28 June 2022

Indian Red Cross Society
Blood Bank
National Headquarters
1-Red Cross Road,
New Delhi - 110001.

Notice Inviting Quotation for consumables items/ Printing Material/ Badges/ Juice Drink etc.

The last date of receiving quotations is being extended to **11th July 2022** and the Technical bid opening to **14h July 2022.**

The average turn over is being edited to "should be atleast 49 lakh INR" instead of 2 Crores published previously

Issued by

Office of Director, Blood Centre

Indian Red Cross Society
Blood Bank
National Headquarters
1-Red Cross Road,
New Delhi - 110001.

Notice Inviting Quotation for consumables items/ Printing Material/ Badges/ Juice Drink etc.

1. On behalf of the Secretary General, Indian Red Cross Society (Blood Centre), sealed quotation are invited under Two Bid System i.e. Technical Bid and Financial Bid from local vendors for consumable Items, kits and printing material for its Blood Bank at the above address:-

2. Schedule of Events:

(a) Last date of received quotation 20th June, 2022.
(b) Date of opening of Technical Bid 30th June, 2022.

3.1 The sealed quotation should reach the Director, Blood Centre, Indian Red Cross Society, New Delhi-z10001 latest by 3.00 pm, on dated 20th June, 2022.

3.2 Please Send
(a) One sealed envelope:
(i) The Technical bid
(ii) Sealed samples as per list at annexure "A" and
(iii) Documentary evidence of total amount of turnover being not less that Rs.2,0000000/- (Rupees two crores only) at least 1 of the less 3 years ending on 31st March, 2022.
(iv) Vender register with DS&D Udyan or supplying in Govt. Hospital/ premier Health Institute.

(b) Acceptable evidence is by way of assessment of GST.
(c) In another sealed envelope the Financial Bid of prices valid for two years:
(d) Both the sealed envelope at (a) and (b) should be put in an outer sealed envelope which should be addressed to the Director, Blood Centre at the address given in paragraph 3.1 above.

Please note that each of the envelopes should have the name, address and telephone number of the bidder.

3.3 Technical bid will be opened by the technical committee only for the bidder who have submitted the bid with the sample.
3.4 The detail technical specification may be referred for submitting the bid documents (Annexure 'A')

3.5 The inner and outer envelops should be marked Bid FOR Consumable Items/ Printing materials/ Badges/Juice Drink in blood centre.

4.1 Technical Committee approved by the competent authority shall evaluate & decide bids are found acceptable after evaluation the equipments on demonstration and the samples of consumables/kits/reagents etc. (As per list of Annexure 'A')

4.2 The bidders whose technical bids are found acceptable by the Technical Committee shall be informed, by email.

4.3 After the opening, the financial bids shall be evaluated.

4.4 To ensure timely supply the 3 lowest bidder L-1 & L-2 & L3 will be short listed. L-2 will be asked to match the rates of L-1; If L2 refuses, L-3 will be asked to match the rates of L-1.

4.5 The order will be split among two suppliers in the ratio of 70 to L-1 and 30 L-2/3.

4.6 If two or more bidders become L-1 after the opening of the Financial bids and the order placed equally among the selected bidders.

5. Bids not received in sealed cover and after the due date will not be considered.

6. The Secretary General has the right to reject or accept any or all bids without assigning any reason.

7. The Supplier (the bidder(s) on whom orders are to be placed will be informed to deposit security money@ 10% of the installment amount of proposed order the security money shall be in the form of a bank draft drawn on any schedule bank in favour of the 'Indian Red Cross Society Blood Bank' New Delhi. The draft should be submitted at the time of collection of order from the society. No interest will be allowed in the above deposit. The security money will be returned to the firm after completing the order.

8. No advance payment to be give to the bidders.

9. The order of the supplier will be placed as per approved specification as per annexure 'A', Number of installment as requirement in installments.

10. If vender not supply the items as per order, security money may be forfeited and 10% penalty charges of total bills will be payable by the vender.

11. In case supply is not made in accordance with the samples provided to Red Cross Blood Centre, the order placed will stand cancelled and the security money will be forfeited.

Director, Blood Centre

Annexure – A

Indian Red Cross Society
National Headquarters
Blood Bank

List of following items and schedule of supply for the year 2022 – 2023 and 2023 – 24 – reg.

