ALL INDIA INSTITUTE OF MEDICAL SCIENCES,
JODHPUR
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Dated: 28th August, 2017

CORRIGENDUM

FOR

RATE CONTRACT FOR SUPPLY REAGENT KITS AT AIIMS JODHPUR

NIT No.	:	Admin/RC/03/2017-AIIMS.JDH
NIT Issue Date	:	14th June, 2017
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Modifications

PAGE NO. 21 > CHAPTER IV – TECHNIAL BID > LIST OF REAGENT KITS:

For:

S. No	Name of Test	Specification
1	Widal	
2	Dengue NS1 Ag Rapid	
3	Dengue NS1 Ag ELISA	
4	Dengue IgM/ IgG Rapid	
5	Chickun gunya IgM Rapid	
6	Chikungunya IgM ELISA	
7	HAV IgM Elisa / Chemi	
8	HBs Ag Rapid	
9	HBs Ag ELISA	
10	HCV Antibody Rapid	
11	HCV Antibody ELISA	
12	HIV1/2 rapid test	
13	HIV1/2 ELISA	
14	Torch Panel (Ab Elisa for Toxo + Rubella + CMV + HSV)	
15	Toxoplasma IgG ELISA	
16	Toxoplasma IgM ELISA	
17	Rubella IgG ELISA	
18	Rubella IgM ELISA	
19	Rubella IgM / IgG Rapid	
20	CMV IgG ELISA	
21	CMV IgM ELISA	
22	HSV 1/2 IgM ELISA	
23	HSV1/2 IgG ELISA	
24	Microfilaria Antigen Rapid	
25	leptospira IgM/IgG, Rapid	
26	Leptospira IgM ELISA	
27	Cryptococcal Antigen	
28	Rotavirus Antien, rapid	
29	Rotavirus Antien, ELISA	
30	Chalmydia Antigen rapid	
31	Chlamydia Antigen ELISA & Ab	
32	Measles IgG ELISA	
33	Varicella Zoster Virus IgG ELISA / Chemi	
34	Malaria Antigen Rapid (Pan Specific / pf)	
35	Anti HbE by ELISA	
36	BORRELIA IgG by ELISA	
37	BORRELIA IgM by ELISA	
38	TREPONEMA SCREEN	
39	VZV IgM	
40	Anti A and Anti B Antisera, monoclonal, WHO and NIB certified for blood bank use, DG registered	1. Antisera must be appropriate for microplate and tube technique. 2. Must be monoclonal antibody.

		3. Should give clear positive reactions with cells bearing the corresponding antigen. 4. Should give clear negative reactions with cells without the corresponding antigen. 5. Should not haemolyse the cells. 6. Should not produce rouleaux. 7. Avidity (time to positive reaction) less than 4 sec. 8. Titre : 256 or more. 9. Must be evaluated and approved by NIB.
41	Anti D IgM + IgG (Monoclonal Blend, low protein) Note: Anti D are to be purchased from two different manufacturers (will be required to be run parallelly as Anti D1 & Anti D2)	1. Antisera must be appropriate for microplate and tube technique 2. Should be blend of IgG and IgM monoclonal antibody 3. Should give clear positive reactions with cells bearing the corresponding antigen 4. Should give clear negative reactions with cells without the corresponding antigen 5. Should not haemolyse the cells. 6. Should not produce rouleaux 7. Avidity less than 10 sec. 8. Titre : 128 or more at room temperature and 256 or more at 37 degree C 9. Must be evaluated and approved by NIB
42	Anti D IgG (Monoclonal, low protein), capable of detecting weak D and partial D	1. Antisera must be appropriate for microplate and tube technique 2. Should be monoclonal antibody 3. Should give clear positive reactions with cells bearing the corresponding antigen 4. Should give clear negative reactions with cells without the corresponding antigen 5. Should not haemolyse the cells. 6. Should not produce rouleaux 7. Avidity less than 10 sec 8. Titre : 128 or more 9. Must be evaluated and approved by NIB
43	AHG Antisera, monoclonal, monospecific anti IgG (Anti-Gamma heavy chain)	1. Antisera must be appropriate for microplate and tube technique 2. Should give clear positive reactions with appropriately sensitised cells 3. Should give clear negative reactions with unsensitised cells 4. Should not haemolyse the cells.

		5. Should not produce rouleaux 6. Titre : a. For polyspecific minimum 128 for IgG and minimum 4 for C3d; b. for monospecific anti-IgG minimum 256 c. for monospecific Anti C3d minimum 16 7. Must be evaluated and approved by NIB and IVD (EC)
44	AHG Anti C3d monoclonal	1. Antisera must be appropriate for microplate and tube technique 2. Should give clear positive reactions with appropriately sensitised cells 3. Should give clear negative reactions with unsensitised cells 4. Should not haemolyse the cells. 5. Should not produce rouleaux 6. Titre : a. For polyspecific minimum 128 for IgG and minimum 4 for C3d; b. for monospecific anti-IgG minimum 256 c. for monospecific Anti C3d minimum 16 7. Must be evaluated and approved by NIB and IVD (EC)
45	AHG gel cards (a. Polyspecific b. Monospecific). Note vendor MUST provide corresponding gel card centrifuge	1. Cassettes/cards should have pre filled Gel impregnated with polyspecific (blend anti IgG & anti c3d) Anti-human globulin for performing cross matching and coombs tests 2. Should be NIB and IVD (EC) approved 3. Should provide gel card centrifuge free of cost along with card. (Same gel card centrifuge may be used in case AHG & grouping cards are from same vendor)
46	Blood Grouping Gel cards Note vendor MUST provide corresponding gel card centrifuge	1. Cassettes/cards should have pre filled Gel impregnated with grouping sera 2. Should be NIB and IVD (EC) approved 3. Should provide gel card centrifuge free of cost along with card. (Same gel card centrifuge may be used in case AHG & grouping cards are from same vendor)
47	Check cells (Coombs control cell)	4. Should be a ready to use 3-5% suspension of O+ve cells sensitized/saturated with Anti D stabilized with approved preservatives. 5. Should have shelf life minimum 3 months (at least 35 days from date of supply).

