">appmission.cip.</a>; and AP Procurement portal i.e. <a href="majority.cip.">apeprocurement.gov.in</a> will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.
  - (b) Any person who has downloaded the tender document should watch for amendment, if any, on the website <a href="mailto:apmsidc.ap.nic.in">apmsidc.ap.nic.in</a>; and AP Procurement Portal i.e. <a href="mailto:apeprocurement.gov.">apeprocurement.gov.</a> in for which APMSIDC will not issue any separate communication to them.
- 2) During tender or price agreement period, if L1 bidder is debarred/deregistered/blacklisted/banned by any Central Government or state Government or its procurement agencies due to quality failure, APMSIDC may purchase the drugs/Items from other qualified bidders who shall match the price of L1 or may go for fresh tender as per discretion of APMSIDC.
- 3) All the bidders are instructed to submit a copy of documents that are submitted online on or before due date in sealed cover.

**APMSIDC:: DRUGS WING** 

#### **B. SPECIAL CONDITIONS**

- 1) Bids shall be submitted **online** only at procurement portal website: <a href="https://apeprocurement.gov.in">https://apeprocurement.gov.in</a>. Manual bids shall not be accepted except for the original documents/instruments as mentioned in tender document.
- 2) Bidders are advised to check the *website of APMSIDC:* <u>msidc.ap.nic.in</u> and Procurement portal website <a href="https://apeprocurement.gov.in">https://apeprocurement.gov.in</a> prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.
- 3) Online Bids and price bid will be submitted on AP e-procurement portal i.e. https://tender.apeprocurement.gov.in/
- 4) The price bid shall be valid for a period of 120 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms & conditions.

#### C. ELIGIBILITY CRITERIA:

- 1) The tender document shall be downloaded from the websites msidc.ap.nic.in; and portal i.e.apeprocurement.gov.in. The bidder shall remit **processing fee** (Non Refundable) Rs. 11,800/- in the form of Demand Draft in the name of The Managing Director, APMSIDC, Mangalagiri/NEFT/RTGS.
- 2) The Earnest Money Deposit referred to shall be Rs. 3 lakh. The Earnest Money Deposit shall be paid in the form of Bank Guarantee or Demand Draft in favour of APMSIDC, payable at Mangalagiri/Online/NEFT/RTGS. In case EMD in form of Bank Guarantee, Irrevocable Bank Guarantee in favour of APMSIDC from any Nationalized/scheduled Bank should be valid for a period beyond 6 months from the date of tender opening. The format of Bank Guarantee. APMSIDC will not pay interest on any deposit held in the form of EMD.
  - a. The tender submitted without sufficient EMD will be summarily rejected.
  - b. The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender with eligible bidder.
  - c. The Earnest Money Deposit (EMD) will be forfeited, if the tenderer withdraws his bid any time after opening of price bid / non submission of

Performance security within the period prescribed/non supply of surgical consumables.

- d. The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract or deposit the performance security deposit within the stipulated time. The EMD shall be forfeited if any of the documents found incorrect.
- e. SSI units situated in AP state, quoted items as manufacturer are exempted from the payment of EMD.(necessary certificates to be submitted).
- 3) (i) Valid manufacturing license/Licenses for manufacturing the products issued by concerned authorities. If any product is declared as new drug/Item by CDSCO, then the firm should have valid license / product permission from DCG India along with the state license. As per the Govt. Memo No.426212/H2/2016, HM&FW(H2) Dept. dated 01-02-2017 approval of Central Drugs Standard Control Organization (CDSCO) by the firms/bidders is mandatory for all antibacterial (Coated) absorbable sutures.

Manufacturerers should submit valid ISO/BIS/CE or any other quality assurance certificates issued by concerned authorities. QMS certificate allowed the product approved by CDSCO which GMP is not issued by CDSCO

- (ii) Valid import license if the product is imported. (Under Form 10 in case of items notified as drugs) Valid Product license (For items notified as Drugs it is from DCA/DCG(I) and for Non-Drug items it is from concerned statutory Departments).
- (iii) Distributors with Valid licenses for distribution of products (in case of authorized distributors wherever applicable) (For items notified as Drugs it is from DCA and for Non-Drug items it is from concerned statutory Departments).(Non drugs-authorization from manufacture and manufacture license) If pesticides and larvicides license issued by Agriculture department.
- 4) A original certificate from their C.A. (Chartered Accountant) or Company Secretary that:
  - I. Average Annual turnover of manufacturer in the last continuous three years i.e. 2020-21, 2021-22 and 2022-23 or 2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25 shall not be less than Rs.5 Crores, 2.5 Crores for AP SSI/MSME Units as Manufacturerers and for authorized Distributors shall not be less than Rs.50 Lakhs.

II.(a) Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted by both manufacturer and distributor. Not less than 12 months from the date of commencement of tender.

Drug item -NCC issued by Drug control department,

Non drugs- issued by CA of the firm.

- (b) Tender should not be submitted for product(s) for which the tenderer has been blacklisted/debarred either by APMSIDC or by any other State/Central Government's organization/Procurement agencies on the grounds of quality failure until completion of the penal period.
- (c) Tender should not be submitted by any tenderer as a whole, who have been blacklisted/debarred either by APMSIDC or by any other State/Central Government's organization/Procurement agencies on the grounds of quality failure or any other grounds of unethical practices such as Fraudulent/Corrupt practices etc., until completion of the penal period
- (d) During the validity of the tender, if the firm / Company is blacklisted/debarred/deregistered/banned by any State Government / Central Government / its Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to APMSIDC along with relevant authentic document by the tenderer firm/ company within one month otherwise a penalty of Rs 1,00,000/-shall be imposed on the firm by APMSIDC.
- (e) The tenderer should confirm that they have read tender document including Amendment(s) to Tender document (if any) along with terms and condition and these terms and condition of tender document including Amendment(s) to Tender document (if any) are acceptable unconditionally to them.
- (f) If the firm has retained their drug manufacturing license but does not have the approved products list duly attested by the licensing authority of which manufacturer has retained, the manufacturer may submit an affidavit (on Rs.100 Non-Judiciary stamp paper) containing the list of products retained by them, license no. and validity against each product along with a statement that they have retained the license vide retention particulars such as fee paid challan no. date

#### D. TECHNICAL BID

The Tenderer should upload the following documents while submitting technical bid. (Scanned copies of each page of all documents should be uploaded while submitting Technical bid).

- (a) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorized signatory (ANNEXURE II) confirming each clause mentioned in Section 2 of eligibility criteria.
- (b) In case the bidder is Importer, they may strike the clause or part of clause not applicable in their case. The surgical &consumables indicated in this undertaking shall only be considered for evaluation and opening of price bid.
- (c) Samples and Offline documents in sealed cover should be submitted to APMSIDC, Mangalagiri on or before the scheduled date given in Tender Document.
  - i. EMD instrument should be submitted to APMSIDC, Mangalagiri on or before the schedule date of technical bid opening.
  - ii. The tenderers are required to upload a certificate from the C.A. (Chartered Accountant) or Company Secretary as per **ANNEXURE IV.** Or any other authorized format for imported products.
  - iii. Authorization letter nominating an officer of the Tenderer on the printed letter head of the company to transact the business with the APMSIDC to be uploaded.
  - iv. And all the documents that are to be submitted as per the tender condition.
- (d) The Tenderer should upload Scanned copy of valid Drug/Kit Manufacturing License/Authorized **Distributor License** for the product.
- (e) Scanned copy of import license (in Form 10 with Form 41)/MD-15(import License), as per Rule 122A of the Drugs and Cosmetics Act 1940, if the product is imported should be uploaded. The license must have been duly renewed up to date and the items quoted shall be clearly highlighted in the license. A copy of a valid license for the sale of Drugs/Items imported by the firms issued by the State Licensing Authority shall be uploaded. Original documents should be produced for verification when demanded.
- (f) Documents, if any, to show that the manufacturing unit/importer has been recognized by any other Indian / International Standard Organizations etc. as applicable. Importer should upload WHO-GMP certificate of manufacturer. /ISO/CE/BIS certificates

- (g) A Checklist shall be uploaded with technical bid. If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will be uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.
- **(h)** All the documents uploaded should also be signed by the authorized official of the Tenderer.

#### E. PRICE BID

Price Bid of the Tenderer.