Sl. No.	Name of Items	Quantity required	Supply in Installment	Specifications	Remarks
1.	Blood bags	40,000 nos.	In installment as per requirement.	As per requirement, double 350ml = 2000 nos. double 450ml=20,000 nos. triple 450ml =10,000 nos.Triple Sagam 450ml =8,000nos.	**Annexure B**
2	HIV Kits	400 kits	04	4th Gen and NIB/Narri / NICD Approved Kit (batch wise) kit must be compiled and run on EVOLIS fully automatic machine, Detail attached	**Annexure C**
3	HCV Kits	400 kits	04	3rd Gen/4Gen and NIB/Narri / NICD Approved Kit (batch wise) kit must be compiled and run on EVOLIS fully automatic machine, Detail attached	**Annexure D**
4	HBs Ag Kits	400 kits	04	- do- NIB/Narri/NICD Approved (batch wise) kit must be compiled and run on EVOLIS fully automatic machine, Detail attached	**Annexure E**
5	VDRL / RPR Kits	(50,000 Test)	08	Antigen Kit –RPR Modified Form which contain the carbon particles to improve the Visual reading of the result.	**Annexure F**
6	Filter Paper	20 Rim	02	% Cotton Fibre:100, with good absorbance, Rim of 500 sheet	
7	Micro Tips	4,00,000 nos.	08	Capacity 5 –100ul colour white	
8	Vacutainer	50,000 nos. Plain 4 ml	05	4 Ml Plain and 4 ml EDTA PET vial with polymer gel/silica clot activator,13x 100 mm plus tube with heamoguard closure	
9	Vacutainer	50,000 nos. EDTA 4 ml	05	- do -	
10	Anti Sera	A=300,B=300,D=200, Blend=50 AB=50,H=20,A1lactin=10, Combs=10 Bovine Serum Albumin=10 nos.	03	Conforming to Quality Control Standards for Anti Sera. Anti Sera should have the titer above 1:256, Monoclonal -10ml/5ml	
11	Garbage Bag	Black, Yellow = 60 Kg. each, Blue 20kg and Red 40 kg = 180kg	01	Black, Yellow & Red Size18”x24” Minimum weight 35 gm/ per bag.	
12	Alcohol Swab	1,00,000 nos.	20	Single Pack Saturated with 70% isopropyl alcohol, ISO13485/ISO9001/FDA/CE, sterile,	

				and strong absorbent.	
13	Printer Roll for Elisa Reader	200 nos.	01	Thermal paper Roll (Good quality)	
14	Tissue Roll	600 nos.	01	Virgin pulp or recycled, sustained quality, strong absorbency, good tensile strength, 2 ply, standard roll. Length (50x2) 100 mtrs.	
15	Voluntary Donor Forms (English)	60,000 nos. & Hindi = 5000 nos.	01	As per requirement	
16	Beaker 100 ml	50 pcs.	01	Borosilicate Glass with either embossed graduations or easy to read printer graduations, wide opening and tapered pour spout. Graduated in millimeters (ml),Chemically	
17	Sticker different type (Big / Small)	30,000 nos. different color (blood gr.) 15,000 nos. different color (Compatibility)	01	As per requirement different colour and different size	
18	Cotton Roll	200 nos. (500 gm) per Roll	04	500 gm, absorbable, comply with IP and BP standard	
19	Distilled Water.	400 Canes	08	5 ltr. Can Ph = 7 ,TDS=less than 50PPM ,Clear, colorless Odorless and tasteless	
20	Sodium Hypochlorite	400 Canes	08	5 ltr Can 4%.The solution shall be a clear liquid free from suspended of particulate matter and shall be miscible in all proportions with distilled water, PH value greater than 11 at 20”C	
21	Copper Sulphate Branded	50 nos. (500 Gm)	02	500 gm crystal Pack branded	
22	Sodium Chloride Branded	10 nos.	02	500 gm crystal Pack branded	
23	Fruit juice drink	50,000 nos. (180ml pack)	In installment as per requirement	Minimum 20-25% pulp it should having FSSAI Licensing Not in glass bottle	
24	Register Printing Different type	10 Nos. different type	02	As per requirement	
25	Gloves (Small. M. Large)	800 Box(50 Pair per box)	04	Unsterilized, Material good flexibility of Latex, Compliance –CE Mark/ISO,Cuff : Beaded, External Surface-smooth Internal Surface “ with Powder	
26	Safety Needle	(50,000 nos.)	01	Sterile hypodermic needle gauze 26 x ½”	
27	Band Aid	50,000 nos.	05	adhesive bandage (Medicated)	
28	Donor Cards (Voluntary)	(30,000 nos.)	01	As per requirement	
29	Badges	5,000 nos.	01	One type badge and good quality	