		6. Should be NIB and European IVD EC approved
48	Reagent Red cells for antibody screen (three or two cell panel)	1. Should be ready for use (0.8% suspension) for gel method 2. Two to three pure reagent cells (not blend), which should include one R1R1 and one R2R2 cells 3. Should be able to screen for antibodies against all clinically significant antigens endemic in Asia (including Mia). 4. Should have shelf life of minimum 3 months (at least 45 days from date of delivery at AIIMS Jodhpur Blood Bank). 5. Should be NIB and European IVD EC approved
49	Reagent Red cell panels (eleven cell panel) for antibody identifiction	1. Should be ready for use (0.8% suspension) for gel method 2. Panel 11 or more completely phenotyped red cells 3. Should include all clinically significant antigens endemic in India 4. Should include homozygous Jka & Jkb cells. 4. Should include homozygous Jka & Jkb cells. 5. Should have shelf life of minimum 3 months (at least 35 days from date of supply). 6. Should be NIB and European IVD EC approved.
51	LISS (Low Ionic Strength Saline Solution)	1. Should be from the same manufacturer who provides the AHG gel card 2. Should preferably have pH 6.65–6.85 at 21-23°C 3. Conductivity should be 3.5–3.8 mS/cm 4. Osmolality should be 270–305 mOsmol/kg 5. Should be IVD approved for immunohematologic tests.
52	Anti A1 (Dolichos biflorus lectin)	1. Ready to use *Dolichos biflorus* Lectin solution 2. Should give 2-3+ reaction with 2 seconds for most normal A1 cells and clearly no reaction with A2 cells and O cells 3. Should have a titre of at least 1:8 for A1 cells and 1:4 for A1B 4. Should not hemolyse or form roleaux 5. Should be Approved by NIB for specific blood bank use for A1/A2 discrimination

53	Anti H (Ulex europeus lectin)	1. Ready to use *Ulex europaeus* Lectin solution 2. Should give 4+ reaction with 3 seconds for most normal O cells and clearly no reaction with Bombay cells. 3. Should have a titre of at least 1:8 for O cells 4. Should not hemolyse or form roleaux 5. Should be Approved by NIB for specific blood bank use
54	Anti A, B antibody	1. Antisera must be appropriate for microplate and tube technique 2. Must be monoclonal antibody 3. Should give clear positive reactions with cells bearing the corresponding antigen 4. Should give clear negative reactions with cells without the corresponding antigen 5. Should not haemolyse the cells. 6. Should not produce rouleaux 7. Avidity (time to positive reaction) less than 4 sec. 8. Titre: 256 or more 9. Must be evaluated and approved by NIB
55	Phenotyping Anti Sera kit	1. Should include individual vials of the following sera: Anti C (Big), Anti c (small), Anti E (Big), Anti e (small), Anti Le^a, Anti Le^b, Anti M, Anti N, Anti S (Big), Anti s (small), Anti P1, Anti K (Big), Anti k (small), Anti Fy^a, Anti Fy^b, Anti Jk^a, anti JK^b,Anti Js^a, Anti Js^b, Anti Lu^a, Anti Lu^b,Anti U, Anti I (Big), Anti i (small), 2. The kit should include its own supply of Anti human globulin reagents including Anti IgG, Anti IgM, Anti IgA, Anti C3 and Anti C4 3. Expiry of Anti sera should be more than 1 Year at the time of supply 4. Should be IVD approved for monor blood group phenotyping purpose
56	Antibody elution kit	1. Ready to use kit for elution of antibodies coated onto Red cells for the purpose of antibody identification after a positive DAT test. 2. Should be CE and IVD approved for immunohematologic testing purpose 3. Should have shelf life of more than 1.5 years from the date of supply.

57	PH calibration fluids of pH 4.01, 7 and 10.01	1. Should include readymade liquid color-coded buffers of 3 pH values (preferably 4.01, 7 & 9.21 or 10.01) 2. Should be CE and ISO 9001 certified 3. Should be compatible with standard commercial pH electrodes include calomel electrode. 4. Buffer pH accuracy and certificate of traceability to national and international standards (including NIST) should be provided.
58	ELISA kits for HBsAg tests Note: Kits are to be selected from two different manufacturers	1. Wells coated with two or more monoclonal anti HBs (murine and human origin) 2. Should detect all subtypes e.g. ad, ay, etc and variants and mutants 3. Ultra-sensitive assay having Sensitivity < 0.1 ng/ml 4. Should be compatible with automated as well as manual ELISA technique 5. Sensitivity should be over 99.9 % of WHO and NIB panels. 6. Specificity should be over 99.8 %. 7. TMB Substrate should be stable over 4 hours at 15-30°C. 8. The kits should be CE- marked and IVD approved 9. Must be evaluated and approved by NIB
59	ELISA KITS for HCV tests Note: Kits are to be selected from two different manufacturers and one of which should include 4th generation.	1. Wells coated with synthetic peptide including NS 3, NS 4, NS 5. 2. Sensitivity should be over 99.8% of WHO and NIB panels. 3. Specificity should be over 99.8%. 4. Should be compatible with automated as well as manual ELISA 5. Studies with PCR correlation for specificity and sensitivity 6. TMB Substrate should be stable over 4 hours at 15-30°C. 7. The kits should be CE- marked and IVD approved 8. Must be evaluated and approved by NIB
60	ELISA Kits for HIV 1, HIV 2 and P24 Test. (4th Generation) Note: Kits are to be selected from two different manufacturers	1. Kit should detect HIV –1, HIV-2, HIV- O and Antigen P24 simultaneously 2. Indirect or competitive inhibition ELISA Kit. 3. Should be compatible with automated