- (i) The Tenderer shall fill in the rate per unit size inclusive of GST (Can provide Rate quoted information in Remarks column)
- (ii) Determination of L1 bidder:
  - In determining the lowest evaluated price, the rate quoted per unit size inclusive of GST as indicated in price bid shall be taken into consideration and lowest landed price will be taken into consideration for determination of L1 Bidder.
- (iii) In case no information is given on GST, it shall be presumed that rates are inclusive of GST and no GST shall be charged by them under any circumstances.

#### F. OPENING OF TENDER

- 5) After the completion of Technical evaluation preliminary objections will be published on APMSIDC portal **www.apmsidc.ap.nic.in** for replies from firms. After scrutiny of these remarks by the technical committee final evaluation will be done.
- 6) Only the technically qualified firms in the bid will be eligible for opening of price bid.

#### **G. OTHER CONDITIONS**

(i) The details of the required surgical & consumables are shown in ANNEXURE
 -VIII. The tender quantity mentioned herein is not a fixed procurement
 quantity and it is only a tentative requirement and may be increased or
 decreased by APMSIDC, at its discretion, depending on its actual need. Though
 the tentative quantity is indicated in the price agreement, the APMSIDC, will

confirm the actual requirement then and there through purchase order/orders. The tenderers shall supply the surgical consumables only on the basis of the purchase order issued from time to time within validity of contract period by the APMSIDC. Any supply without a valid purchase order will not be acceptable by APMSIDC and the APMSIDC shall not be responsible for any loss on this account.

- (ii) The Tenderer shall fill in manufacturing capacity per year in units, Shelf life in months and manufacturing batch size in units for each quoted surgical consumable in required column of **ANNEXURE –V and upload along with technical bid.** In case the bidder is Importer, the importer is required to sign and upload ANNEXURE V on behalf of the exporter which would be supported by documentary evidence provided by the manufacturer.
- (iii)However, once the purchase order/orders is/are issued by the APMSIDC, the tenderer shall no trenege from the commitment of supplying the quantity mentioned in the acceptance of tender for price agreement.
- (iv)The rates quoted shall not be varied with the ordered quantity during the full contract period.
- 2) Rates (inclusive of Customs duty, packing & forwarding charges, transportation, insurance and any incidental charges, all taxes, GST) should be quoted for each of the required surgical consumables separately on door delivery basis to all 13 Central Drug stores located in District headquarters of AP state according to the unit ordered. Tender for the supply of surgical consumables. With cross conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the purchase order placed with Tenderers.
- 3) Each bid must quote not only the unit rate but also the total value of each item quoted for supply in the respective columns. The aggregate value of all the items quoted in the tender shall also be furnished.

#### H. FALL CLAUSE:

1) If at any time during the execution of the contract, the controlled price becomes lower or the supplier reduces the sale price or sells or offers to sell such stores, as are covered under the contract, to any person / organization including the purchaser or any department of Central government/state Govt. or its procurement agencies at a price lower than the price chargeable under the contract, he shall forthwith notify such reduction or sale or offer of sale to the purchaser and the price payable under the contract for the stores supplied

- after the date of coming into force of such reduction or sale or offer of sale shall stand correspondingly reduced.
- 2) The rates quoted and accepted will be binding on the Tenderer for the full contract period of two years and any increase in the price will not be entertained till the completion of this contract period. Accordingly, this clause will be applicable for all orders placed during the contract period. However, Price agreement validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.
- 3) No Tenderer shall be allowed at any time and on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by them. Representation to make correction in the tender documents on the ground of Clerical error, typographical error, etc., committed by the Tenderers in the Bids shall not be entertained after submission of the tenders. Cross Conditions such as "SUBJECT TO AVAILABILITY", "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the tenders of those who have mentioned such conditions shall be treated as incomplete and accordingly the Tender will be summarily rejected.
- 4) The Tenderer shall allow inspection of the factory at any time after the opening of technical bid and during the entire contract period by a team of Experts/Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/Firm does not allow for any such inspection, their tenders will be rejected. If any such situation arises after placement of contract, the same shall be cancelled at the firm's risk cost.
- 5) "AP Govt Supply Not for Sale" should to be printed on each unit/label by the successful bidders. However, this is exempted for imported items.

#### I. ACCEPTANCE OF TENDER

- 1) (i). The purchase order shall be issued to L1 bidder and L2 bidders simultaneously as per discretion of APMSIDC depending upon requirement. In case, L2 bidder does not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. In case, order is placed only on L1 bidder and if they fail to supply in stipulated time or due to quality failure, the purchase order shall be issued to L2 bidder.
  - (ii). Negotiation if required will be done at APMSIDC premises.
  - (iii). Successful bidders pay a **Corpus Fund fee of 0.04%** (max ₹10k/₹25k) and a **Transaction Fee (eProcurement fee) of 0.03%** (max ₹10k/₹25k) of the Estimated Contract Value (ECV) to APTS, as mandated by various Government Orders like GO Ms. No. 4 (2005) for services, collected via the portal. These are

non-refundable fees, capped at ₹10,000 for ECV up to ₹50 Cr and ₹25,000 for ECV above ₹50 Cr, paid before agreement.

- 2) APMSIDC reserves the right to accept or reject the tender for the supply of all or any one or more items of the s tendered for in a tender without assigning any reason.
- 3) **APMSIDC** also reserves right to place one-time purchase order for certain quantity of any surgical consumables even without price agreement, for such surgical consumables' suppliers are required to pay performance security deposit @ 5 % of value of order of such item in the form of DD.
- 4) The acceptance of the tenders for Price Agreement for two years period will be communicated to the Tenderers.

#### J. PERFORMANCE SECURITY DEPOSIT

- 1) Performance Security Deposit:
- 2) On being informed about the acceptance of the tender for 2 years price agreement, the successful tenderer shall be required to pay a Performance Security Deposit of 5% of the contract value subject to a maximum of **Rs.5 lakhs** per product in the form of *Demand Draft* drawn infavor of MD, APMSIDC Mangalagiri from any nationalized/scheduled Bank.
- 3) The Tenderer shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons whatsoever.
- 4) All notices or communications relating to and arising out of this price agreement or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to him or left at the premises, places of business or abode as provided by the tenderer.
- 5) If the lowest selected Tenderer fails to deposit the required Performance Security Deposit (PSD) within the time specified or withdraws the tender, after the intimation of the acceptance of the tender or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the tenderer along with the tender shall stand forfeited by the APMSIDC and the firm will also be liable for all damages sustained by the APMSIDC apart from blacklisting and other penal actions.
- 6) The performance security deposit of supplier will be returned after the end of rate contract period by APMSIDC only after the supplier has given undertaking to replace items supplied and indemnify APMSIDC against any losses on account of quality parameters.

7) **SSI-**units situated in A.P are exempted from payment of Performance Security Deposit.

#### K. METHODOLOGY FOR PLACING ORDERS

For the above purpose the following procedures will be adopted

- 1) After the conclusion of Price Bid opening, the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed.
- 2) The successful Tenderer is eligible for the placement of Purchase Orders only after depositing the required amount as Performance Security.
- 3) If two or more than two Tenderer's are declared as lowest suppliers for the same item(s), such Tenderers are eligible for price agreement and the placement of Purchase Orders for such item(s) for which they are declared as lowest. Placement of order shall be shared equally amongst these bidders subject to their manufacturing capacity.
- 4) In the case of purchase of goods where the quantity offered at the lowest price is less than the total quantity required, the APMSIDC may, after placing orders with the lowest evaluated Tenderer for the entire quantity offered by such Tenderer subject to his ability to supply, require all the other eligible Tenderers who participated in the tender and offered a price higher than that offered by the lowest evaluated Tenderer, to submit sealed offers of the quantity they would be willing to supply at the price quoted by the lowest evaluated Tenderer, and thereafter place orders for the remaining required quantity with all those who match the lowest evaluated price such that those who bid lower prices in the original tender get a higher priority for supply.
- 5) If a supplier fails to execute supply order (0% execution) Performance Security Deposit of the product mentioned in purchase order shall be forfeited.
- 6) Notwithstanding anything contained in para (e) above, the supplier, after committing the default in supply either partly or fully, can inform the APMSIDC about his willingness to execute the Purchase Order during the tender period. The APMSIDC at discretion may consider the willingness of the supplier on merit. However, such supplies will be subjected to the levy of Liquidated Damages, unexecuted fine and other penalties as stipulated in the tender document, price agreement and purchase order.
- 7) The supplier shall start supply of the surgical consumables required by APMSIDC at 13 Central Drug Stores (CDS), in Andhra Pradesh or any other place decided by APMSIDC within the stipulated period.