30	Couch Roll	200 Nos.	04	Size 9” x 160 Mtr. Strong absorbency, good tensile strength,2 ply	
31	Plastic Tube 6” long	60 Kg.	01	Size 6” long	
32	Denatured Spirit	200 Liter	04	Denatured Spirit 95%	
33	Dustbin plastic	30 nos.	01	First number plastic, good quality	
34	Scissor	24 nos.	1	Six inch long, mode of SS one side sharp and one side blunt.	
35	Micro slide	5000 pkts. (1 pkt = 50 nos.) = 250000 nos.	2	Good quality glass, uniform thickness and ground edges, Constantly clean, highly strong, Accurate Shape & Size75mm x 25mmx1.35mm pkt of 50	
36	Disposable syringes (2ml)	10,000 nos.	4	Sterile, non toxic non Pyrogenic – Luer Mount (ISI mark)	
37	B.P. Machine	30 nos.	1	Dial type portable	
38	Malaria Kits	50,000 Test	10	Detect both for Pan/PF Detective of Malaria Parasite (Antigen) all 4 plasmodium parasite i.e. PF –P. Virax and P Falciparum, P. Ovale & P. Malaria. The accessories needed for conducting the test	

ANNEXURE - B

Technical specification of Blood Bags for use in licensed Blood Banks:

(A) General Specifications:

(a) Plastic Blood Bags should meet all the standards as laid down in ISO 3826, for the manufactures have to produce documentary evidence from the laboratories approved by Government of India.

(b) Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supported by the test reports of the following.
   1. Cell culture cyto-toxicity
   2. Hemolysis
   3. Systemic infections (acute toxicity)
   4. Sensitization
   5. Intra-cutaneous injection (Irritation)
   6. Pyrogentest
   7. Sterility

(c) To assess quality of stored blood, manufacturer should provide documented evidence of following Bio-chemical parameters of blood stored in CPDA/CPDA-1/CPD-SAGM containing DEHP plasticized PVC blood bags manufactured by the company on $28^{th}/35^{th}/42^{nd}$ day of storage. The parameters are:
   1. Plasma pH
   2. ATP (% of initial volume)
   3. 2,3-DPG (% of initial volume)
   4. Plasma K+ (mEq/L)
   5. % of viable red cells (24 hours post transfusion)
   6. DEHP leaching (mg/100ml).
   7. DEPH should not be more than 0.01% w/v in the PVC

(d) All internal reports of manufacturer pertaining to the quality of blood bags must be provided along with each batch and a copy of the same should be available with each box/ carton of blood bags.

(e) All supportive documents, test reports and certificates provided in compliance to specifications should not be older than three years from the date of tender publication.

(f) The plastic blood bag should have a shelf life of minimum 2 years. Stability reports from a recognized laboratory must be produced.

(g) Slit present at the bottom of the bag should be “adequate to hang the blood bag during transfusion”.

(h) Packing size of goods: Individual plastic blood bags should be packed in plastic pack, 1-10 bags should be packed in aluminum foil pack/ Transparent Polymer- Polythelene, PE. The label of the aluminum foil/transparent Polymer- Polythelene, PE pack should read as ‘Aluminum foil/ Transparent Polymer-Polythelene, PE pack once opened, the bags should be used within ten days. Ten such aluminum foiled packs/Transparent polymer-polythelene, PE should be packed in the corrugated boxes which should indicate clearly and legibly the name of the manufacturer, name of the product, batch number, quantity, date of manufacturing , date of expiry, gross and net weight and consignee’s name and address and other particulars as required. It should also mention “storage temperature not to exceed 30°C”. It should be the responsibility ofthe manufacturer to ensure proper transportation of the consignment of blood bags in temperature controlled conditions.