		as well as manual ELISA 4. One step procedure with specificity of 99 % and Sensitivity should be over 99.9 % of WHO and NIB panel. 5. TMB Substrate should be stable over 4 hours at 15-30°C. 6. The kits should be CE- marked and IVD approved
61	Rapid Kit For HBsAg Tests	1. Should be immunoassay/capture principle 2. Should be lateral flow device 3. Should have in built quality control band or dot 4. Should have short interpretation time not more than 30 minutes 5. Should have specificity and sensitivity of 100 % 6. Must be evaluated and approved by NIB
62	Rapid Kit For HCV Tests	1. Should be 3rd generation 2. Should have antigen immobilised on immunofiltration membrane 3. Should have in built quality control band or dot 4. Should have short interpretation time not more than 30 minutes 5. Should have specificity and sensitivity of 100 % 6. Must be evaluated and approved by NIB
63	Rapid Kit For HIV1 and HIV2 Tests	1. Should be based on immunofiltration membrane (flow through) 2. Should have antigen immobilised on immunofiltration membrane 3. Should be 04th Generation i.e. include detection of HIV1 p24 Ag in addition to HIV 1 & 2 Ab. 3. Should have in built quality control band or dot 4. Should have short interpretation time not more than 30 minutes 5. Should have specificity and sensitivity of 100 % 6. Should be approved and evaluated by NIB
64	Rapid Malaria Antigen detection kit, Panspecific, pLDH based, should be certified by WHO, and NIB for blood bank screening purpose	1. Should be based on pLDH antigen detection on plastic cassette (not dipstick) 2. Should be Approved by WHO and NIB for Blood Bank screening use. 3. Pan specific band should detect all

		species endemic in India and additional species specific bands may be there. 4. Sensitivity of the kit at least 95% of P. falciparum infection/cases at 200 parasites per µl of blood and higher at higher parasite density. 5. Should be stable at temperatures up to 40ºC, wrapped individually to protect from moisture and supplied along with a dropper and dessicant.
65	RPR (Rapid plasma Reagin) for Syphilis, should be certified by WHO, and NIB for blood bank screening purpose	1. Should be certified by WHO and NIB for blood bank screening purposes. 2. Should be based on modified VDRL antigen (balanced quantities of cardiolipin, lecithin and cholesterol) combined with charcoal particles 3. Flocculation should be macroscopically visible
66	Antihuman globulin antisera (AHG) Polyspecific monoclonal blend	1. Antisera must be appropriate for microplate and tube technique 2. Should give clear positive reactions with appropriately sensitised cells 3. Should give clear negative reactions with unsensitised cells 4. Should not haemolyse the cells. 5. Should not produce rouleaux 6. Titre : a. For polyspecific minimum 128 for IgG and minimum 4 for C3d; b. for monospecific anti-IgG minimum 256 c. for monospecific Anti C3d minimum 16 7. Must be evaluated and approved by NIB and IVD (EC)

To be read as follow:

S. No.	Name of Test	Specification
1	Widal	
2	Dengue NS1 Ag Rapid	• Should be a rapid test based on lateral flow technique. • Test must be able to detect Dengue virus NS1 Ag from Day 1 of fever. • Should be able to detect all the 4 Dengue serotypes (DEN-1, DEN-2, DEN-3, and DEN-4). • Test should provide results within 20 minutes • Should have long shelf life: 24 months. • It should have a convenient pack size : 25 tests • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation

S. No.	Name of Test	Specification
		of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Sensitivity- > 95% and Specificity- 99%
3	Dengue NS1 Ag ELISA	• ELISA kit should be a direct sandwich ELISA for the qualitative detection of NS1 Ag in human serum. • Test should have high accuracy of detection for all 4 dengue serotypes (DEN1,2,3, and 4) • Performance: Sensitivity should be > 93% & Specificity 99% • Simple and easy to use: All necessary reagents should be included in the kit • High stability for at least 18 months. • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
4	Dengue IgM/ IgG Rapid	• Test should be a solid phase *in vitro* immunochromatographic test for the qualitative and differential detection of IgG and IgM antibodies to dengue virus serotype DEN-1, 2, 3 and 4 in human serum, plasma or whole blood • The test should be able to differentially detect IgG and IgM antibodies against all 4 serotypes of Dengue virus • Results should be available in 15-20min. • Test should be able to give a presumptive differentiation between primary & secondary dengue infections • Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease • Dengue IgG/IgM (Plasma Serum WB) : Sensitivity 94%, Specificity ≥ 96%

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S. No.	Name of Test	Specification
		Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees
5	Chickun gunya IgM Rapid	• Test should be preferably a solid phase immunochromatographic assay for the rapid, qualitative detection of IgM antibodies to Chikungunya virus in human serum, plasma, or whole blood. • Results should be available in 10- 15 minutes • Should have a minimum shelf life of 24 months. • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
6	Chikungunya IgM ELISA	• Kit should be a qualitative test for the detection of IgM antibody to *Chikungunya virus* in human serum. • Test should be useful to distinguish Chikungunya from dengue virus infection • Should be able to detect chikungunya antibody (IgM) after 5 days of fever onset. • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin

S. No.	Name of Test	Specification
		• In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Should be simple and easy to use • All necessary reagents to be included in the kit • Should have a Sensitivity of > 95% & 99% Specificity • Kit should be highly stable with shelf life of at least 18 months at 2~8 °C
7	HAV IgM Elisa / Chemi	• Kit should be a sandwich enzyme immunoassay for the measurement of IgM antibodies to hepatitis A virus. • Should be compatible with all common ELISA readers • Serum or plasma could be used for testing • Sensitivity : 100% • Specificity : 100% • Shelf life of at least 12 months at 2-8℃ • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
8	HBs Ag Rapid	• Should be solid phase/ particle coated with monoclonal antibodies to Hbs Ag • Can identify HBsAg in serum, plasma, or whole blood specimens with a high degree of sensitivity. • Detect all the 11 subtype of HBsAg. • Antigen Sensitivity- 0.5 ng/ml • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I)

S. No.	Name of Test	Specification
		• In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of > 12 months. • Total procedure time shall not be more than 30 minutes. • See through Device for easy result interpretation. • Sensitivity : should be > 95% Specificity : >95% • Shelf life should be > 12 months at 2-8℃
9	HBs Ag ELISA	• Test kit should be able to qualitatively detect Hepatitis B surface antigen in human serum or plasma. • System configuration compatible with all common ELISA reader equipment's • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have shelf life of > 12 months. • The assay component should include reactive and non-reactive controls • The assay should have sensitivity of more than or equal to 99% and specificity of more than or equal to 98% • The assay should have analytical sensitivity of detecting less than or equal to 0.5 ng/ml
10	HCV Antibody Rapid	• Should be preferably immunochromatographic rapid test for the qualitative detection of antibodies specific to HCV in human serum, plasma, or whole blood. • Should be solid phase / particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS 4, and NS5. • 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. • The kit to be procured should have approval of the statutory authority in its country of origin.

S. No.	Name of Test	Specification
		• In case of imported kits it should have been registers and licenses in India by DCG (I). • In case of indigenous manufacturers they should be licenses by the competent authority defined under Drugs and Cosmetics Act 1940, after appropriate evaluation by the centers approved by the DCG (I). • The kit should have minimum shelf life of 12 months. • The total procedure time shall not be more than 30 minutes. • The assay component should include positive and negative control in each pack of 50 tests. • The assay should have sensitivity of more than or equal to 99% and specificity of more than or equal to 98%.
11	HCV Antibody ELISA	• Test should be indirect sandwich ELISA for the qualitative detection of IgG antibodies specific to HCV in human serum or plasma. • Micro plate ELISA coated with recombinant/ synthetic peptide antigens for core, NS3, NS4, and NS5 • Compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 60% of 12 months (whichever is more) at the port of discharge of consignees • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity of more than or equal to 99.5% and Specificity of more than or equal to 99.5% 99.5% (approximately)
12	HIV1/2 rapid test	• Test should be an immunochromatographic assay for the differential and qualitative detection of all isotypes(IgG, IgM, IgA) antibodies specific to HIV-1 including subtype O and HIV-2 simultaneously, in human serum, plasma or whole blood. • Test should be highly sensitive even to IgM during early infection stage • Test should be able to differentiate between HIV type I and II by clear band formation (3-lines)

S. No.	Name of Test	Specification
		• Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, bio safety methodologies, validity criteria, limitation of assays, manufacturing & expiry date should be provided with each kit. • The kit should have approval of the statutory authority in its country of origin. • In case of importee kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers should be licensed issued by the competent authority defined under Drugs and cosmetics Act 1940 & also be evaluated by the centers approved by DCG (I) • The assay should have sensitivity level of more than or equal to 99.5% and specificity level of more than or equal to 98%. • The kit should have minimum shelf life of > 24 months.
13	HIV1/2 ELISA	• Test should be a solid phase sandwich ELISA for the qualitative detection of antibodies to all isotypes (IgG, IgM, IgA) specific to HIV-1 including subtype-O and HIV-2 simultaneously in human serum or plasma • Should have p24, gp41, and gp36 as Capture antigens • Should be compatible with all common ELISA reader • The assay should detect HIV 1 and 2 antibodies. • Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, bio safety methodologies, validity criteria, limitation of assays, manufacturing & expiry date should be provided with each kit. • The kit should have approval of the statutory authority in its country of origin. • In case of importee kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers should be licensed issued by the competent authority defined under Drugs and cosmetics Act 1940 & also be evaluated by the centers approved by DCG (I) • The kit should have minimum shelf life of > 12 months. • The assay component should include reactive and non-reactive controls with each kit • The assay should have sensitivity level of more than or equal to 99.5% and specificity level of more than or equal to 98%. • The pack size should be 96 tests/kits.
	Torch Panel (Ab Elisa for Toxo + Rubella + CMV + HSV)	

S. No.	Name of Test	Specification
14	Toxoplasma IgG ELISA	• Kit should be able to detect IgG against *Toxoplasma gondii* in patient's serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of > 12 months. • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98% (approximately)
15	Toxoplasma IgM ELISA	• Kit should be able to detect IgM against *Toxoplasma gondii* in patient's serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 60% of 12 months (whichever is more) at the port of discharge of consignees • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
16	Rubella IgG ELISA	• Kit should be able to quantitatively measure IgG antibodies against Rubella in human serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit.

