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(A Govt. of Odisha Undertaking)
(Assuring Quality, Saving lives

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No. 4815 /01/2019 (I) Dt. 08/04/2019

BLOOD BAGS, TEST KITS AND REAGENTS ON RATE CONTRACT BASIS FOR THE FINANCIAL YEAR 2018-19.

[Bid Ref. No.: **OSMCL/2018-19/ BLOOD BANK-SBTC/09**

CORRIGENDUM

- **Revised** Last Date & Time of online bid submission - **22.04.2019, 6.00 P.M**.
- **Revised** Start date for submission of Original EMD and Tender Documents **– 24.04.2019, 10 AM**
- **Revised** End Date and time for submission of EMD and Tender Documents**- 01.05.2019, up-to 11 AM**
- **Revised** Date & time of online Technical bid opening **– 01.05.2019, 11: 30 AM**
- Date of opening of Price Bid - To be informed to the qualified bidders.

- Total No. of prospective bidders/ representatives present in the pre-bid meeting were: **12(Twelve).**

- The queries raised by the prospective bidders in the meeting and through e-mail on the above mentioned tender reference were discussed in detail and subsequently the recommendations/clarifications/amendments mentioned below are made for approval. The detailed recommendations are as follows:-

Sl. No	Item Name/ Particulars	Details as mentioned in the tender document	Queries raised by the prospective bidders	Clarifications/ Amendments in response to the queries.
Bid Ref. No.:- OSMCL/2018-19/ BLOOD BANK-SBTC/09 **Queries relating to General Terms and Conditions**				
1	Clause No. **5.2.1**, **5.2.4** and **6.7.1** Page No. **43**.	Only **Manufacturer** having valid own manufacturing license/loan license with drug endorsement or Direct **Importer** holding valid import license with product registration certificate issued by the Drugs Controller General of India can participate in the tender.	Authorized Distributors may be allowed to participate.	**Amended** In addition to the instant clause the following amendments are made:- **Authorised Distributors** with **Annual Turnover of Rs. 50 Lakhs or More** in each year during **last (3) Three** financial years in India are also **eligible** to participate in the tender for all the tendered items with proper **authorization from the**

				original manufacturers/ importers. Authorisation Format is attached at **Annexure-I** Further, in case of **bidder as distributor**, the bidder has to submit all relevant documents like **Manufacturing License, Drug endorsement, GMP, Market standing etc**. of the **original manufacturer** as per tender clause 5.2 i.e. pre-qualification criteria.
2	Clause No. **5.2.4** and **6.7.1** Page No. **59**	Before opening of the Price Bid, the sample of the item(s) submitted if any as per Section-IV for the technically qualified bidders (based on document submitted) shall be verified by the technical committee of the tender inviting authority in order to verify the quality standard as asked in the technical specification. After the sample verification by the technical committee if required, the KIT items shall be tested at OSMCL empanelled laboratory/ any other laboratory/Govt. Laboratory by the tender inviting authority in order to verify the quality standard as asked in the technical specification.	How many no. of samples and when to be submitted may be clarified	**Amended** In addition to the instant clause the following amendments are made:- No. of samples (item wise) along with In-house/ NABL test report to be submitted **at the time of technical bid submission** is as follows:- I. **Category A** (Sl. No. **01** to **05** of Section – IV) No. of samples to be submitted- **05 no's of each item.** II. **Category B** (Sl. No. **06** to **08** of Section – IV) No. of samples- **96 tests X 2 sets of each item.** III. **Category B** (Sl. No. **09** to **12** of Section – IV) No. of samples to be submitted- **05 no's of each item.** IV. **Category B** (Sl. No. **13** to **23** of Section – IV) No. of samples to be submitted- **05 no's of each item.**