(i) External sterility of the plastic blood bags should be ensured. The outer surface should be moisture free.
(j) Each carton should contain:
- A Copy of test reports.
- A certificate mentioning “blood may be collected up to the expiry date marked on the label which will be compatible with shelf life of components prepared as per required standards”

(k) Satisfactory Reports from reputed Government users for last two years to be provided.
(l) At least five bags should be provided for the technical evaluation at the time of quotation.
(m) Should have a needle protection device to reduce the risk of needle stick injury which is easy to use with needle protector permanently sleeved over the needle once the needle once removed from the van puncture site prior to disposal
(n) Disposal of the blood bags should be possible through modalities as per Biomedical Waste Management Rules 2016 as amended from time to time.
(o) In case of imported / indigenous manufacturers the product should be licensed under the provision of Drugs & Cosmetics Act and Rules and / or Medical Devices Rules 2017 in India
(p) Lab Report from Authorized Laboratory should not be more than 5 years old. including the latest Report

Capacity:
• Double bag
Primary bag (350 ml /450 m)
One Satellite bag (300ml)

Design and shapes:
1. Flexible pre-stenlized
2. Non pyrogenic
3. Non-toxic, non-haemolytic, biocompatible material
4. No risk of contamination and air embolism (closed system) with all leak proof seals (Disposable Bags).
5. Slits at both sides of the bags should be enough to accommodate 5 - 10ml volume test tubes
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from the seam when it is filled up with the requisite volume of blood

Tubing of bag:
1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The minimum length of tubing from primary bag to needle should be 80cm
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Needle:
1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and beveled tip
3. Rust proof
4 Tightly fixed with hub covered with sterile guard
5. Hermetically scalco

6 The needle should not separate from the tube at any point of time, especially while removing it from the vein for donor safety
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round. External Port:

External Port

1. Tamper proof and shouldn't be re-capped
2 Easily accessible

Package:

1. Protective dual packaging (Individual &Aluminum/Transparent Polymer Polythelene, PE) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPDA/CPDA-1: The quantity of anticoagulant/ pre (49 ml/63 ml)
2 Clear & colorless
3. No discoloration on storage at room temperature 4. Manufacturer to supply anticoagulant quality check certificate
4. Manufacturer to supply anticoagulant quality check certificate.

Labels:

1. Non-peel off
2. Heat sealed/ pressure embossed labels
3. Remain attached between room temperature to 40 degrees * C with a transparent adhesive
4. Date of manufacturing, date of expiry and lot number must be mentioned on each bag
5. The expiry date should be at least 2 years from the date of manufacturing of blood bags and residual shelf life at the time of supply should be at least 3/4th of the total shelf life

Resistance to distortion:

Filled to normal capacity

- Bag shall withstand a acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted
- Bag should be able to withstand temperature upto -80°C without breakage

Diversion pouch with multiple sampling device:

- For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection

1. Technical Specifications of Triple Blood Bags (350ml/ 450ml.) (Without SAGM):

Blood collection bag made up of DEHP(D-) –ethylhexy phthalate) plasticized PVC (polyvinylchloride), collapsible non-vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination.

Capacity:

Triple blood bag

Primary bag-350 ml/450 ml)

First Satellite bag (of 300 ml capacity)

Second Satellite bag (of 300 ml capacity) for platelet storage for 5 days

Design and shapes:

1. Flexible pre-sterilized
2. Non-pyrogenic
3. Non-toxic, non-haemolytic, biocompatible material
4. No risk of contamination and air embolism (closed system) with all leaks proof seals (Disposable Bags)
5. Slit on the both sides of the bags should be enough to accommodate 5- 10 ml volume test tubes.
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from the seam when it is filled up with the requisite volume of blood

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The minimum length of tubing from primary bag to needle should be 80cm.
6. The tube should have multiple printed 10/Segment numbers. The numbers should be legible and clear. 7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and beveled tip tube for maintaining sterility of the collected blood and sample collection
    - The sampling pouch should be of 20 - 35ml capacity
    - It should be easy to insert Vacum tubes for blood sampling

2. Technical Specifications of Triple Blood Bags (350ml./ 450ml.) (with SAGM)

Blood collection bag made up of DEHP (D 2-ethylhexyl phthalate) plasticized PVC (polyvinylchloride), collapsible non-vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination

Capacity:

Triple blood bag
Primary bag - 350ml / 450 ml

First Satellite bag (of 300 ml capacity) with additive solution for red cell storage upto 42 days
Second Satelite bag (of 300 ml capacity) for platelet storage for 5 days

Design and shapes:

1. Flexible pre-sterilized
2. Non-pyrogenic
3. Non-toxic, non-haemolytic, biocompatible material
4. No risk of contamination and air embolism (closed system) with all leaks proof seats (Disposable Bags).
5. Sit on the both sides of the bags should be enough to accommodate 5- 10ml volume test tubes.
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from the seam when it is filled up with the requisite volume of blood.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3 Transparent
4. Leak-proof
5. The minimum length of tubing from primary bag to needle should be 80 cm.
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear
7. A clamp should be provided for closed system.

Needle:-

1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and bevelled tip
3. Rust proof
4. Tightly fixed with hub covered with sterile guard
5. Hermetically sealed
6. The needle should not separate from the tube at any point of time, especially while removing it from the vein for donor safety
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (Individual &Aluminum/ Transparent Polymer Polythelene, PE) eliminating microbial contamination on surface maintaining the contents of the bag.
2. Easy to handle

Anticoagulant and preservative solution:

1. CPD: (49 ml for 350ml / 63 ml for 350 ml.) in primary bag
2. SAGM (78ml / 100 ml) in first satellite bag
3. Clear &coloriess
4. No discoloration on storage at room temperature
5. Manufacturer to supply anticoagulant quality check certificate

Label:

1. Non-peel off
2 Heat sealed/ pressure embossed labels
3. Remain attached between room temperature to 4 degrees * C with a transparent adhesive
4 Date of manufacturing, date of expiry and lot number must be mentioned on each bag
5. The expiry date should be at least 2 years from the date of manufacturing of blood bags and residual shelf life at the time of supply should be at least 3/4th of the total shelf life

Resistance to distortion:

Filled to normal capacity.

- Bag shall withstand a acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted
- Bag should be able to withstand temperature up to - 80°C without breakage.

Diversion pouch with multiple sampling device:

- . For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20- 35ml capacity
- It should be easy to insert Vacuum tubes for blood sampling

3. Technical Specifications of Quadruple Blood Bags (ml./450ml.)(with S SAGM):

Blood collection bag made up of DEHP (Di-2-ethylhexyl phthalate) plasticized PVC(polyvinylchloride), collapsible non-vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination.

Capacity:-

Quadruple blood bag:

Primary bag) - (350mL/450 ml) with top and top

First Satellite bag (of 300 ml. capacity with additive solution for 42 days red cell storage

Second Satellite bag (of 300 ml capacity) for platelet storage for 5 days Third Satellite bag (of 300 ml capacity)

Design and shapes:-

1. Flexible pre-sterilized
2. Pyrogen free
3. Non-toxic, non-haemolytic, biocompatible material
4. No risk of contamination and air embolism (closed system) with all leaks proof seals (Disposable Bags).
5. Slit on the both sides of the bags should be enough to accommodate 5 10 ml volume test tubes.
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from the seam when it is filled up with the requisite volume of blood.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The minimum length of tubing from primary bag to needle should be 80 cm.
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear. 7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and bevelled tip
3. Rust proof
4. Tightly fixed with hub covered with sterile guard
5. Hermetically sealed
6. The needle should not separate from the tube at any point of time, especially while removing it from the vein for donor safety.
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (Individual &Aluminum/ Transparent Polymer Polythelene, PE) eliminating microbial contamination on surface maintaining the contents of the bag.

2. Easy to handle

Anticoagulant and preservative solution:

1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag
2. SAGM (78 ml for 350ml / 100 ml for 450 ml) in first satellite bag
3. Clear & colorless
4. No discoloration on storage at room temperature
5. Manufacturer to supply anticoagulant quality check certificate

Label:

1. Non-peel off
2. Heat sealed/ pressure embossed labels
3. Remain attached between room temperature to 4°C with a transparent adhesive
4. Date of manufacturing, date of expiry and lot number must be mentioned on each bag
5. The expiry date should be at least 2 years from the date of manufacturing of blood bags and residual shelf life at the time of supply should be at least 3/4thof the total shelf life.

