# Specification

**HBs Ag ELISA**:

The solid phase of the test kit should be standard micro plate (90 wells) ELISA coated with monoclonal antibodies. The assay should be at least fourth generation ELISA approved by accredited centers by WHO. The assay should be able to detect HBs Ag of all sub-types. The assay should include reactive and non- reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months (at ambient temperature) at the port of discharge of consignee's end whichever is applicable. Adequate literature provided with each kit.`Methodologies, Validity criteria, Performance characteristics, Storage conditions, Manufacturing date, Expiry dates, should be provided with each kit. The kit procured should have an approval of the National Health Laboratory (a copy of the Certificate).The assay should have at least: Sensitivity of 99.8% (detects less than 0.1 mg/ml of both ad and ay subtypes of HBs Ag) Specificity of 99.8%. The kit size should be 96 wells and be strip plate format.

**HCV ELISA test kits**:

The solid phase of the test kit should be standard micro plate
(96 wells) ELISA coated with recombinant/synthetic peptide antigens for core, NS3, NS4, and NS5. The assay should be at least fourth generation ELISA, approved by accredited centers by WHO. The assay should be able to detect HICV Ab of al Geno- types. The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months (at ambient temperature) at the port of discharge of consignee's end whichever is applicable. Adequate literature provided with each kit Methodologies, Validity criteria, Performance characteristics, Storage conditions, Manufacturing date, Expiry date should be provided with each kit. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate).The assay should have at least: Sensitivity of 99.8%.Specificity of 99.8%.The kit size should be 96 wells and be strip plate format.

**HIV ELISA KITS**:

The solid phase of the test kit should be standard micro plate ELISA coated with HIV I, II, including subgroup (O) recombinant and /or synthetic peptide antigens. The assay should detect HIV-1 (all subtypes) and II antibodies and P24 Antigen. The assay should be able to detect antibodies to HIV I/II during early sero- conversion period. Evidence based sero-conversion data should be from WHO accredited. The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months (at ambient temperature) at the port of discharge of consignee's end whichever is applicable. Adequate literature provided with each kit: Methodologies, Validity criteria, Performance characteristics, storage conditions, Manufacturing Date, Expiry dates. Should be provided with each kit. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate).The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate).The assay should have at least a sensitivity of 99.8%, specificity of 99% (Ag + ab) (Forth Generation).

**Syphilis ELISA Test kits**:

The solid phase of the test kit should be standard micro plate (96 wells) ELISA coated with Treponema palladium extract antigen. The test should be able to detect total. Human antibodies to Treponema palladium. The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months (at ambient temperature) at the port of discharge of consignee's end whichever is applicable. Adequate literature provided with each kit: Methodologies, Validity criteria, Performance characteristics, Storage conditions, Manufacturing date, Expiry dates should be provided with each kit. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate) should be provided with each. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate). The assay

should have at least: Sensitivity of 99.8%.Specificity of 99.8%.The kit size should be 96 wells and the strip plate format.

**HBs AG Simple/Rapid test Kits**:

The solid phase of the test kit should be coated

with monoclonal antibodies (Anti-HBs).The assay should be able to detect HBs AG to all sub-types. The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months at the port of discharge of consignee's end whichever is applicable. Adequate literature provided with each kit: Methodologies, Validity criteria, Performance chrematistics, Storage conditions, Manufacturing date, Expiry dates should be provided with each kit.

The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate). The assay should have at least a sensitivity of 99.8% (detects less than 1 mg/ml).Specificity of 99%.The total procedure time should not be more than 30 minutes. The kit should enable performing a single test at a time. The packing size should not be more than 50 test per kit.

**HCV Simple/Rapid test Kits**:

The solid phase of the test kit should be coated with

monoclonal/synthetic peptide antigens for core, NS3, NS4, and NS5.The assay should be able to detect HCV to all geo-types. The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should also be included. The kit should have a shelf life of minimal 12 months at the port of discharge of consignee's end whichever is applicable.

Adequate literature provided with each kit. Methodologies, Validity criteria, Performance characteristics, Storage conditions, Manufacturing date, Expiry dates should be provided with each kit. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate).The total procedure time should not be more than 30 minutes. The kit should enable performing a single test at a time. The packing size should not be more than 50 tests per kit.

**HIV Simple/Rapid test Kits**:

The solid phase of the test kit should be coated with

Synthetic/recombinant HIV I, HIV II including HIV I subtype (O) The assay should be able to detect HIV I & HIV II antibodies by immune-enzymatic/agglutination/any other acceptable principle. The product should be able to detect antibodies of HIV I & HIV II during early sero-conversion period. The product should include reactive and non-reactive controls and all reagents and accessories necessary to perform the test.The kit should have a helf life of minimal 12 months at the port of discharge of consignee's end whichever is applicable. The kit procured should have an approval of the National Health Laboratory (A copy of the Certificate).The assay should have at least a sensitivity of 99.8%.Specificity of 99% .Adequate literature provided with each kit: Methodologies, Validity criteria, Performance characteristics, Storage conditions, Manufacturing date, Expiry dates should be provided with each kit. The total procedure time should not be more than 30 minutes. The kit should enable performing a single test at a time. The packing size should not be more than 50 test per kit.

**Syphilis Rapid test**:

The solid phase of the test kit should be a serological

chromatographic or agglutination test using recombinant antigen.

The assay should include reactive and non-reactive controls with each kit. All reagents and accessories necessary to perform the test should be included.