- 8) The surgical consumables supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. APMSIDC will not be responsible for the loss to the supplier and will not entertain any demand/claim.
- 9) After completion of supplies, the documents related to tax invoice, test reports of supplied batches or any other document shall be submitted to APMSIDC for proper acknowledgement of stocks. Supplier need to upload all the required details in eAushadhi portal prior to supply to CDS. APMSIDC will not be responsible for any delay in uploading the documents by the supplier which may lead to unforeseen penalties or any wrong entries due to typographical errors.
- 10)It is the duty of the supplier to supply Drugs/Medicines at the 13 CDS in AP or any other place decided by APMSIDC and supply shall conform to the conditions mentioned in the provisions of tender documents, viz., logo, nomenclature, specification etc. having a minimum of 5/6<sup>th</sup> of the shelf life
- 11).APMSIDC reserves the right to place up to 50% additional purchase order of the quantities as contracted within validity of contract.

#### L. SUPPLY CONDITIONS

- 1) Purchase orders will be issued to the Tenderer(s) at the discretion of the APMSIDC as per actual requirements. All the supplies shall be received at the 13 CDS in AP or any other place decided by APMSIDC.
- 2) Within 4 days from the receipt of purchase orders, the Tenderer should inform APMSIDC through eAushadhi for the receipt of the purchase order.
- 3) The Tenderer should also Communicate and mail the details of supply dates as specified in Annexure, to APMSIDC within 7 days from the receipt of the purchase order. In case, the supply shall not be made by the date as conveyed by the supplier, supply order shall be cancelled at their risk and cost. If no response is received within 7 days from the supplier / tenderer about supply of surgical consumables as per purchase order, it shall be presumed that the supplier/tenderer is not interested to supply the surgical consumables ordered as per purchase order and APMSIDC shall purchase the surgical consumables from alternative sources.
- **4)** Supplies against a purchase order shall be completed within **60 days** otherwise liquidated damages are levied by APMSIDC as mentioned in clause 18.1.
- 5) If the Tenderer fails to execute the supply within the stipulated time, the APMSIDC is at liberty to make alternative arrangement for purchase of the items for which the Purchase orders have been placed, from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the defaulted supplier and in such cases the APMSIDC has every right to recover the cost and impose Liquidated Damages as

- mentioned in Clause 18. In case of any variation in prices during alternative procurement will be charged to L1 bidder or defaulted supplier.
- 6) The liquidated damages as specified in clause 18.1 and 18.2 of the tender conditions will be levied. However, the supplier must take prior approval from APMSIDC for supply of Surgical and consumables beyond stipulated delivery period in Purchase order.
- 7) The Tenderer must submit an Analysis report for every batch of surgical consumables along withinvoice. In case of failure on part of the supplier to furnish such report, the batch of surgical consumables will be returned to the suppliers and he is bound to replenish the same with Govt. approved lab test report. The Surgical Consumables supplied by the successful Tenderer shall be of the best quality and shall comply with ISO/BIS/CE and the specifications specified in the tender.
- 8) If at any time the Tenderer has, in the opinion of the APMSIDC delayed the supply of surgical consumables due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest, floods or other exceptional events at the manufacturing premises, the time for supplying the surgical consumables may be extended by the APMSIDC at discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 20 days from the date of occurrence of such event with necessary documentary evidence. The exceptional events do not include the Increase in the cost of raw material, Electricity failure, Labour disputes/Strikes, Insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.
- 9) The supplier shall not be liable to pay LD and forfeiture of performance security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.
- 10) If the product is not consumed prior to its expiry date, i.e., within six months before expiry, the supplier shall be responsible for replacing the near-expiry stock at no additional cost.

The supplier will be notified about the short-expiry surgical consumables. Upon receipt of such information, the supplier shall replace, at their own cost (including to-and-fro transportation), the short-expiry/expired quantity with fresh stock having a longer shelf life. Failing this, an amount equivalent to the cost of the expired quantity will be deducted from the supplier's bills or any other payment due to the firm

#### M. LOGOGRAMS

Logogram means, wherever the context occurs, the design as specified in ANNEXURE-I. The name of the product shall be mentioned in English /Telugu as per pharmacopoeia and its strength.

- 1) Tenders for the supply for Surgical and consumables., shall be considered only if the Tenderer gives an undertaking that the product(s) will be prepared as per the specifications such as name, strength, minimum size and packed with appropriate size as per the design enclosed as per ANNEXURE –I.
- 2) Failure to supply Surgical and consumables with the printed logogram of proportionate size will be treated as breach of the terms of price agreement / violation of tender conditions. The purchase order shall be cancelled at the risk and cost of the supplier. However, if such failure continuous despite notice, will be viewed as a serious lapse and APMSIDC will initiate suitable action.
- 3) For imported surgical consumables, the supplies will be accepted as per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by APMSIDC.

#### N. PACKING

- 1) The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration.
- 2) The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements, as shall be provided for in the contract and subject to clause 18 and any subsequent instructions ordered by the purchaser.

#### O. QUALITY TESTING

 Samples of supplies from each batch will be chosen at the point of dispatch at supplier's site or receipt of supply or distribution/storage points for testing at discretion of APMSIDC. The samples will be sent to different laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing as

- decided by the APMSIDC. Handling and testing charges will be borne by APMSIDC for the above purpose.
- 2) In the event, if the samples fails in quality tests or found to be not as per specifications, APMSIDC is at liberty to make alternative purchase of the items of items for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in such cases the APMSIDC has every right to recover the cost and impose penalty as mentioned in Clause 19.
- 3) The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the APMSIDC. In case of any complaint in the field, the B.M.R/B.P. R for the particular batch of the product(s) supplied shall be produced when demanded.
- 4) The products should conform to the standards of ISO/BIS/CE/ISI as the case may be. In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. For imported products, respective Country.

#### P. PAYMENT PROVISIONS

- 1) No advance payments towards costs of surgical consumables will be made to the Tenderer.
- 2) 16.2. Payments towards the supply of items will be processed and uploaded in CFMS within 60 to 90 days after supply and submission of all required documents as per the terms and conditions of PO. The payment will be made through AP Government Finance portal CFMS / RTGS (Real Time Gross Settlement System)/Core Banking/NEFT. The Tenderer shall furnish the relevant details in original (MANDATE FORM) to make the payment through CFMS/RTGS/Core Banking/NEFT.
- 3) All bills/Invoices should be raised in duplicate and the bills should be drawn as per GST Rules in the name of MD, APMSIDC. Mangalagiri, Andhra Pradesh.
  - (i) Company / Supplier will be able to raise the invoice for the supplied quantity only after completion of minimum 95% of the purchase order quantity and payment will be processed accordingly for the supplied quantity only after receipt of confirmation from the Company / Supplier that they will not be able to supply the balance quantity.

- (ii) In case, if the Company / Supplier supplies a partial quantity which is less than 95% of the purchase order quantity, then the Company / Supplier will be able to raise the invoice for the supplied quantity along with confirmation from the Company /Supplier that they will not be able to supply the balance quantity. In such cases, payments will be processed for supplied quantity at the discretion of APMSIDC by imposing a penalty of 10% on the value of unexecuted quantity and this is apart from the liquidated damages.
- (iii) The payment for part supply if any will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.
- 4) If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the APMSIDC immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.
- 5) In case of any increase or decrease in the GST after the date of submission of tenders and during the tender period, such variation in the GST will be to the account of the APMSIDC. For claiming the additional cost on account of the increase in GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to APMSIDC from the concerned authorities and also must claim the same in the invoice separately.
  - a) However, the basic price structure and the price of the surgical approved under the tender shall not be altered. Similarly, if there is any reduction in the GST as notified by the Govt., after the date of submission of tender, the Tenderer will be paid based on the unit rate worked out on the basis of the reduced GST without any change in the basic price or the price structure of the surgical approved under the tender. Any increase or decrease in GST will be considered based on the notification issued by the Government.
  - b) However, if the firm supplies after originally stipulated delivery period, increase in GST shall be borne by the supplier. In case of decrease in taxes/GST due to statutory variation in taxes/GST, the same shall be passed on by the supplier to the APMSIDC.
  - c) Subject to the conditions mentioned in the Purchase Order, Tender Document, Price Agreement and here under, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 30 days from the date of receipt of payment.