3	Clause No. **6.28.12** Page No. **66**	The name of the item shall be mentioned in English. The items quoted are to be supplied in standard packing with wordings "Govt. of Odisha Supply – NOT FOR SALE" shall appear in primary, secondary and tertiary packing of all products.	The items quoted are to be supplied in standard packing with wordings "Govt. of Odisha Supply – NOT FOR SALE" shall appear in secondary and tertiary packing of all products.	**No change** **Clarification.** All the products should be supplied with Printing of **"Govt. of Odisha Not for Sale"** both in ***English*** *and* ***Odia*** *Script* along with **OSMCL Logo** on the primary, secondary and tertiary packaging of all products.
4	Annexure IC Page No. **97**	MRP of the bag/kit/reagent/ brand name should not be printed any where on the strip/primary pack. Generic name should be printed in bold letter.	MRP printing may be relaxed	**No change.** **Clarification** MRP should not be printed in any of the packaging during supply.
Queries relating to Technical specifications				
10	**Section – IV** Page No. **20- 42**	Technical specification of the tendered items	Various queries regarding the technical specification of the items	**Amended.** Details attached at **Annexure-II.**

General Clarification:

- The bidders have to quote the prices as per the format mentioned in Price Bid BOQ in the e-tender portal. The prices (Rates) are to be quoted per **Piece / Bag/Vial /Amp/Bottle/Test**(as the case may be) and not in unit pack, the quoted price includes packing, forwarding / transportation & Door Delivery and excludes GST.

- **The amendments mentioned above are to be treated as amendments in the technical specification(s) and term(s) and condition(s) of the above tender references. Except above cited aspects all other technical specifications and terms conditions remain unchanged.**

Sd/

Managing Director

OSMC Ltd., Odisha

Annexure-I

(To be submitted in ***Part – I Technical Bid***)

MANUFACTURER'S AUTHORISATION FORM

*(to be submitted by authorized distributor in a **letterhead** in case the bidder is the authorized distributor)*

No. Dated:

To

The Managing Director

Odisha State Medical Corporation Ltd, Odisha

Dear Sir / Madam,

Bid Reference No:

Item Name:

1. We ..... (name of the manufacturer) are the original manufacturers of the above item having registered office at ..... (full address with telephone number/fax number & email ID and website), having factories at _____ and _____ , do hereby authorize M/s._____ (Name and address of bidder) as _____(Distributor) to submit bids, and subsequently negotiate and sign the contract with you against the above bid no..
2. **No company or firm or individual** other than M/s._____ are authorized to bid, negotiate and conclude the contract in regard to this business against this specific bid reference no.
3. We also hereby declare that we have the capacity to manufacture and supply the quantity of the items bided within the stipulated time.

(Name)

for and on behalf of M/s._____

Date: (Name of manufacturers)

Place:

Seal

Note: *This letter of authority should be on the letterhead of the manufacturing concern and should be signed by a person competent and having the power of attorney to bind the manufacturer.*

Annexure-II

(Revised Technical Specification)

Technical Specification for Blood Bags

1. Blood Collection Bag CPD-A1 100 ml (Single) (S02166)

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: Single blood bag – 100 ml

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 leak 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.

Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supplied by the test reports of the following:

I. Cell culture cyto-toxicity
II. Hemolysis
III. Systemic infections (acute toxicity)
IV. Sensitization
V. Intra-cutaneous injection (irritation)
VI. Pyrogen test
VII. Sterility

The bio- compatibility test report must reflect in the test report of each batch supply that the said plastic material has been used in manufacturing of the concerned batch.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The tubing should have same ID/Segment number as that on the bag
6. The tubes should have multiple printed ID/Segment numbers

Needle:

1. 16 gauge ultra thin triple bevel design to reduce penetration force and enable painless vein puncture.
2. Sharp regular 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.

The needle must confirm to ISO1135-3 standard.

External Port:

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

Package:

1. Protective dual packaging (Individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPDA-1 (14ml)
2. Clear & colorless
3. No discoloration on storage at room temperature
4. Manufacturer to supply anticoagulant quality check certificate

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 28th/35th/42nd day of storage. The parameters are:

I. Plasma pH
II. ATP (% of initial volume)
III. 2,3-DPG (% of initial volume)
IV. Plasma K+ (mEq/L)
V. % of viable red cells (24 hours post transfusion)
VI. DEHP leaching (mg/100ml)
VII. DEHP should not be more than 0.01% w/v in the PVC

The blood bag should have self-life of minimum 2 years. Stability report from a recognized laboratory must be produced at the time of supply.