S. No.	Name of Test	Specification
		• The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of > 12 months. • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity & specificity of more than or equal to 98% (approximately).
17	Rubella IgM ELISA	• Should be able to qualitatively measure IgM class antibodies against Rubella Virus in Human serum and plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of > 12 months. • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity & specificity of more than or equal to 98%.
18	Rubella IgM / IgG Rapid	• Test should be rapid, qualitative, and differential test for the detection of IgG/IgM antibody to Rubella virus in human serum or plasma. • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I)

S. No.	Name of Test	Specification
		• Result should be available within 20 -30 minutes • Should have a minimum shelf life of 12 months at 1-30°C • Test should have a sensitivity & specificity of more than or equal to 98%.
20	CMV IgG ELISA	• Kit should be able to detect IgG antibody to cytomegalovirus (CMV) in human serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers, they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life > 12 months. • The assay component should include reactive and non-reactive controls. Test should have a sensitivity & specificity of more than or equal to 98%.
21	CMV IgM ELISA	• Kit should be able to detect IgM antibody to cytomegalovirus (CMV) in human serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of > 12 months. • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity & specificity of more than or equal to 98%.
22	HSV 1/2 IgM ELISA	• Kit should be able to qualitatively and quantitatively determine IgM antibodies against Herpes simplex virus 1 and 2 in human serum and plasma.

S. No.	Name of Test	Specification
		• Should be a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 60% of 12 months (whichever is more) at the port of discharge of consignees • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
23	HSV1/2 IgG ELISA	• Kit should be able to qualitatively and quantitatively determine IgG antibodies against Herpes simplex virus 1 and 2 in human serum and plasma. • Should be a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. • Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 60% of 12 months (whichever is more) at the port of discharge of consignees • The assay component should include reactive and non-reactive controls. Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
24	Microfilaria Antigen Rapid	• Should be a rapid Immunochromatographic test • Test should be able to detect Antigen of *Wucheraria bancrofti* from human serum or plasma or whole blood.

S. No.	Name of Test	Specification
		• Each test kit should contain all the material required for conducting the • Each batch of Rapid tests should have sensitivity and specificity at minimum of > 98%. • Each kit should be packed in a hermetically sealed and non-permeable pouch and should have moisture adsorbent material • Kit should have a pack size of 25 such test cards/strips • Result should be available in 20 minutes • Adequate literature detailing the components methodologies, validity criteria, storage conditions, expiry date and limitations of test should be provided • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees
25	Leptospira IgM/IgG, Rapid	• Test should be a rapid, qualitative, and differential test for the detection of antibodies (IgM or IgG or IgM/IgG) to *Leptospira interrogans* in human serum, plasma, whole blood. • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 18 months at 1-30℃ • The assay component should include reactive and non-reactive controls. Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
26	Leptospira IgM ELISA	• Kit should be able to detect IgM antibodies against leptospira antigen in human serum. • Should be a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle.

S. No.	Name of Test	Specification
		• Should be compatible with all common ELISA reader • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 18 months at 1-30℃ • The assay component should include reactive and non-reactive controls. Test should have a Sensitivity of more than or equal to 97% and Specificity of more than or equal to 99%
27	Cryptococcal Antigen	• Kit should be a rapid latex agglutination test for qualitative or semi-quantitative detection of polysaccharide antigens associated with *Cryptococcus neoformans* infection in serum or CSF. • Adequate documents detailing principle, components, bio safety, methodologies, limitations of assays, manufacturing & expiry dates should be provided with each kit. • The kit to be procured should have approval of the statutory authority in its country of origin. • In case of imported kits it should have been registered and licensed in India by DCG (I) • In case of indigenous manufacturers they shall have license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I) • The kit should have minimum shelf life of 60% of 12 months (whichever is more) at the port of discharge of consignees • The assay component should include reactive and non-reactive controls. • Test should have a Sensitivity of more than or equal to 95% and Specificity of more than or equal to 95%
28	Rotavirus Antien, Rapid	• A solid phase sandwich Immunochromatographic assay for the detection of Group A rotavirus in fecal specimens. • Early detection of rotavirus antigen of all serotypes of group A • Convenient test & easy to perform • Total test time to give results: 10-20min • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation

S. No.	Name of Test	Specification
		of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 18 months at the port of discharge of consignees Test should have a Sensitivity of more than or equal to 90% and Specificity of more than or equal to 98%
29	Rotavirus Antien, ELISA	• Test kit should be able to detect rotavirus antigen in stool samples. • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 18 months at the port of discharge of consignees Test should have a Sensitivity of more than or equal to 95% and Specificity of more than or equal to 95%
30	Chalmydia Antigen rapid	• Test should be a solid phase immunochromatographic assay for the rapid, qualitative detection of Chlamydia antigen directly from endocervical swab, cytology brush specimens.. • Test must be easy to perform • All materials for testing along with ready to use reagents to be provided. • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit

S. No.	Name of Test	Specification
		• The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 18 months at the port of discharge of consignees Test should have a Sensitivity of more than or equal to 95% and Specificity of more than or equal to 95%
31	Chlamydia Antigen ELISA & Ab	• Test should be ELISA assay for the qualitative detection of Chlamydia antigen directly from endocervical swab, cytology brush specimens. • Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
32	Measles IgG ELISA	• Kit should be able to detect and the quantitatively determine the specific IgG antibodies against Measles in serum and plasma. • compatible with all common ELISA reader • Specimen : Serum or plasma • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I)