#### **Q. TESTING CHARGES:**

In all supplies, testing charges will be borne by APMSIDC as per the Batch sizes provided by Firm. For Excess batches beyond their batch size confirmation will be charged double testing charges from their payable bills.

#### R. LIQUIDATED DAMAGES AND OTHER PENALTIES:

Category of Products	Stipulated supply period as per Tender clause	% of Penalties
Surgical consumables	60 days	Nil
	60 to 75 Days	0.5% per day.
	76 to 90 Days	The supply period can be extendable for another 15 days beyond 76 days upon request @ 0.5% per day.At sole discretion of MD,APMSIDC.

- \* Liquidated damages shall not be more than 10% (for all manufacturing firms outside AP) and not more than 5% (for all SSI manufacturing firms within AP) as per clause 9.7.9 of Manual Procurement of Goods-2017.
- \* Beyond 105 days if the PO is not executed, the PO will be deemed to be cancelled and the firm will be declared as undependable.
- a) If the supply is received in damaged condition, open delivery of the supplies shall be received, wherein it is possible to physically inspect the shipment, damaged products shall not be accepted.
- b) All the Tenderers are required to supply the product(s) with printed "Andhra Pradesh Govt. Supply Not for Sale" and logogram of appropriate size. If there are any deviations in this condition, action will be taken to blacklist the product and/or a separate damage will be levied @ 5% of value of the defaulted quantity irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.14.11 and 13.4. Imported products can be exempted from this condition.

#### S. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF QUALITYFAILURE:

- 1) If the samples do not conform to statutory standards, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the issue of the letter from the APMSIDC Such stock shall be taken back at the expense of the Tenderer. Further, actual testing charges (including handling charges for conducting those tests) shall be paid to APMSIDC by the supplier otherwise these charges shall be recovered from their pending bill/EMD/performance security deposit. The APMSIDC has the right to destroy such "NOT OFSTANDARD QUALITY" if the Tenderer does not take back the goods within the stipulated time.
- 2) The decision of the APMSIDC or any officer authorized by him, as to the quality of the supplied surgical consumables shall be final and binding. In such cases, the APMSIDC will be at liberty to terminate, the contract either wholly or in part on 30 days' notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Performance Security Deposit.
- 3) For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the APMSIDC, and the Tenderer shall be liable to pay for all losses sustained by the APMSIDC in consequence of the termination which may be recovered from the Tenderer, as per rules besides forfeiture of Performance Security Deposit.
- 4) Non-performance of any of the contract conditions and provisions will disqualify a firm from participating in the tender for the next 2 years besides forfeiture of Performance Security Deposit.
- 5) In the event of making Alternative Purchase, as specified in Clause 12.4 (a), Clause 14.11 and in Clause 15.3 penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the APMSIDC in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Performance Security Deposit or from any other money due and become due to the supplier and in the event of such

amount being insufficient, the balance will be recovered personally from the supplier as per rules.

6) In all the above conditions, the decision of the MD, APMSIDC shall be final and binding.

#### T. BLACK LISTING:

## BLACKLISTING IN THE EVENT OF WITHDRAWL FROM THE TENDER, AND NON-ADHERENCE TO THE QUALITY STANDARDS AND SUPPLY SCHEDULE

#### **BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER**

If the Tenderer(s) fails to perform the obligations under the tender conditions / commits default in the performance of the contract, such Tenderers will be blacklisted for a period of 2 years by APMSIDC from the date of observing the defect besides forfeiture of Performance security deposit.

#### **BLACKLISTING FOR QUALITY FAILURE**

#### QUALITY TEST BY THE EMPANELLED LABORATORIES OF APMSIDC

- a. Each batch of supplied surgical consumables shall be subjected to quality test by the empanelled laboratories.
- b. The samples collected from each batch of supply of each surgical consumable will be sent to the empanelled testing laboratories for testing the quality of surgical consumables. In addition to the above APMSIDC hall also draw the samples of products supplied to the health facilities and get the same tested, to make sure the products are conforming to quality requirements.
- c. If sample passes quality tests in all respects, APMSIDC will instruct its CDS to release such items for usage.
- d. If the sample of any batch fails in quality test and report is received stating Not of Standard Quality such batch of product shall be rejected.
- e. If the supplier challenges and requests for retesting after an NSQ is received from empanelled laboratory (other than Government Laboratory), the other portion of the same batch shall be sent to State Drugs Control Laboratory, AP or any other Government testing laboratory or NABL accredited laboratory as decided by APMSIDC. The test report received from any of these laboratories

(second opinion) will be final for any decision and will be binding to the supplier. The cost of such retesting shall be recovered from the supplier.

If two batches of item supplied by the same supplier is reported to be NOT OFSTANDARD QUALITY (NSQ) in specifications as given in table under clause 20.2.2(b), then the product of the firm shall be blacklisted for 2 years after observing procedure laid down in Para 20.2.3.

#### **QUALITY TEST BY STATUTORY AUTHORITIES:**

a. If any item is declared "NOT OF STANDARD QUALITY", by any of the Government testing laboratory (DCL, AP or CDTLs or NIB, Noida or any other Government labs), the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals/CDS will be retrieved.

b.

S.No (A)	Formulation (B)	Test Parameters in which sample fails	No. Of Batches that fail the test (D)
1	Surgical consumables	Failing in test for Sterility, Fungal Growth	02
	Consumables	Any other parameter	03
2	Diagnostic kits	Incorrect result	03

As per the above table if number of batches of same product (shown in column D) of a particular firm are declared as NSQ in tests shown in above table then that particular surgical consumable of the firm will be blacklisted against the firm for a period of 2 years.

The amount of the NSQ batch shall be deducted/ withheld from the amount payable to the firm or from the performance security deposit of the firm. No purchase orders will be placed for the blacklisted item of the firm.

- c. In case a firm is supplying more than one product and one of the products is declared as NSQ, in such case, in addition to the measure suggested above, 10% of total bill amount submitted by the firm will be withheld for a period of four months and will be paid after monitoring satisfactory supply of all other products.
- d. If two items of any firm are blacklisted, then the entire firm will be blacklisted, and it will not be allowed to participate in tender for 2 consecutive years from the date of blacklisting.

e. If any batch of any product(s) supplied by the company/firm declared, NOT OF STANDARD QUALITY in specification by the Government Authorities during the relevant tender period or during quality check within shelf life period, suitable action will be taken for blacklisting of the product/ firm.

#### PROCEDURE FOR BLACKLISTING:

- 1) On receipt of complaint from CDS or report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item is "NOT OF STANDARD QUALITY" (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the MD, APMSIDC may take appropriate action on merits of the case and impose penalty including the blacklisting of the item of the product/company or firm as deemed fit besides forfeiture of Performance Security Deposit.
- 2) If a particular product has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for that particular item floated by the APMSIDC until the period of blacklisting is over.
- 3) If a supplier company/firm is blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the APMSIDC until the period of blacklisting is over.

#### **BLACKLISTING FOR NON-SUPPLY:**

Due to non-supply of item against any purchase order, 5 % value of purchase order shall be recovered from the supplier in addition of other penal like risk purchase. In case of repeated circumstances of non-supply of items i.e. 3times, the supplier may be blacklisted for 2 years in addition of forfeiture of Performance Security Deposit/ EMD and other penal action.

#### APPEAL (s) IN CASE OF BLACKLISTING:

I. A supplier/firm whose product or the supplier/firm, itself have been blacklisted by the corporation which is displayed in the corporation website i.e.://msidc.ap.nic.in// may within 15 days from the date of display, may appeal to the Director General, Drug Control Administration, A.P.

The Director General, Drug Control Administration, A.P., after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto, as he thinks fit.

II. If the firm is not satisfied with the outcome may appeal within 15 days to the Principle Secretary, Health, Medical & Family Welfare, A.P. for review. The State

Government after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto, as it thinks fit.

#### **U. SAVING CLAUSE**

No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.

APMSIDC reserves the right to make modification, alteration or relaxation in any of the clauses or conditions given in this tender document.

#### V. RESOLUTION OF DISPUTES

The APMSIDC and the supplier shall make every effort to resolve, amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the contract.