Label:

1. Non-peal off
2. Heat sealed Labels / Pressure embossed Labels
3. Remain attached between room temperature to -80°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 supply of blood bags to the institute

Resistance to distortion:

Filled to normal capacity shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted and should withstand temperature up to -80°C without breakage.

Quality Standards:

1. Plastic Blood Bags should meet all the standards as laid down in ISO 3826
2. Manufacturer should have ISO13485 certified
3. The needle must confirm to ISO1135-3 standard
4. Each Batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

2. Blood Collection Bag CPD-A1 350 ml (Single) (S02167)

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:

Single blood bag – 350 ml

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 leak 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

Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supplied by the test reports of the following:

- Cell culture cyto-toxicity
- Hemolysis
- Systemic infections (acute toxicity)
- Sensitization
- Intra-cutaneous injection (irritation)
- Pyrogen test
- Sterility

The bio- compatibility test report must reflect in the test report of each batch supply that the said plastic material has been used in manufacturing of the concerned batch.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The tubing should have same ID/Segment number as that on the bag
6. The tubes should have multiple printed ID/Segment numbers

Needle:

1. 16 gauge ultra thin triple bevel design to reduce penetration force and enable painless vein puncture.
2. Sharp regular 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.

The needle must confirm to ISO1135-3 standard.

External Port:

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

Package:

1. Protective dual packaging (Individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPDA-1 (49 ml i.e. 14 ml/100 ml of blood)
2. Clear & colourless
3. No discolouration on storage at room temperature
4. Manufacturer to supply anticoagulant quality check certificate

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 28th/35th/42nd day of storage. The parameters are:

- Plasma pH
- ATP (% of initial volume)
- 2,3-DPG (% of initial volume)
- Plasma K+ (mEq/L)
- % of viable red cells (24 hours post transfusion)
- DEHP leaching (mg/100ml)
- DEHP should not be more than 0.01% w/v in the PVC

The blood bag should have self-life of minimum 2 years. Stability report from a recognized laboratory must be produced.

Label:

1. Non-peal off
2. Heat sealed labels / Pressure embossed Labels
3. Remain attached between room temperature to -80°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 supply of blood bags to the institute

Resistance to distortion:

Filled to normal capacity shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted and should withstand temperature up to -80°C without breakage.

Quality Standards:

1. Plastic Blood Bags should meet all the standards as laid down in ISO 3826
2. Manufacturer should have ISO13485 certified
3. The needle must confirm to ISO1135-3 standard
4. Each Batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

3- Blood Collection Bag CPD 350 ml (Triple) with SAGM additive solution (S02170)

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:

Triple blood bag

Primary Bag – 350 ml

First Satellite bag of not less than 300ml capacity.

Second satellite transfer bag of 350ml with 78 ml SAGM capacity for platelet storage of 5days

Design and shapes:

- Flexible pre-sterilized
- Pyrogen free
- Non-toxic, non-haemolytic, biocompatible material
- No risk of contamination and air embolism (closed system) with all leak proof seals (Disposable Bags)
- Slit on the both sides of the bags should be enough to accommodate 5 – 10 ml volume test tubes
- 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

Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supplied 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. Pyrogen test
7. Sterility

The bio- compatibility test report must reflect in the test report of each batch supply that the said plastic material has been used in manufacturing of the concerned batch.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The tubing should have same ID/Segment number as that on the bag
6. The tubes should have multiple printed ID/Segment numbers

Needle:

1. 16 gauge ultra thin triple bevel design to reduce penetration force and enable painless vein puncture.
2. Sharp regular 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.
   The needle must confirm to ISO1135-3 standard.