The kit should have a shelf life of minimal 12 months at the port of discharge of consignee’s end whichever is applicable

Adequate literature provided with each kit:

Methodologies Validity criteria

Performance characteristic Storage conditions, Manufacturing date

Expiry date

Should be provided with each kit

The kit procured should have an approval of the National Health Laboratory ( A copy of the certificate)

The assay should have at least a sensitivity of 99.8 % Specificity of 99.8 %

The total procedure time should not be more than 30 minutes. The kit should enable performing a single test at time.

The packaging size should not be more than 50 test per kit.

**Single blood bag:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl 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 450 ml

Design and shape:

1. Flexible pre sterilized
2. Pyrogen free
3. Nontoxic, non-hemolytic, biocompatible material
4. No risk of contamination and air embolism (close system) with leaks proof seals
5. Slit on both sides of the bags should be enough to accommodate 5-10 ml test tubes.
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from 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 the needle should be 80 cm.
6. The tube should have multiple printed ID/Segment number. The number 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 sealed

6. The needle should not separate from the tube at any point of time, especially while removing it from the vein for the donor safety

External port:

1. Tamper proof and should not be re-capped

2. Easily accessible

Package:

1. Protective dual packaging (individual & Aluminum) eliminating microbial contamination on surface maintaining the contents of the bag

2. Easy to handle

Anticoagulant and preservative solution:

1. CPDA-1 the quantity of anticoagulant/ (63 ml)

2. Clear & colorless

3. No discoloration on storage at room temperature

4. 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 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.

**Triple blood bag 20% with RBC additive Solution:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl 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 300 ml capacity)

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

Design and shape:

1. Flexible pre sterilized
2. Pyrogen free
3. Nontoxic, non-hemolytic, biocompatible material
4. No risk of contamination and air embolism (close system) with leaks proof seals
5. Slit on both sides of the bags should be enough to accommodate 5-10 ml test tubes.
6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from 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 the needle should be 80 cm.
6. The tube should have multiple printed ID/Segment number. The number 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 sealed
6. The needle should not separate from the tube at any point of time, especially while removing it from the vein for the donor safety

External port:

1. Tamper proof and should not be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (individual & Aluminum) eliminating microbial contamination on surface maintaining the contents of the bag

2. Easy to handle

Anticoagulant and preservative solution:

1. CPDA-1 The quantity of anticoagulant/(49 ml/63 ml)

2. Clear & colorless

3. No discoloration on storage at room temperature

4. 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 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

Bag should be able to withstand temperature up to -80˚C without breakage

20% with RBC additive Solution.

**Triple blood bag:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl 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 300 ml capacity)

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

Design and shape:

7. Flexible pre sterilized

8. Pyrogen free

9. Nontoxic, non-hemolytic, biocompatible material

10. No risk of contamination and air embolism (close system) with leaks proof seals

11. Slit on both sides of the bags should be enough to accommodate 5-10 ml test tubes.

12. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from seam when it is filled up with the requisite volume of blood

Tubing of bag:

8. Flexible non kinking

9. Non sticking

10. Transparent

11. Leak proof

12. The minimum length of tubing from primary bag to the needle should be 80 cm.

13. The tube should have multiple printed ID/Segment number. The number should be legible and clear

14. A clamp should be provided for closed system

Needle:

7. 16 gauge ultra-thin walled and straight

8. Sharp, regular and smooth margins and beveled tip

9. Rust proof

10. Tightly fixed with hub covered with sterile guard

11. Hermetically sealed

12. The needle should not separate from the tube at any point of time, especially while removing it from the vein for the donor safety

External port:

3. Tamper proof and should not be re-capped

4. Easily accessible

Package:

3. Protective dual packaging (individual & Aluminum) eliminating microbial contamination on surface maintaining the contents of the bag

4. Easy to handle

Anticoagulant and preservative solution:

5. CPDA-1 the quantity of anticoagulant/ (49 ml/63 ml)

6. Clear & colorless

7. No discoloration on storage at room temperature

8. Manufacturer to supply anticoagulant quality check certificate

Label:

6. Non peel- off

7. Heat sealed/ pressure embossed labels

8. Remain attached between room temperature to 4 ˚C with a transparent adhesive

9. Date of manufacturing, date of expiry and lot number must mentioned on each bag

10. 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

Bag should be able to withstand temperature up to -80˚C without breakage.

**Quadruple blood bag With RBC additive solution:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl 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 bags:

• Primary bag (350/450 ml) with top and top

• First satellite bag (of 300 ml capacity containing 78 ml/ 100 ml 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 shape:

1. Flexible pre sterilized

2. Pyrogen free

3. Nontoxic, non-hemolytic, biocompatible material

4. No risk of contamination and air embolism (close system) with leaks proof seals

5. Slit on both sides of the bags should be enough to accommodate 5-10 ml test tubes.

6. The capacity of the bag should be enough to prevent any ballooning/ rupture of the bag from 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 the needle should be 80 cm.
6. The tube should have multiple printed ID/Segment number. The number 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 sealed
6. The needle should not separate from the tube at any point of time, especially while removing it from the vein for the donor safety

External port:

1. Tamper proof and should not be re-capped
2. Easily accessible

Package:

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

Anticoagulant and preservative solution:

1. CPDA-1 The quantity of anticoagulant/( 63 ml)
2. Additive solution- first satellite bag (100 ml for 450ml blood 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 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

Bag should be able to withstand temperature up to -80˚C without breakage

With RBC additive solution.

**Pediatric blood bag:**

Penta Blood bags, Size (ml)-450ml Anticoagulant –CPDA, Bag 1: 450ml Bag, 2: 150ml Bag, 3:150ml Bag, 4: 150mlBag, 5:150ml, with leucocyte depleted filter. Sampling System: Needle 15G with protective cover and other sampling items.