#### **FRAUDULENT AND CORRUPT PRACTICES:**

#### For bidders:

If the APMSIDC determines that a Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the APMSIDC may, after giving 7 days' notice to the Supplier, terminate the Supplier's engagement under the Contract and cancel the contract, and the procurement will be made at the risk and cost of the supplier besides blacklisting the bidder for 2 years with forfeiture of Performance security deposit apart from other penal actions.

It is purchaser's policy to ensure that suppliers and their authorized representatives/agents observe the highest standard of ethics during the procurement and execution of such contracts. (In this context, any action taken by a bidder, supplier, contractor, or by their authorized representatives/agent, to influence the procurement process or contract execution for undue advantage is improper) In pursuance of this policy, the purchaser;

- (a) defines, for the purposes of this provision, the terms set forth below as follows:
  - i. "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party ("another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes staff and employees of other organizations taking orreviewing procurement decisions.

- ii. "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission "is intended to influence the procurement process or contract execution).
- iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party ["parties "refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, noncompetitive level].
- iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a"party" refers to a participant in the procurement process or contract execution).
- v. "obstructive practice" is
  - (a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or acts intended to materially impede the exercise of the purchaser's inspection and audit rights provided for under sub-clause (e) below.
  - (b)will reject a proposal for award if it determines that the bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;
  - Iwill cancel the contract if the purchaser determines at any time that the bidder, supplier and contractors and their sub-contractors engaged in corrupt, fraudulent, collusive, or coercive practices.
  - (d)will sanction a firm or individual, including declaring in eligible, either indefinitely or for a stated period of time, to be awarded a contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract; and
  - (e) will have the right to inspect the accounts and records of the bidders, supplier, and contractors and their subcontractors/authorized representatives and to have them audited by auditors appointed by the purchaser.

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#### W. JURISDICTION

In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Honorable Civil Courts within the city of Vijayawada only.

#### X. FORCE MAJEURE

- For purposes of this clause "Force Majeure" means an event beyond the
  control of the supplier and not involving the supplier's fault or negligence and
  not fore-see-able. Such events may include but are not limited to, acts of the
  purchaser either in its sovereign or contractual capacity, wars or revolutions,
  floods, epidemics, quarantine restrictions and freight embargoes.
- If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such conditions with documentary evidence and the cause thereof. Unless otherwise directed by the purchaser in writing the supplier shall continue to perform its obligations under the contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

#### **ANNEXURE -I**

#### **DESIGN FOR LOGOGRAMS**

## SPECIMEN LABEL FOR OUTER CARTON AND INNER INDIVIDUAL PACK OF THE PRODUCT

A.P. GOVT.

**SUPPLY** 

**NOT FOR SALE** 

(or)

**DECLARATION** 



I do hereby declare that I will supply the surgical consumables as per the above design.

Signature

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### <u>ANNEXURE –II</u> (On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)

## **DECLARATION**

I/We M/s represented by its Proprietor/Managing Partner /Managing Director having its registered office at and its factory premises at do hereby declare as under: -
(I) that I/we have carefully read all the terms and conditions of tender in ref. no including Amendment(s) to Tender document (if
any) issued by APMSIDC, Mangalagiri and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).
(II) I/We hereby declare that all required annexures and documents are uploaded.
(III) lam / We are aware of the Tender inviting Authority's right to forfeit the Earnest Money Deposit and /or Performance security deposit and blacklist me/us for a period of 2 years if, any information furnished by us proved to be false at time the of inspection and also not complying with any of the tender conditions.
Name of the bidder:
Address:
Name of the authorized signatory:
Sign and Seal:

## **ANNEXURE-III**

## Ref. Clause No.4.1(b)

{Format	for a certi	ificate from the C.A. (Char	tered Accountant) o	or Company Secreta	ry}
/Ltd./Prop GST regis The author	orietorship stration no orized sigr	that M/s/Partnership company/fic They have filed Incornatory of the company/firm	rm and they h ne tax returns and n is Shriand	nave PAN no and GST returns up to d	ate.
2021-22,	2022-23 a	furnover of M/sand 2023-24 <b>or</b> 2022-23, atement is true and correc	2023-24 and 2024-		
	S. No	Financial Year	Turnover in Lakh	ıs (Rs.)	
	1				
	2.				
	3.				
	TOTAL	_	Rs	Lakh	
	Average	Turnover per annum	Rs	Lakn	
-		has Pro			that ture
M/s has Production &financial capacity to manufacture and deliver the Surgical Consumables quoted by them in the tender as per quantity & delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.					
Or <b>(ONL)</b> manufact quantity	<b>f</b> i <b>n case</b> ure and d &delivery	of IMPORTER) It is certiful eliver the surgical consumers schedule mentioned in acity, inventory of raw Material and material acity.	fied that M/s h nables quoted by th tender. This certifi	nem in the tender as icate is based on t	per
Director	of Industr	e of SSI/MSME Manufis Micro and Small ies appropriate authoritie and	Enterprises (MSE) s for quoted prod	)/SSI and registered lucts against APMS	with
		aria .	onglore for externipul	on or paying Livib.	

(Name, Signature & Stamp) Registration no.

## ANNEXURE- IV CHECK-LIST

#### (Documents to be Uploaded)

S.No	Check List	YES	NO	PAGE
1	Processing Fee The bidder shall remit processing fee Rs.11,800/-(NON REFUNDABLE) through ape-procurement site.			
2	EMD Rs. 3,00,000/- in the form of Demand Draft / NEFT/ RTGS/ Online Uploaded NSIC or MSME certificate of AP state as manufacturer for quoted products for EMD exemption if any.			
3	Scanned copy of Valid Manufacturing License, if participated as manufacturer. (Applicable for Bidder participated as Manufacturer)			
4	Scanned copy of Distributor license issued by Drug Licensing Authority and Copy of Manufacturer Authorization along with valid manufacturing license. (Applicable for Bidder participated as Distributor).	1		
5	Scanned copy of Valid ISO/BIS/CE/ISI/Any other Quality Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company.	1		
6	Scanned copy of Valid Import License, if Imported and wholesale Drug license			
7	Scanned copy of valid Non-Conviction Certificate issued in the name of firm by the licensing authority for Drug Items/ Non Drug items-CA certificate as per tender document.	I		
8	Scanned copy of ANNEXURE II (Declaration for eligibility in participating the tender) original Annexure II delivered to APMSIDC.			
9	Scanned copy of ANNEXURE III Certificate from the C.A. (Chartered Accountant) or Company Secretary.			
10	Scanned copy of ANNEXURE-VI (Mandate form)			
11	Scanned copy of ANNEXURE V (Details of Quoted Products)			

NOTE: -EMD instrument and Processing Fee are to be delivered in original to APMSIDC, Mangalagiri on or before stipulated dates give in document.

Name and signature of authorized signatory (with company seal).

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### **ANNEXURE-V**

#### **DETAILS OF THE PACK SIZES FOR QUOTED ITEMS**

	we			_ naving registered				
off	ice							
at_								
	do hereby declare that default pack sizes of quoted product are as follows and we							
	110	he below mentioned o	uoted products in the	following pack				
siz	es.							
<b>Example</b>	<u>e format:</u>							
			Manufacture	Available pack				
S No	Item Code	Item Name	Name	size				
1								
2								
3								
* The san	ne Excel sheet ha	s to submitted in mai	to <u>tendersapmsidc@g</u>	mail com under				
			to tendersupmistacies	dian.com under				
the subject: Tender No :								
Date:								
Signature	e Seal:							
o .								
	sed Signatory)	D: 11						
Name and Address of the Bidder								

## MANDATE FORM (ANNEXURE VI)

S.No.	Details Required		
1.	Company Name		
	PAN Number		
	TIN Number		
	GST NO.		
	Date of Inception		
	Legal status of the Bidder		
	(Proprietorship/ Partnership/		
	Pvt. Ltd. Company/ Limited		
	Company)		
	License No. & Date		
	Issued By		
	Valid Up to		
2.	Postal Address of the		
	Company		
	Telephone No.		
	Fax No.		
	E-mail ID		
	Alternate E-mail ID		
3.	Name of the Managing		
	Director / Director / Manager		
	Mobile No. / Phone No		
	E-mail ID		
4.	Name and Designation of the	Name:	
	authorized company official	Designation:	
	Mobile No.		
	E-mail ID		
5.	Bank Details		
	a) Name of the Bank		
	b) Branch Name & address		
	c) Branch Code No.		
	d) Branch Manager Mobile		
	No.		
	e) Branch Telephone no		
	f) Branch E-mail ID		
	g) 9-digit MICR code number		
	of the bank and branch		
	appearing on the MICR		
	cheque issued by the bank		

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S.No.	Details Required	
	Branch	
	h) Type of Account (Current / Savings)	
	i)Account Number (as appear	
	in cheque book)	

(In lieu of the bank certificate to be obtained, please upload the original cancelled cheque issued by your bank for verification of the above particulars).