Resistance to distortion:

* Filled to normal capacity
- Bag shall withstand a acceleration of 5000g for 30 min at temperature 4°C to24°C without becoming permanently distorted
- Bag should be able to withstand temperature up to - 80°C without breakage

Diversion pouch with multiple sampling device:-

- For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection
- tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20-35ml capacity and length of 350 mm from Needle hub to U Connector.
- Easy to insert Vacuum tubes during blood sampling

ANNEXURE - C

Technical Specifications of HIV (ELISA) Testing Kits IV Generation

1. Should be solid phase micro plate coated HIV I & II recombinant and / or synthetic peptide antigens and antibody to HIV 1 p24.
2. The assay should detect HIV I and II antibodies and HIV I p24 antigen.
3. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2 and p24| Antigen, 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 statutory authority in its country of origin
5. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics Act and rules and / or Medical Devices Rules 2017 in India.
6. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and rules and or Medical Devices Rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940.
7. The kit should have minimum remaining shelf-life of 5 / 6^{th}or 12 months (whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive (for both antibody as well as antigen) and non-reactive controls with each kit.
9. The assay should have sensitivity level of 100% and specificity level of more than or equal to 98%.
10. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport the kits at 2°C - 8°C . The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every pack of kits.
11. The pack size should be 96 tests / kit.

ANNEXURE - D

Technical Specifications of HCV (ELISA) Testing Kits III Generation

1. Microplate ELISA coated with recombinant/synthetic peptide antigens for core, NS3, NS4, and N$5 and antibody to HCV core Antigen.

2. Adequate documents detailing the principle, components, bio-safety. methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.

3. The kit to be procured should have approval of the statutory authority in its country of origin

4. The kit should have approval of the statutory authority in its country of origin 5. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics Act and rules and / or Medical Devices Rules 2017 in India.

6. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and rules and or Medical Devices Rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940.

7. The kit should have minimum shelf-life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees

8. The assay component should include reactive (for antibody) and non-reactive controls

9. The assay should have a sensitivity of 100% and specificityof more than or equal to 98%.

10. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2°C - 8°C The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every pack of kits.

11. The pack size should be 96 tests / kit

ANNEXURE – E

Technical Specifications of Hepatitis B Surface Antigen (ELISA) Testing Kits III Generation:-

1. Micro plate ELISA coated with monocional antibodies to HBsAg.
2. The assay should be able to detect surface antigen to Hepatitis B virus.
3. Adequate documents detailing the principle, components, 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 statutory authority in its country of origin
5. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics Act and rules and / or Medical Devices Rules 2017 in India.
6. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and rules and or Medical Devices Rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940.
7. The kit should have minimum shelf-life of 5/6thor 12 months (whichever ismore) at the port of discharge of consignees
8. The assay component should include reactive and non-reactive controls.
9. The assay should have sensitivity of more than or equal to 100% and specificity of more than or equal to 98%.
10. The assay should have analytical sensitivity of detecting less than or equal to 0.5ng / ml.
11. The manufacturer/authorized agent should ensure maintenance of cold chain during storage& transport the kits at 2°C - 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every box of kits.
12. The kit size should be 96tests / kit.

ANNEXURE - F

Technical Specifications of RPR (Rapid Plasma Reagin) Testing Kits:

1. The kit should have approval of the statutory authority in its country of origin
2. In case of imported kits it should be registered and licensed under the provisions of Drugs & Cosmetics Act and rules and / or Medical Devices Rules 2017 in India.
3. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and rules and or Medical Devices Rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940.
4. The assay should allow for qualitative and semi quantitative determination of Reagin antibodies in serum or plasma for sero-diagnosis of syphilis based on flocculation principle using non treponemal antigens.
5. The assay should be suitable to perform with either serum or plasma
6. The assay should have sensitivity of more than or equal to 85% in primary syphilis and a specificity of more than or equal to 93%.
7. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from manufacturer.
8. The test should be able to yield results within 20 minutes.
9. The pack size of RPR test kit should be less than or equal to 50 tests per kit.
10. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
11. 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.
12. The kit should have minimum shelf-life of 5 /6thor 12 months (whichever is more) at the port of discharge of consignees.
13. The curnulative time temperature indicator technology used should be pre-qualified by WHO
14. Literature, detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each kit.