S. No.	Name of Test	Specification
		• In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%.
33	Varicella Zoster Virus IgG ELISA / Chemi	• Kit should be able to detect IgG antibody to VZV in human serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
34	Malaria Antigen Rapid (Pan Specific / pf)	• Should be a rapid Immunochromatographic test • Test should be able to detect and differentiate between Antigen of *P.falciparum* (HRP-2/ LDH) and Pan Plasmodia against *P.falciparum*, *P.vivax*, *P.ovale*, *P.malariae* (LDH) from human serum or plasma or whole blood • The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies specific for antigen target • Each test kit should contain all the material required for conducting the • Each batch of Rapid tests should be tested during time of delivery to ensure sensitivity and specificity of > 99%. • Each kit should be packed in a hermetically sealed and non-permeable pouch and should have moisture adsorbent material • Kit should have a pack size of 25 such test cards/strips • Result should be available in 20 minutes

S. No.	Name of Test	Specification
		• Adequate literature detailing the components methodologies, validity criteria, storage conditions, expiry date and limitations of test should be provided • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees
35	Anti HbE by ELISA	• Kit should be able to detect IgG antibodies to Hepatitis E Virus (HEV) in human serum or plasma. • Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
36	BORRELIA IgG by ELISA	• Kit should be able to quantitatively measure IgG antibodies against Borrelia in serum or plasma or CSF samples • Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs

S. No.	Name of Test	Specification
		and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Test should have a Sensitivity of more than or equal to 98% and Specificity of more than or equal to 98%
37	BORRELIA IgM by ELISA	• Kit should be able to quantitatively measure IgM antibodies against Borrelia in human serum or plasma or CSF Or synovial fluid • Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Should have a Sensitivity of greater than or equal to 95% and Specificity of greater than or equal to 95%
38	TREPONEMA SCREEN	• Test should be a solid phase sandwich treponemal antigen-based Enzyme Immunoassay • Should have a Sensitivity of greater than or equal to 99% and Specificity of greater than or equal to 99% • Should have a minimum shelf life of 12 months at 2-8°C • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
39	VZV IgM	• Kit should detect IgM antibody to VZV in human serum or plasma.

S. No.	Name of Test	Specification
		• Should be compatible with all common ELISA reader • Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Should have a Sensitivity of greater than or equal to 98% and Specificity of greater than or equal to 98%
40	Anti A and Anti B Antisera, monoclonal, WHO and NIB certified for blood bank use, DG registered	• Antisera must be appropriate for microplate and tube technique. • Must be monoclonal antibody. • Should give clear positive reactions with cells bearing the corresponding antigen. • Should give clear negative reactions with cells without the corresponding antigen. • Should not haemolyse the cells. • Should not produce rouleaux. • Avidity (time to positive reaction) less than 4 sec. • Titre: 256 or more. • Must be evaluated and approved by NIB.
41	Anti D IgM + IgG (Monoclonal Blend, low protein) Note: Anti-D, are to be purchased from two different manufacturers (will be required to be run parallelly as Anti D1 & Anti D2)	• Antisera must be appropriate for microplate and tube technique. • Should be blend of IgG and IgM monoclonal antibody • Should give clear positive reactions with cells bearing the corresponding antigen • Should give clear negative reactions with cells without the corresponding antigen • Should not haemolyse the cells. • Should not produce rouleaux • Avidity less than 10 sec. • Titre: 128 or more at room temperature and 256 or more at 37 degree C • Must be evaluated and approved by NIB
42	Anti D IgG (Monoclonal, low protein), capable of detecting weak D and partial D	• Antisera must be appropriate for microplate and tube technique • Should be monoclonal antibody

S. No.	Name of Test	Specification
		• Should give clear positive reactions with cells bearing the corresponding antigen • Should give clear negative reactions with cells without the corresponding antigen • Should not haemolyse the cells. • Should not produce rouleaux • Avidity less than 10 sec • Titre : 128 or more • Must be evaluated and approved by NIB
43	AHG Antisera, monoclonal, monospecific anti IgG (Anti-Gamma heavy chain)	• Antisera must be appropriate for microplate and tube technique • Should give clear positive reactions with appropriately sensitised cells • Should give clear negative reactions with unsensitised cells • Should not haemolyse the cells. • Should not produce rouleaux • Titre : a) For polyspecific minimum 128 for IgG and minimum 4 for C3d; b) for monospecific anti-IgG minimum 256 c) for monospecific Anti C3d minimum 16 • Must be evaluated and approved by NIB and IVD (EC)
44	AHG Anti C3d monoclonal	• Antisera must be appropriate for microplate and tube technique • Should give clear positive reactions with appropriately sensitised cells • Should give clear negative reactions with unsensitised cells • Should not haemolyse the cells. • Should not produce rouleaux • Titre : **a)** For polyspecific minimum 128 for IgG and minimum 4 for C3d; **b)** for monospecific anti-IgG minimum 256 **c)** for monospecific Anti C3d minimum 16 • Must be evaluated and approved by NIB and IVD (EC)
45	AHG gel cards (a. Polyspecific b. Monospecific). Note vendor MUST provide corresponding gel card centrifuge	• Cassettes/cards should have pre filled Gel impregnated with polyspecific (blend anti IgG & anti C3d) Anti-human globulin for performing cross matching and coombs tests • Should be NIB and IVD (EC) approved • Should provide gel card centrifuge free of cost along with card. (Same gel card centrifuge may be used in case AHG & grouping cards are from same vendor)
46	Blood Grouping Gel cards Note vendor MUST provide corresponding gel card centrifuge	• Cassettes/cards should have pre filled Gel impregnated with grouping sera • Should be NIB and IVD (EC) approved