I / We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all the reasons of incomplete or incorrect information, I would not hold APMSIDC responsible. I have read the conditions of the tender / Price agreement and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

Date: Place:

Company Seal......Signature (Name of the person signing & designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

## **TENDER ITEMS**

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
1	2021070	Percutaneous Tracheostomy Tubes Size 4	1	Percutaneous Tracheostomy Tubes Size 4	1,000
2	2021077	Elisa Printer Roll 57x20mm	1	Elisa Printer Roll 57x20mm	1,200
3	10279	Zesisphaco tubing sets	1	Zesisphaco tubing sets	1,000
4	10278	Zesisphaco sleeves	1	Zesisphaco sleeves Guage 19 and 20 Color White Each	500
5	5712	Disposable Perilaryngeal Airways	1	Should have ultra thin cuff for a high volume low pressure seal. Cuff should be positioned in the upper Hypo pharynx. Should have gently curved ramp near distal end for insertion of Bronchoscope. Should have the facility of ramping any ET Tube through i	516
6	5783	H1 Lectin 5ml	1	Halilectin 1 (H 1) 5ml	4,200
7	10264	Lapro sheath 5mm	1	5mm	500
8	10251	96 Hours Online Iv Bacterial Filters 0.2 Micron Size	1	0.2 Micron Size 16	
9	2021052.2	Tourniquet Adult thighs	1	Tourniquet Adult thighs	2,077
10	5938	Synthetic Pyrethroids water Dispersible Powder(WDP)/Wet table Powder	1	Synthetic Pyrethroids water Dispersible Powder(WDP)/Wettable Powderequivalent 2.5 percentage conforming to following (1).Cyfluthrin WHO/IS/98.2.2 (2).Lambdacytha	1,000

#### **APMSIDC :: DRUGS WING**

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
11	5821	Tracheostomy speaking valve	1	Tracheostomy Speaking Valve is designed to allow tracheostomy patients to vocalize without the need for finger occlusion. The valve provides low resistant one way airflow using a thin silicone diaphragm that opens on inspiration and closes on expiration. An exclusive feature of this valve is a cough release mechanism eliminating valve or tube dislodgment as a result of coughing or excessive airway pressure. Attaches securely to any tracheostomy tube with a 15mm connector	1,000
12	10238	Gigglys Saw wire Overall length 12inch	1	Overall length 12 inch (304.8mm) Standard grade stainless steel gigli saw wire for use with Gigli saw handles	14,023
13	5914	Barburs thread Size No 20	1	Size 20 No Each	64
14	5930	BP Cuff size Paediatric	1	size Paediatric	3,062
15	2021047	Mucus Suckers Penguin	1	Mucus Suckers Penguin type	10,341
16	10275	Trial boxes	1	Trial Boxes Each	500
17	10265	vaccum extractor for baby	1	Silastic and disc shaped KIWI CUPS 2 SIZES disposable	172
18	2021120	Red Rubber Urinary Catheter	1	Size 8 Fr	2,000
19	10282	Retinal bond 240	1	Retinal bond 240 Each	5,000
20	10280	Vitrectomy cutters	1	Vitrectomy cutters Each	500
21	10277	Microscope bulbs 12x100	1	Microscope Bulbs 12X100 mono pack	500
22	10276	Microscope bulbs15x150	1	Microscope Bulbs 15X150 mono pack	500
23	5823	Absorbable surgical suture USP (Synthetic) sterilized surgical needle suture 0 (Box of 12 Foils)	Box of 12 Foils	Sterilized surgical needle suture (coated braided polyglycolic acid suture) - 40 heavy needle (Size 1-0, 90cm, 1/2 Circle RB 40mm Heavy), Box of 12 Foils.	1,618
24	5701	Absorbable, Braided, violet, Polyglycolic acid (PGA), Sterile	Box of 12 Foils	1/2 Circle, Tapercut, 40mm needle, Suture Length 90cm , Box of 12 Foils	3,781

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
		surgical suture 1-0 (Suture Code: 2518) (Box of 12 Foils)			
25	2021008	Closed wound Suction Drain No.14	1	Closed wound Suction Drain No.14 - Twin Tubes	12,699
26	2021007	Closed wound Suction Drain No.10	1	Closed wound Suction Drain No.10 - Twin Tubes	1,740
27	2021055	Diathermy earth REM pad Disposable	1	Adult dual plate, with 3m (10) pre- attached cord, USFDA Approved	204
28	10208	Endotracheal Tube dia 9.5mm	1	Cuffed (Sterile, Disposable) dia 9.5mm, Each	200
29	5934	Foleys 3 way 22G	1	22G	2,026
30	915	Intercostal drainage bag kit including IC tube	1	Sterile, Disposable, under water sealed drainage system, soft, kink resistant, nontoxic PVC Bag with 1000ml capacity, graded at 50ml interval, with long tubing with a air tight clamp, loop for hanging or carrying., Each	11,032
31	5835	Kher T tube	1	Medical Grade PVC make siliconised tube for Common Bile Duct drainage. Super smooth siliconized low friction surface, Radio opaque line throughout its length for X-ray visualization. Sterile, individually packed in peelable pouch pack.14 No, Each	1,400
32	5786	Needle & Hub cutter	1	Stainless Metal Body with 22G Electrical, Each	3,764
33	2021067	Non Absorbable, blue Monofilament, Polypropylene Sterile Surgical Suture No 2- 0	Box of 12 Foils	Non Absorbable, blue Monofilament, Polypropylene Sterile Surgical Suture No 2-0 (Box of 12 Foils)	5,195
34	2021030	Oro Pharyngeal Airways 0	1	Oro Pharyngeal Airways 0	2,080
35	2021029	Oro Pharyngeal Airways 00	1	Oro Pharyngeal Airways 00	1,899
36	2021028	Oro Pharyngeal Airways 000	1	Oro Pharyngeal Airways 000	833
37	2021031	Oro Pharyngeal	1	Oro Pharyngeal Airways 1	5,695

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
		Airways 1			
38	2021032	Oro Pharyngeal Airways 2	1	Oro Pharyngeal Airways 2	11,367
39	10268	PAP SMEAR KIT	1	Consists of 1 pair gloves,1 Brush,1 Spatular along with 1 micorslide., Each	57,202
40	2021061	Polyamide with cutting neddle Size 2-0	Box of 12 Foils	Size 2-0 (Box of 12 Foils)	1,546
41	10237	Re-breathing bags	1	Rebreathing Bags, Latex Free (Neoprene),hour glass-shaped ,2 LITRES with neck of 22 mm Bush, non-slip textured surface, Tri-pleat design., Each	18
42	5568	Spino Epidural set, (CSE)	1	Sterile, Disposable, Combined spinal epidural anesthesia kit, combined spinal epidural needles are a combination of Tuohy and Sleeved Spinal Needles Design, Features a back-eye lumen situated in the heel of a Tuohy bevel to allow the sleeved spinal needle, Each	1,192
43	5618	Sterile Blood Lancects Ethylene Oxide	1	Disposable	60,35,000
44	2021058	Titanium clips -400 Large Size	1	LT 400 Large Size (6 Clips per Catridge, Box of 20 Catridges)	527