External Port:

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

Package:

1. Protective dual packaging (Individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPD (49 ml i.e. 14 ml/100 ml of blood)
2. Clear & colourless
3. No discoloration on storage at room temperature
4. Manufacturer to supply anticoagulant quality check certificate

To assess quality of stored blood, manufacturer should provide documented evidence of following Bio-chemical parameters of blood stored in CPD/CPDA/CPDA-1/CPD-SAGM containing DEHP plasticized PVC blood bags manufactured by the company on 28th/35th/42nd day of storage. The parameters are:

- Plasma pH
- ATP (% of initial volume)
- 2,3-DPG (% of initial volume)
- Plasma K+ (mEq/L)
- % of viable red cells (24 hours post transfusion)
- DEHP leaching (mg/100ml)
- DEHP should not be more than 0.01% w/v in the PVC

The blood bag should have self-life of minimum 2 years. Stability report from a recognized laboratory must be produced.

Label:

1. Non-peal off
2. Heat sealed labels / Pressure embossed Labels
3. Remain attached between room temperature to -80°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 supply of blood bags to the institute

Resistance to distortion:

Filled to normal capacity shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted and should withstand temperature up to -80°C without breakage.

Quality Standards:

1. Plastic Blood Bags should meet all the standards as laid down in ISO 3826
2. Manufacturer should have ISO13485 certified
3. The needle must confirm to ISO1135-3 standard
4. Each Batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

4 - Blood Collection Bag CPD 450 ml (Triple) with SAGM additive solution (S02171)

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:
Triple blood bag
Primary Bag – 450 ml
First Satellite bag of not less than 300 ml capacity.
Second satellite transfer bag of 450ml with 100ml SAGM capacity.

Design and shapes:

- Flexible pre-sterilized
- Pyrogen free
- Non-toxic, non-haemolytic, biocompatible material
- No risk of contamination and air embolism (closed system) with all leak proof seals (Disposable Bags)
- Slit on the both sides of the bags should be enough to accommodate 5 – 10 ml volume test tubes

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
Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supplied 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. Pyrogen test
7. Sterility

The bio- compatibility test report must reflect in the test report of each batch supply that the said plastic material has been used in manufacturing of the concerned batch.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. The tubing should have same ID/Segment number as that on the bag
6. The tubes should have multiple printed ID/Segment numbers

Needle:

1. 16 gauge ultra thin triple bevel design to reduce penetration force and enable painless vein puncture.
2. Sharp regular 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.

The needle must confirm to ISO1135-3 standard.

External Port:

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

Package:

1. Protective dual packaging (Individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPD (63 ml i.e. 14 ml/100 ml of blood)
2. Clear & colourless
3. No discolouration on storage at room temperature
4. Manufacturer to supply anticoagulant quality check certificate

To assess quality of stored blood, manufacturer should provide documented evidence of following Bio-chemical parameters of blood stored in CPD/CPDA/CPDA-1/CPD-SAGM containing DEHP plasticized PVC blood bags manufactured by the company on 28th/35th/42nd 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. DEHP should not be more than 0.01% w/v in the PVC

The blood bag should have self-life of minimum 2 years. Stability report from a recognized laboratory must be produced.

Label:

1. Non-peal off
2. Heat sealed labels / Pressure embossed Labels
3. Remain attached between room temperature to -80°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 supply of blood bags to the institute

Resistance to distortion:

Filled to normal capacity shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted and should withstand temperature up to -80°C without breakage.

Quality Standards:

1. Plastic Blood Bags should meet all the standards as laid down in ISO 3826
2. Manufacturer should have ISO13485 certified
3. The needle must confirm to ISO1135-3 standard
4. Each Batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

5 - Blood Collection Bag CPD 450 ml (Quadruple) with SAGM additive solution (S02173)

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:

The quadruple top and bottom bag to collect blood and prepare blood component through buffy method.

Primary Bag-450 ml with Top and Bottom should be made with PVC mixed with a plasticizer di-ethyl hexyl phthalate (DEHP). The leaching rate of the plasticizer should not be more than 15 mg/100 ml blood.

Two Satellite transfer bag of 450 ml capacity each.

Bottom satellite transfer bag of 450ml with 100 ml SAGM solution. The donor tube should be provided with luer adaptor, for online withdrawal of blood samples without contamination.

Needle Injury Protector, Predonation Bag should also be provided to ensure more safety. The needle guard should be such that the needle can be drawn from venipuncture site smoothly in a single step directly into the needle guard.

The platelet bag should be suitable for 5days storage.