S. No.	Name of Test	Specification
		• Should provide gel card centrifuge free of cost along with card. (Same gel card centrifuge may be used in case AHG & grouping cards are from same vendor)
47	Check cells (Coombs control cell)	• Should be a ready to use 3-5% suspension of O+ve cells sensitized/saturated with Anti D stabilized with approved preservatives. • Should have shelf life minimum 3 months (at least 35 days from date of supply). • Should be NIB and European IVD EC approved
48	Reagent Red cells for antibody screen (three or two cell panel)	• Should be ready for use (0.8% suspension) for gel method • Two to three pure reagent cells (not blend), which should include one R1R1 and one R2R2 cells • Should be able to screen for antibodies against all clinically significant antigens endemic in Asia (including Mia). • Should have shelf life of minimum 3 months (at least 45 days from date of delivery at AIIMS Jodhpur Blood Bank). • Should be NIB and European IVD EC approved
49	Reagent Red cell panels (eleven cell panel) for antibody identification	• Should be ready for use (0.8% suspension) for gel method • Panel 11 or more completely phenotyped red cells Should include all clinically significant antigens endemic in India • Should include homozygous Jka & Jkb cells. • Should include homozygous Jka & Jkb cells. • Should have shelf life of minimum 3 months (at least 35 days from date of supply). • Should be NIB and European IVD EC approved.
51	LISS (Low Ionic Strength Saline Solution)	• Should be from the same manufacturer who provides the AHG gel card • Should preferably have pH 6.65–6.85 at 21-23°C • Conductivity should be 3.5–3.8 mS/cm • Osmolality should be 270–305 mOsmol/kg • Should be IVD approved for immunohematologic tests.
52	Anti-A1 (Dolichos biflorus lectin)	• Ready to use *Dolichos biflorus* Lectin solution • Should give 2-3+ reaction with 2 seconds for most normal A1 cells and clearly no reaction with A2 cells and O cells • Should have a titre of at least 1:8 for A1 cells and 1:4 for A1B • Should not hemolyse or form roleaux • Should be Approved by NIB for specific blood bank use for A1/A2 discrimination
53	Anti H (Ulex europeus lectin)	• Ready to use *Ulex europaeus* Lectin solution • Should give 4+ reactions with 3 seconds for most normal O cells and clearly no reaction with Bombay cells. • Should have a titre of at least 1:8 for O cells • Should not hemolyse or form roleaux

S. No.	Name of Test	Specification
		• Should be Approved by NIB for specific blood bank use
54	Anti A, B antibody	• Antisera must be appropriate for microplate and tube technique • Must be monoclonal antibody • Should give clear positive reactions with cells bearing the corresponding antigen • Should give clear negative reactions with cells without the corresponding antigen • Should not haemolyse the cells. • Should not produce rouleaux • Avidity (time to positive reaction) less than 4 sec. • Titre: 256 or more • Must be evaluated and approved by NIB
55	Phenotyping Anti Sera kit	• Should include individual vials of the following sera: Anti C (Big), Anti c (small), Anti E (Big), Anti e (small), Anti Le^a, Anti Le^b, Anti M, Anti N, Anti S (Big), Anti s (small), Anti P1, Anti K (Big), Anti k (small), Anti Fy^a, Anti Fy^b, Anti Jk^a, anti JK^b,Anti Js^a, Anti Js^b, Anti Lu^a, Anti Lu^b,Anti U, Anti I (Big), Anti I (small) • The kit should include its own supply of Anti human globulin reagents including Anti IgG, Anti IgM, Anti IgA, Anti C3 and Anti C4 • Expiry of Anti sera should be more than 1 Year at the time of supply • Should be IVD approved for monor blood group phenotyping purpose
56	Antibody elution kit	• Ready to use kit for elution of antibodies coated onto Red cells for the purpose of antibody identification after a positive DAT test. • Should be CE and IVD approved for immunohematologic testing purpose • Should have shelf life of more than 1.5 years from the date of supply.
57	PH calibration fluids of pH 4.01, 7 and 10.01	• Should include readymade liquid color-coded buffers of 3 pH values (preferably 4.01, 7 & 9.21 or 10.01) • Should be CE and ISO 9001 certified • Should be compatible with standard commercial pH electrodes include calomel electrode. • Buffer pH accuracy and certificate of traceability to national and international standards (including NIST) should be provided.
58	ELISA kits for HBsAg tests Note: Kits are to be selected from two different manufacturers	• Wells coated with two or more monoclonal anti Hbs (murine and human origin) • Should detect all subtypes e.g. ad, ay, etc. and variants and mutants • Ultra-sensitive assay having Sensitivity < 0.1 ng/ml