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
45	5816	Tracheostomy Tubes Cuffed 7.0	1	Sterile, Disposable, Made of thermosensitive material with Sufficient initial rigidity for insertion which softens at body temperature to accommodate individual patient anatomy. Soft flexible, anatomically shaped flange for easy fixation, 15 mm connector which can be rotated in 360 degree direction to facilitate the safe connection to breathing system from any direction. Radio opaque blue line for X-ray visualization. Soft low pressure cuff which dynamically adjusts the pressure at the point of contact during the breathing cycle, thus minimizing the risk of tracheal trauma & other complications. Pilot balloon with non return valve for cuff inflation & deflation. Sould be supplied with cotton neck tape. Individually Blister packed. Cuffed 7.0, Each	1,065
46	5817	Tracheostomy Tubes Cuffed 8.0	1	Sterile, Disposable, Made of thermosensitive material with Sufficient initial rigidity for insertion which softens at body temperature to accommodate individual patient anatomy. Soft flexible, anatomically shaped flange for easy fixation, 15 mm connector, Each	621
47	10229	Tracheostomy Tubes PVC Cuffed 9.0	1	PVC Cuffed 9.0, Each	81
48	972	Urinary Bag	1	Sterile, Disposable, PVC Soft and Kink resistant tube with Optimum length 100CM, Conical inlet connector with cap for easy milking & Better flow Drainage from upper side to avoid leakage, Efficient NRV to avoid back flow of Urine, Precession double sealing to avoid leakage. Capacity of 2 litres, With non-	8,40,983

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
				return valve, Bag graduated in ml , Each	
49	10225	White Apron (Terricot) XL	1	Readymade Aprons (XL) Made Of White Terricot Suiting Cloth As Per Is no 15853/2009, Each	11,833
50	10236	Urine collection bag with volume measuring chamber/ meter 2Lts/200- 250ml	1	Sterile, Disposable, Graduated in ml with measured volume meter for accurate measurement of urine and bottom outlet, Conical inlet connector with cap, Closed circuit system to eliminate the risk of contamination, Soft and kink resistant PVC tubing with provision to hang the bag on the patient cot, Inlet tube length:  100 cm Capacity:2000 ml Capacity of Volume meter: 200-250ml	82,000
51	10272	Polyglactin suture double Arm 7/0	Box of 12 Foils	Polyglactin 910 double arm 7/0 (pack of 12)	450
52	10274	Polypropylene suture double Arm 10/0	Box of 12 Foils	10/0 Polypropylene suture double Arm (Box of 12 Foils)	500
53	5694	Absorbable surgical suture USP sterilized surgical needle suture Size 6 0 (Box of 12 Foils)	Box of 12 Foils	Undyed Monofilament 3/8 circle reverse cutting 16 mm Needle violet brided coated 45cm Polygrecaporene Box of 12 Foils.	500
54	10269	P D CATHETERS (PERITONIAL DIALYSIS CATHETERS)	1	P D Catheters (Peritonial Dialysis Catheters)	1,225
55	5940	Bacillus thuringiensisvarisraele nsi(Bti) Strain 164,Serotype,H- 14 W.P	1	Bacillusthuringiensisvar israelensi (Bti) Strain 164 Serotype H 14 W.P(TAC approved).	28,800

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
56	5718	Proctoscopes	1	Adult each	3,500
57	10304	Bacillus Thuringiensis Var Israelensis(BTI) Aqueous Suspension (in Liters)	1	Serotype H-14 (Liquid) - Endotaxicity 2%	27,800
58	21234	2/3 Half round cut edge atraumatic needles (pack of 6)	1	2/3 Half round cut edgeatraumaticneedles6/pack	3,100
59	2189	Pyriproxifen 0.5 percentage GR	1	Pyriproxifen 0.5 percentage GR	5,800
60	21215	Leuko Deplition Filter Sets(Bed Side)	1	Specifications given below	4,700
61	21216	Leuko Deplition Filter Sets-Lab side LD Filter	1	Leuko Deplition Filter Sets-Lab side LD Filter	4,700
62	10315	Diflubenzuron 25 percentage WP in Kgs	1	Insect Growth Regulator Larvicide, Each Kilogram	9,800
63	15052302	TISAB-III Solution (HANNA) Cat No H1401006	1	500ml	320
64	15052301	TISAB-III Solution (orion USA) Cat No 940911	1	475ml	40
65	20221098	True Nat Hepatitis - B virus PCR test kits (closed)	1	True Nat Hepatitis - B virus PCR test kits (closed)	23,310
66	20221099	True Nat Hepatitis - C virus PCR test kits (closed)	1	True Nat Hepatitis - C virus PCR test kits (closed)	13,136
67	21244	Curved Probes/Explorer	1	Curved Probes/Explorer	16,000
68	21242	Mouth Mirrors	1	Mouth Mirrors	16,000
69	21243	Straight Probes	1	Straight Probes	16,000
70	21237	Suction Tips (pack of 100pcs)	1	Disposal copper plated wire inside, soft tips 142 to 160mm thickness for saliva suction set of 100 pieces/box	10,000
71	21245	Tweezers	1	Tweezers	16,000
72	240814	1 percentage (W/W) Toluidine blue 200ml bottle	1	1 percentage (W/W) Toluidine blue 200ml bottle	1,20,000
73	15052303	Toluene Solution (preservative)	1	500ml	900

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
74	20221168	HIV (RAPID) Test Kits- 3 (Principal excluding Agglutination and Dot Immune Assay)/(Immune- Concentration)	1	Specifications given below	20,000
75	12500	Dengue NS1 Antigen detection kit by Elisa (96 wells)	1	Specifications given below	160
76	5742	Single Blood Bags with CPDA Solution 350ml	1	For whole blood collection, 350ml Packaging: Sterile, disposable Secondary Packaging is made of laminated polyester/aluminium/polyeth ylene Tubing: Memoryless tubing for better yield of components without damage during blood collection, Very clear thermal transfer printing for easy identification of pilot samples, Stable wall thickness and inner diameter for smooth flow and collection of blood Label: Labels should be clear and easy to understand, should be resistant to tear, water and centrifugation force, the labels have to be barcoded. Outlet Port Pouch: Each outlet port fitted with a hermetically sealed tamper evident protector to maintain sterility of the internal surface, should be amenable to open with single - hand operation Needle: Ultra-thin walled silicone coated needle, High quality needle for smooth phlebotomy Needle Protector: Composed of two parts. The outer layer is made of hard poly- propylene to ensure rigidity of cap. The inner layer is made of PVC to ensure hermetic closure with the hub Break off valve: The big break off valve to help in a smooth flow of component and duces	2,00,850

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
				processing time. The uniform break force of the click tips to ensure easy breakability.	

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
77	5779	Pediatric Blood Bags (with CPDA solution) 100 ml	1	Pediatric Blood collection, 100ml Packaging: Sterile, disposable Secondary Packaging is made of laminated polyester/aluminum/polyeth ylene Tubing: Memoryless tubing for better yield of components without damage during blood collection, Very clear thermal transfer printing for easy identification of pilot samples, Stable wall thickness and inner diameter for smooth flow and collection of blood Label: Labels should be clear and easy to understand, should be resistant to tear, water and centrifugation force, the labels have to be barcoded. Outlet Port Pouch: Each outlet port fitted with a hermetically sealed tamper evident protector to maintain sterility of the internal surface, should be amenable to open with single - hand operation Needle: Ultra-thin walled silicone coated needle, High quality needle for smooth phlebotomy Needle Protector: Composed of two parts. The outer layer is made of hard poly- propylene to ensure rigidity of cap. The inner layer is made of PVC to ensure hermetic closure with the hub Break off valve: The big break off valve to help in a smooth flow of component and duces processing time. The uniform break force of the click tips to ensure easy breakability	2,500
78	2308001	PROFESSIONAL DIGITAL BP APPARATUS	1	Specifications given below	17,900
79	5787.1	Whole blood finger prick test kit (HIV 1/2 ANTI BODY	1	Specifications given below	20,225

S No	Item Code	Item Name	Unit	Specification	Tender Probable Qty
		RAPID TEST KIT) pack of 50 Tests			
80	2307001	HIV test kit 1 (ELA)	1	Specifications given below	10,06,000
81	21308	Anti D (Rho) IgM+IgG	1	Anti D (Rho) IgM+IgG	1,800
82	5721	RPR Kits (1X100)	1	Specifications given below	20,000
83	10252	MICRO DRIP IV SETS WITH DIAL FLOW REGULATORS	1	Micro Drip IV Sets With Dial Flow Regulators	1,50,000

#### Note:

Quantities mentioned are tentative, PO quantity may increase or decrease as per requirement.

Samples for each item quoted has to be submitted for sample verification by the end of the Bid submission date with offline documents.