Design and shapes:

- Flexible pre-sterilized
- Pyrogen free
- Non-toxic, non-haemolytic, biocompatible material
- No risk of contamination and air embolism (closed system) with all leak proof seals (Disposable Bags)
- Slit on the both sides of the bags should be enough to accommodate 5 – 10 ml volume test tubes

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

RBC Transfer tube attached to the mother bag of the top and bottom blood bag system should have a minimum ID of 3.8 + 0.1mm for easy component transfer.

Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supplied by the test reports of the following:

- Cell culture cyto-toxicity
- Haemolysis
- Systemic infections (acute toxicity)
- Sensitization
- Intra-cutaneous injection (irritation)
- Pyrogen test
- Sterility

The bio- compatibility test report must reflect in the test report of each batch supply that the said plastic material has been used in manufacturing of the concerned batch.

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof
5. Blood bag tubings should have unique hot marked segment numbers which helps in traceability. This must be as per ISO 3826-1 international standard.
6. The tubing should have same ID/Segment number as that on the bag
7. The tubes should have multiple printed ID/Segment numbers

Needle:

1. 16 gauge ultra thin triple bevel design to reduce penetration force and enable painless vein puncture.
2. The integrated 16 G needle should be triple bevel cut, silicon lubricated with ultra-thin walled design for smooth penetration, superior flow and optimal collection time.
3. Sharp regular margins and bevelled tip
4. Rust proof
5. Tightly fixed with hub covered with sterile guard
6. Hermetically sealed
7. The needle should not separate from the tube at any point of time, especially while removing it from the vein for donor safety.

The needle must confirm to ISO1135-3 standard.

External Port:

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

Package:

1. Protective dual packaging (Individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
2. Easy to handle

Anticoagulant and preservative solution:

1. CPD (63 ml i.e. 14 ml/100 ml of blood)
2. Clear & colourless
3. No discolouration on storage at room temperature
4. Manufacturer to supply anticoagulant quality check certificate

To assess quality of stored blood, manufacturer should provide documented evidence of following Bio-chemical parameters of blood stored in CPD/CPDA/CPDA-1/CPD-SAGM containing DEHP plasticized PVC blood bags manufactured by the company on 28th/35th/42nd day of storage. pH data should be available for red cells stored in SAGM/SAGM-II solution on 21st , 35th and 42nd day. The parameters are:

1. Plasma pH
2. ATP (% of initial volume)
3. 2,3-DPG (% of initial volume)
4. K+ (mEq/L)
5. % of viable red cells (24 hours post transfusion)
6. DEHP leaching (mg/100ml)
7. DEHP should not be more than 0.01% w/v in the PVC

The blood bag should have self-life of minimum 2 years. Stability report from a recognized laboratory must be produced.

Label:

1. Non-peal off
2. Heat sealed labels / Pressure embossed Labels
3. Remain attached between room temperature to -80ºC 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 supply of blood bags to the institute

The product labels should be bar-coded as per ISBT-128.Secondary packing and shipping cartons should be bar-coded as per GS1-128.

Resistance to distortion:

Filled to normal capacity shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted and should withstand temperature up to -80°C without breakage.

Quality Standards:

1. Plastic Blood Bags should meet all the standards as laid down in ISO 3826
2. Manufacturer should have ISO13485 certified
3. The needle must confirm to ISO1135-3 standard
4. Each Batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.

Technical Specifications for ELISA Kits

Specific Requirement all the Kits:-

1. The supplier should supply 96 tests x 2 sets along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification.
2. A "Cold Chain indicator" is to be supplied with the kits with the following specification:
    a. A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2-8 degree C
    b. The cumulative time-temperature indicator technology used should be prequalified by WHO
    c. The indicator should change colour uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters.
    d. The colour change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.
    e. Each batch supplied should be accompanied with quality assurance test result from NABL approved Lab as well as in house lab.
3. Each test Kit should contain all the materials required for performing the test.
4. The test Kit should detect infection at all stages.

6. HIV (ELISA) test KIT Specification (S02174)

The kit should be of 4th Generation.