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S. No.	Name of Test	Specification
		• Should be compatible with automated as well as manual ELISA technique • Sensitivity should be over 99.9 % of WHO and NIB panels. • Specificity should be over 99.8 %. • TMB Substrate should be stable over 4 hours at 15-30°C. • The kits should be CE- marked and IVD approved • Must be evaluated and approved by NIB
59	ELISA KITS for HCV tests Note: Kits are to be selected from two different manufacturers and one of which should include 4th generation.	• Wells coated with synthetic peptide including NS 3, NS 4, and NS 5. • Sensitivity should be over 99.8% of WHO and NIB panels. • Specificity should be over 99.8%. • Should be compatible with automated as well as manual ELISA • Studies with PCR correlation for specificity and sensitivity • TMB Substrate should be stable over 4 hours at 15-30°C. • The kits should be CE- marked and IVD approved • Must be evaluated and approved by NIB
60	ELISA Kits for HIV 1, HIV 2 and P24 Test. (4th Generation) Note: Kits are to be selected from two different manufacturers	• Kit should detect HIV –1, HIV-2, HIV- O and Antigen P24 simultaneously • Indirect or competitive inhibition ELISA Kit. • Should be compatible with automated as well as manual ELISA • One step procedure with specificity of 99 % and Sensitivity should be over 99.9 % of WHO and NIB panel. • TMB Substrate should be stable over 4 hours at 15-30°C. • The kits should be CE- marked and IVD approved
61	Rapid Kit For HBsAg Tests	• Should be immunoassay/capture principle • Should be lateral flow device • Should have in built quality control band or dot • Should have short interpretation time not more than 30 minutes • Should have specificity and sensitivity of 100 % • Must be evaluated and approved by NIB
62	Rapid Kit For HCV Tests	• Should be 3rd generation • Should have antigen immobilised on immunofiltration membrane • Should have in built quality control band or dot • Should have short interpretation time not more than 30 minutes • Should have specificity and sensitivity of 100 % • Must be evaluated and approved by NIB
63	Rapid Kit For HIV1 and HIV2 Tests	• Should be based on immunofiltration membrane (flow through) • Should have antigen immobilised on immunofiltration membrane

S. No.	Name of Test	Specification
		• Should be 04th Generation i.e. include detection of HIV1 p24 Ag in addition to HIV 1 & 2 Ab. • Should have in built quality control band or dot • Should have short interpretation time not more than 30 minutes • Should have specificity and sensitivity of 100 % • Should be approved and evaluated by NIB
64	Rapid Malaria Antigen detection kit, Panspecific, pLDH based, should be certified by WHO, and NIB for blood bank screening purpose	• Should be based on pLDH antigen detection on plastic cassette (not dipstick) • Should be Approved by WHO and NIB for Blood Bank screening use. • Pan specific band should detect all species endemic in India and additional species specific bands may be there. • Sensitivity of the kit at least 95% of P. falciparum infection/cases at 200 parasites per µl of blood and higher at higher parasite density. • Should be stable at temperatures up to 40ºC, wrapped individually to protect from moisture and supplied along with a dropper and dessicant.
65	RPR (Rapid plasma Reagin) for Syphilis, should be certified by WHO, and NIB for blood bank screening purpose	• Should be certified by WHO and NIB for blood bank screening purposes. • Should be based on modified VDRL antigen (balanced quantities of cardiolipin, lecithin, and cholesterol) combined with charcoal particles • Flocculation should be macroscopically visible
66	Antihuman globulin antisera (AHG) Polyspecific monoclonal blend	• Antisera must be appropriate for microplate and tube technique • Should give clear positive reactions with appropriately sensitised cells • Should give clear negative reactions with unsensitised cells • Should not haemolyse the cells. • Should not produce rouleaux • Titre : a) For polyspecific minimum 128 for IgG and minimum 4 for C3d; b) for monospecific anti-IgG minimum 256 c) for monospecific Anti C3d minimum 16 • Must be evaluated and approved by NIB and IVD (EC)
67	Stained Salmonella Antigen set for Widal tests (Tube)	• Kit should provide following Salmonella antigen for performing Tube Widal agglutination tests preferably. • Widal antigen S. typhi 'O' -5 ml • Widal antigen S. typhi 'H' -5 ml • Widal antigen S.paratyphi 'AH' -5 ml • Widal antigen S.paratyphi 'BH' -5 ml

S. No.	Name of Test	Specification
		• Adequate literature detailing the components methodologies, validity criteria, storage conditions, expiry date and limitations of test should be provided • The kit to be procured should have approval of the statutory authority in its country of origin • In case of imported kits it should be registered and licensed in India by DCG (I) • In case of indigeneous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I) • Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees • Should have a Sensitivity of greater than or equal to 98% and Specificity of greater than or equal to 98%.
68	Bovine Albumin 22%	
69	Anti-Human Globulin Sera IgG (Monospecific)	
70	Anti-Human Globulin Sera C3d (Monospecific)	
71	Copper Sulphate CuSo4.5H2O- AR Grade	
72	Ulex Europens Seeds- for lectin preparation	
73	Dolichos Biflorus Seeds- for lectin preparation	
74	Arachis Hypogea seeds- for lectin preparation	
75	Thrombin from bovine plasma-lyophilized powder	
76	Protamine sulfate reagent	
77	Epsilon amino caproic acid- reagent grade	
78	Sodium dihydrogen phosphate- reagent grade	
79	Disodium hydrogen phosphate- reagent grade	
80	Bovine Albumin 6%- reagent grade	
81	Papain powder- reagent grade	
82	Ficin powder- reagent grade	
83	Phosphate buffer	
84	Dithiothreitol (DTT)	
85	Glycine- reagent grade	
86	2- Mercaptoethanol- reagent grade	
87	Chloroquine- diphosphate- reagent grade	
88	3350 MW PEG	

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Page No. 5 > Point No. 11: DOCUMENTS COMPRISING BID:

For:
(d) Price list of the items from the principal.

Read As: **DELETED**

For:
(g) VAT/CST with documents

Read As:
(g) GST registration certificate

Page No. 15 > Chapter - III Contract Form > TENDER FORM - 1 - TECHNICAL INFORMATION AND UNDERTAKING. > Point No. 13:
For:
Copy of VAT/CST/ST Registration

Read As:
Copy of GST Registration

Page No. 29 > Chapter – V > Financial Bid:
For:
Note: Financial Bid Format must be submitted by Bidder also in Excel (*.xls / *.xlsx) Format written on Compact Disk (CD) as a Soft Copy with Financial Bid.

Read As: **DELETED**

Administrative Officer