#### Specification for Leuko Deplition Filter Sets-BED SIDE

- 1. Filter should be able to Leuko-deplete red cell from leukocyte contamination separately for one-unit red cell
- 2. Filter should be having the capacity of log 4 reductions (99.99%)
- 3. Filter should not carry any charges it should be neutrally charged
- 4. Filter material should be polyester woven non-woven
- 5. Leukocytes should be consistently averaging less than 0.5 X 105 residual leucocytes for one unit of red cell and 0.2 X 106 for two units of red cell, RBC recovery should be averaging more than 90%
- 6. Filter should have soft housing for optical monitoring
- 7. Filtration loss should be not more than 40m1 for one-unit red cell
- 8. Should have integrated 40 µm micro aggregate filter
- 9. Should be US FDA I European CE Certificate
- 10. Filters should be sterilized by Gamma rays
- 11. It should have spike for bag connection
- 12. Filter should be DEHP-PVC tube compatible with sterile connection
- 13. Filtration time should be consistently averaging less than 20 min
- 14. Filters should have shelf life of 24 months
- 15. Filter should have air vent
- 16. The representative of application should respond if any need required.

### Technical Specification of Dengue NS1 Antigen detection kit by ELISA under NVBDCP

- The ELISA kit should be designed for qualitative detection of dengue NS1 antigen of all 4 dengue serotypes in human serum.
- 2) The kit should be provided with the following materials and reagents:
  - a) Anti- NS1 Antibody Coated Breakway Microwells (12\*8=96 wells). Desiccant should be provided for storing the unused microwells which are to be resealed immediately.
  - b) Horseradish peroxidase conjugated Anti-NS1 monoclonal antibody with preservatives
  - c) Chromogenic substrate in buffer
  - d) Positive Control in the form of recombinant antigen with preservatives and antibiotics
  - Negative control in the form of confirmed negative human serum with preservatives and antibiotics
  - f) Calibrators in the form of recombinant antigen with preservatives and antibiotics
  - g) Sample diluents
  - h) Wash buffer
- The time required for performing the test for detection of dengue NS1 antigen by ELISA should range between 2-4 hours.
- 4) The ELISA kit for detection of dengue NS1 antigen should have a sensitivity of >90% and a specificity of >95% taking RT-PCR as the gold standard.
- The kit should have a shelf-life of at least 6 months when stored at an ambient temperature of 2°C - 8°C.
- 6) Transportation should be under cold chain.

# Technical Specifications of HIV Test kits 1, 2 & 3 for detection of Antibodies against HIV by either of the Principles: Dot Immuno Assay / Immunochromatography (Lateral Flow) / Immunoconcentration

- 1. HIV test kit should have either of the following principles:
  - a) Dot immuno Assay
  - b) Immunochromatography (lateral flow)
  - c) Immunoconcentration
- 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.
- 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 24 months and at least 5/6th 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.
  - 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.
    - 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.

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### Technical Specification of Whole Blood Finger Prick test kit for HIV, kit -4

- The assay should be able to detect antibodies to HIV 1 & HIV 2, including all the subtypes by the rapid test in whole blood/ and serum/ plasma.
- The assay should have sensitivity of 100% and specificity of ≥98%.
- The clinical data to determine the performance characteristics of the kit on whole blood sample should be made available by the manufacturer.
- The assay should have solid phase/particles coated with synthetic and or recombination or both types of antigens of HIV 1 and HIV 2.
- 5. Total procedure time should not be more than 30 minutes
- 6. The kits should have a shelf life of 24 months, at least 5/6<sup>th</sup> of the minimum shelf life must remain at the time of dispatch to the consignee
- 7. 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 principal of lateral flow
- 8. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
- The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8°C. The cumulative time temperature indicator technology used should be pre - qualified by WHO.
- 10. Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act 1940 & Rule 1945 and/or Medical device rule 2017
- 11. The imported rapid test kits should have the approval of the statutory authority in the country of Origin/ manufacturers and should satisfy the requirements of Drugs & Cosmetics Act in India. The imported kits should also get evaluated in our country
- 12. The manufacturers should ensure that:
  - a) The test kit should be packed such that there is a provision to conduct single test at a time
  - The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the test (10% negative and 10% positive controls); and
  - c) The pack size of HIV rapid test kits should not be more than 50 tests per Kit

## Technical Specification of HIV (Rapid) Test kits -3 (Principle excluding Agglutination and (Dot Immune Assay)

- Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
- 2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
- Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 2, bio safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
- 4. The kit should have approval of the statuary authority from the country of origin.
- 5. In case of Imported kits, it should be registered and licensed by the DCG(I).
- Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
- 7. The time required for the performing the test should not be more than 30 minutes.
- 8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
- 9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
- 10. The assay should have sensitivity of 100% and specificity of ≥98%.
- 11. 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.
  - 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 30 tests per kit.
- 12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 8° C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

#### <u>Technical Specification of Rapid Plasma Reagin (RPR) for Syphilis</u> <u>Testing</u>

- The indigenous RPR (Rapid Plasma Reagin) kits should have been manufactured under manufacturing license issued by the State Licensing Authority under the Drugs and Cosmetics Act, the imported kits should have been imported under import license issued by the DCG(I) under the Drugs and Cosmetics Act 1940 & Rule 1945 and / or medical devices rule 2017.
- 2. Literature detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing, limitations and expiry date should be provided with each kit.
- The assay should be calibrated to WHO reference standards from a third party accredited laboratory.
- 4. The assay should be suitable to perform with either serum or plasma.
- The assay should allow for qualitative and semi quantitative determination of Reagin antibodies in serum or plasma for sera-diagnosis of syphilis based on flocculation principle using non - treponemal antigens.
- 6. The assay should have sensitivity of ≥85% or more in primary syphilis and a specificity of ≥93% or more.
- 7. The test should be able to yield results within 30 minutes.
- The pack size of RPR test kit should be less than or equal to 50 tests per kit.
- The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).
- 10. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.
- 11. The kits should have a shelf life of 24 months, at least 5/6<sup>th</sup> of the minimum shelf life must remain at the time of dispatch to the consignee.
- 12. The kit should have a storage temperature of 2° C to 8°C and supplier/local agent should have the facility to store kits at 2° C to 8°C.
- 13. Cumulative Time Temperature Indicator should be part of the kit as per specifications defined in the terms and conditions.

PR	OFESSIONAL DIGITAL BP APPARATUS Specifications				
Calibration:	Professional moderate volume ( No calibration up to 30,000 readings)				
Professional Model:	Model (S) designed for professional use in hospital settings (Personal and home - based use models not to be included)				
Validation and standards	<ol> <li>Device must have the validation as per international standards and the publication of the device validation should be available.</li> <li>model (s) meets at least 1 of 3 global standards.</li> <li>✓ AAMI/ANSI/ISO</li> <li>✓ BHS</li> <li>✓ ESH-IP</li> </ol>				
Cuff Size	<ul><li>1. At least two cuff sizes Medium (M) 27-34 cms &amp; Large (L) 35-44 cms</li><li>2. Minimum two cuffs to be supplied for each machine</li></ul>				
Power source	Should be operable in both inbuilt rechargeable battery or Rechargeable batteries (double the number required for apparatus) with battery recharging device and electrical outlet (220V)				
Method of measurement	Fully automated Oscillometric method				
Measurement range	Pressure: 0-280 mmHg: Pulse rate: 40-180 beats per minute.				
Display & Memory	<ul><li>1. LCD display brightly illuminated backlist display</li><li>2. Data storage (and transmission)capability preferred.</li></ul>				
Service & Warranty	<ul> <li>1. Minimum – Three (3) years warranty</li> <li>2. Availability of replacement cuff/sleeve</li> <li>3. Service centre should be available in the state.</li> </ul>				
Device protection	<ol> <li>Built-in surge protection to prevent damage to instrument in case of power surge.</li> <li>Devices should increase a temperature – Stabilizing system, which allows for use in extreme weather conditions.</li> <li>Device should be waterproof</li> <li>Carrying case/bag to be provided</li> </ol>				
Quality Certifications	Should have at least one the following certifications ISO 13485 ISO 9001 EU CE/US FDA/ BIS				
Others	<ol> <li>Device should be handy and portable</li> <li>Inflation should be fully automated by electric motor</li> <li>Rate of inflation / deflation to be specified by vendor.</li> <li>Low Battery indicator and error indicators.</li> <li>Defective devices during installation should be replaced within a week</li> </ol>				