1. Should be solid phase microplate coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies.

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 form the country of origin.
5. In case of Imported kits it should be registered and licensed by the DCG(I) .
6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG(I)
7. The kit should have minimum 5/6th or more of the shelf life at the port of discharge of consignees.
8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
9. The assay should have sensitivity of > 99 % and specificity of > 99%.
10. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8 Degree C
11. **Shelf life of the Kits should be not less than 12 months.**
12. The pack size should be 96 tests/ kit.
13. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.
14. **Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.**

7. HBV (ELISA) TEST KITS (S02175)

Hepatitis B Surface Antigen ELISA Kits (3rd generation)

1. Microplate ELISA Coated with monoclonal antibodies to HBsAg (murine and human)
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 from the country of origin and by CDSCO and declared of "Standard Quality" by NIB (Noida)
5. In case of Imported kits it should be registered and licensed by the DCG (I) .
6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centers approved by the DCG (I)
7. The kit should have minimum 5/6th or more of the shelf life at the port of discharge of consignees.
8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
9. The assay should have sensitivity of > 99 % and specificity of > 99%.
10. The assay should have analytical sensitivity of detecting < 0.1ng/ml.
11. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8 °C
12. The pack size should be 96 tests/kit.
13. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers.
14. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.

15. **Shelf life of the Kits should be not less than 12 months.**

Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.

8. TECHNICAL SPECIFICATIONS FOR HCV (ELISA) TEST KITS (S02176)

HCV (ELISA) TEST KITS OF 3rd Generation

1. Micro plate ELISA coated with recombinant and / or synthetic peptide antigens for Core. NS3, NS4 and NS5.
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 should have approval of the statutory authority from the country of origin.
4. In case of Imported kits it should be registered and licensed by the DCG (I) .
5. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG (I).
6. The kit should have minimum 5/6th or more of the shelf life at the port of discharge of consignees.
7. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
8. The assay should have sensitivity of > 99 % and specificity of > 99 %.
9. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8 °C.
10. Shelf life of the Kits should be not less than 12 months.
11. The pack size should be 96 tests/ kit.
12. The Kit Should be compatible to both semi automated and fully automated Elisa analyzers. The volume of all the chemicals used should be adequate enough (not less than 1 litre) for automated Elisa analyzer. The volume should cover the dead volume for automated ELISA system.
13. Each batch supplied should be accompanied with quality assurance test result from NABL approved lab as well as in house lab.

TECHNICAL SPECIFICATIONS FOR HCV/HBV/HIV (RAPID) Test Kits/VDRL Kits

Specific Requirement:

1. The supplier should supply 5 sets of kits along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**
2. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
3. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
4. The test Kit should detect infection at all stages.
5. The kit should have minimum 5/6th or more of the shelf life at the port of discharge of consignees.

9 .HCV Rapid Test Kit (S02180)

Requirements:

1. Should be solid phase/particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS4 and NS5.
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 should have approval of the statutory authority form the country of origin.
4. In case of Imported kits it should be registered and licensed by the DCG(I) .
5. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG (I).
6. The kit should have minimum $5/6^{th}$ or more of the shelf life at the port of discharge of consignees.
7. The time required for performing the test should not be more than 30 minutes.
8. The assay component should include sufficient volume of controls to perform for minimum of three (3) batches as per protocol.
9. The assay should have sensitivity of > 99 % and specificity of > 99 %.
10. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
11. The pack size should not be more than 50 test wherein each test is individually packed.
12. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
13. The test Kit should detect infection at all stages.

Inspection & Tests:

- Deleted

Product and Package Specifications:

1. The required packing standards and labelling must meet the requirements given in this Technical Specification and Part.
2. Not only the Goods but also the packaging components should also meet specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tampered-proof.
3. All labelling and packaging inserts shall be in the language requested by the Purchaser or English if not otherwise stated
4. Goods requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
5. Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request

Product Information:

1. The following information will be required for each pharmaceutical product offered by the Bidder:
    i) International Non-Proprietary Name (INN), if applicable;
    ii) Brand Name (if it appears on label);
    iii) Name and address of the manufacturer;
    iv) Country of origin; and
    v) Compendia standards
2. Upon award, the supplier shall, on demand, provide a translated version in English, of the prescriber's information for any specific product, the Purchaser may request.

3. Failure to include any of this information, at the discretion of the Purchaser, may render the bid non-responsive.

Expiration Date:
All products must indicate the dates of manufacture and expiry

Recalls:
If products must be recalled because of problems with product quality as a result of quality check carried out during the life span of the drug or adverse reactions to the pharmaceutical, the supplier will be obligated to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals, or withdraw and give a full refund if the product has been take off the market due to safety problems.

Labelling Instructions:
1. The label for each Goods shall include: (a) the Purchaser's logo and code number and any specific color coding if required (b) content per pack (c) instructions for use (d) special storage requirements (e) batch number (f) date of manufacture and date of expiry (in clear language, not code) (g) name and address of manufacture with license number (h) any additional cautionary statement.
2. The outer case or carton should also display the above information
3. Details of Packing/Cases
4. All cases should prominently indicate the following:
   i) The generic name of the product;
   ii) Date of manufacture and expiry (in clear language not code);
   iii) Batch number
   iv) Quantity per case.
5. No case should contain drugs from more than one batch.
6. Unique Identifier
7. The Purchaser shall have the right to request the Supplier to imprint a logo on the containers used for packaging and in certain dosage forms such as tablets and this will be indicated in Part A of the Technical Specifications. The design of such logo shall be provided to the supplier at the time of Contract award.

Qualifications of Manufacturer:
The bidder shall furnish a certificate from the competent FDRA that the manufacturer of the pharmaceutical or vaccine product covered by this

Standards and Quality Assurance Requirements:
1. All products must:
   (a) Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin;
   (b) Conform to all the specifications contained herein; and
   (c) Must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products.
2. The Bidder is required to furnish to the Purchaser:
   (a) With each consignment, a certificate of quality assurance test results concerning quantitative assay, chemical analysis and other tests, as applicable to the product being supplied and Part A of these Specifications.
   (b) Assay methodology of any or all tests if requested.
   (c) Evidence of basis for expiration dates and other stability data on the offered package (as per climatic conditions prevalent in India) concerning the commercial final package upon request.
   (d) Package integrity test results.

3. The Bidder will also be required to provide the purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished Goods.

4. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**

10 .HIV (I&II) Rapid Diagnostic Kit (S02177)

HIV Rapid (3rd generation)

1. The test should be lateral flow technology 3rd generation assay and based on double antigen sandwich principle
2. The membrane should be coated with highly purified antigen gp41, gp120 for HIV1 and gp36 for HIV 2
3. Rapid visual and qualitative test
4. The test should detect IgM, IgG & IgA antibodies formed after HIV infections
5. P24 fusion protein should be used to detect the first antibody formed against HIV1
6. Assay should have two separate test bands to differentiate between HIV1 and HIV2
7. Synthetic peptides should be used for efficient differentiation.
8. The assay should have a sensitivity and specificity of more than 99%.
9. The test should be externally evaluated for diagnostic sensitivity and specificity.
10. The test should have a valid manufacturing license.
11. The assay time should not be more than 30 minutes.
12. The test should be free from possible interferences with potentially cross-reactive sera.
13. The shelf life should be upto two years / more than 5/6th after the date of manufacturing.
14. The storage should be at room temperature.
15. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
16. The test Kit should detect infection at all stages.
17. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
18. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**

11 . HBV Rapid Diagnostic test Kit (S02178)

1. The test should be lateral flow technology based on sandwich principle
2. The membrane should be coated with highly purified antibodies directed against immune dominant ‘a’ epitope of HBsAg.
3. The assay time should not be more than 30 mins
4. The assay should be able to detect all major genotypes of HBsAg.
5. The test should have clinical sensitivity and specificity more than 99%
6. Rapid qualitative, two side sandwich immune assay.
7. Hetetrophile blocking reagent should be used to minimise the interference of heterophile antibodies.
8. The pack size should be 25T or 100T suitable for less and bulk use.
9. The test should have analytical sensitivity better than 0.5 ng/ml
10. The analytical sensitivity of the test should be evaluated with WHO reference panel
11. Storage should be at room temperature.
12. The test should have a valid manufacturing license.
13. The shelf life should be upto two years after the date of manufacturing
14. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
15. The test Kit should detect infection at all stages.

16. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
17. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**

12. VDRL Rapid Diagnostic test Kit (S02179)

1. Sensitivity comparison Test: Results of the test lot should be similar to/greater than reference or passed lot.
2. Detection limit test: Results of the test lot should be similar to/greater than reference or passed lot.
3. Migration time: ≤2 minutes in case of clear samples
4. Background clearance: Background of the test should be ≤ 1 at the end 20 minutes
5. Reproducibility test: All devices should give same intensity
6. Sensitivity test: Sensitivity of the lot should be ≥ 95%
7. Specificity test: Specificity of the lot should be ≥ 95%
8. Format of the test:- Cassette type
9. Each test Kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, alcohol swabs and sample dropper.
10. The test Kit should detect infection at all stages.
11. The manufacturer/ authorized agent should ensure maintenance of adequate temperature during storage & transport the kits at 2- 30 °C.
12. The supplier should supply **5sets of kits** along with its Protocol **at the time of submission of technical bid** as sample for random evaluation during sample verification**.**

Specification for Reagents/Anti-sera

13 **D48001** - Anti – D (IgM only) for tube and slide method
Vial of 10ml each

14 **D48002** - Anti - D, IgM and IgG combination, Monoclonal IgM and IgG blood typing antibodies for slide and tube method
For Rh blood typing
Vial of 10ml each and storage at +2° to + 8°C
Titre ≥ 1:32with D positive cell in immediate spin and ≥ 1:128 after 30-40 minutes incubation

15 **D48003** - Anti - A, Monoclonal blood grouping IgM antibody for slide and tube method. For ABO blood grouping
Vial of 10ml each and storage at +2° to + 8°C
Titre ≥ 1:256 with A cell and negative with B cell

16 **D48004** - Anti - A1, lectin, Monoclonal IgM antibody for tube and slide method.
To detect A1 red cell antigen from A2
Vial of 5ml each
Titre 1:8

17 **D48005** - Anti - AB, Monoclonal IgM antibody for slide and tube method.
For ABO blood grouping
Vial of 10ml each and storage at +2° to + 8°C
Titre ≥ 1:256 with A cell and B cell

18 **D48006** - Anti - B, Monoclonal blood grouping IgM antibody for slide and tube method. For ABO blood grouping
Vial of 10ml each and storage at +2° to + 8°C
Titre ≥ 1:256 with B cell and negative with A cell

19 **D48007** - Anti - Human Globulin (Green), polyspecific, containing anti – IgG and anti C3d
To detect IgG antibodies as in cross matching, DAT and IAT tests
Vial of 10ml each and storage at +2° to + 8°C
AHG should give 2+/3++/4+ reactions with Coombs cheque cell (IgG)

20 **D48008** - Anti Human Globulin, Monospecific, containing Anti-IgG to detect IgG Ab in DAT test. Vial of 10ml each and storage at +2° to + 8°C. Titre -1 : 64

21 **D48009** - Anti Human Globulin, Monospecific, containing Anti-C3d to detect C3d in DAT test. Vial of 10ml each and storage at +2° to + 8°C. Titre -1 : 4

22 **D48010** - Bovine serum Albumin 22% solution for serological applications, protein concentration and pH should be adjusted to 22% and 7.1 respectively. To enhance immunological reactions and increase test sensitivity
Vial of 10ml each and storage at +2 ° to + 8°C.

23 **D48011** – Anti –H Lactin should be ready to use purified extract of Ulex Europacus seeds. It should be specific for detection of H antigen on human red cell. It should show negative reaction with red blood cells of Bombay blood group. It can be used for slide as well as tube test method. Physical appearance should be clear without any turbidity. It should not show any rouleux formation, prozone and hemolysis. Reagent should be approved by Govt. / NABL/ DCGI for in vitro diagnostic use in laboratory. Vial 10 ml each should provided with dropper and storage at +2 ° to + 8°C.