Subject: **Minutes of meeting of the Technical Committee for specifications of "Kits and Consumables for Early Infant Diagnosis (EID) and Diagnostic Kits for Blood banks" held on 24th August 2012.**

A meeting of the Technical Committee for specifications of "Kits and Consumables for Early Infant Diagnosis (EID) and Diagnostic Kits for Blood banks" was held under the chairmanship of Dr. B.D.Athani, Addl. DGHS & Medical Superintendant in his chamber at Safdarjang Hospital , New Delhi on 24th August 2012 at 3.30PM.

The following members attended the meeting:

1. Dr. B. D. Athani, Addl. DGHS & Medical Superintendant, Safdarjung Hospital, New Delhi — Chairman
2. Dr.K.Bangarurajan Dy. Drug Controller General of India, MOH & FW
3. Dr. Manjula Singh, Scientist C, ICMR H.Q, New Delhi
4. Dr.G.R.Soni, Scientist Gr I, National Institute of Biologicals, Noida
5. Dr. Mohd.Shaukat, ADG (CST), NACO
6. Dr. Sandhya Kabra, ADG (BS & LS), NACO
7. Dr. Lalit Dar, Professor, Department of Microbiology, AIIMS, New Delhi
8. Dr. Anita S.Desai, Addl. Prof, Dept. of Neurovirology, NIMHANS, Bangalore
9. Dr. Rajeev Thakur, Professor, Department of Microbiology, IHBAS, New Delhi
10. Dr. Namita Singh, Consultant, CHAI, New Delhi

The agenda of the meeting was as follows:

1. Review of Technical Specifications of Kits and Consumables for Early Infant Diagnosis (EID) [Dried Blood Spot Collection Kits, Whole Blood Collection Kit. Laboratory Consumables for 10 Kits of 96 tests each]
2. Review of Technical Specifications of HIV (ELISA)
3. Review of Technical Specifications of HIV (Rapid)
4. Review of Technical Specifications of HCV(ELISA)
5. Review of Technical Specifications of HCV (Rapid)

6. Review of Technical Specifications of Hepatitis B Surface Antigen ELISA Kits
7. Review of Technical Specifications of Hepatitis B Surface Antigen Rapid Kits

All the agenda items were discussed in the meeting and the following decisions were taken:

Agenda Item No. 1: Review of Technical Specifications of Kits and Consumables for Early Infant Diagnosis (EID)

The technical specifications are based on the products already being supplied by donor agency and used in the programme since two years. The committee approved the technical specifications for Kits and Consumables for EID [Dried Blood Spot Collection Kits, Whole Blood Collection Kit. Laboratory Consumables for 10 Kits of 96 tests] of each as follows:

Dry Blood Spot (DBS) Collection Kit for Collection of 10 samples:

S.No.	Item	Number supplied in 10 card DBS Kit	Product Description
1	DBS Cards	10	Whatman 903
2	Glassine Envelope	10	Light weight, semi-transparent material resistant to moisture
	Flexible Packaging	1	Zip locked Bag 150 x 180mm (approx.), Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
3	Silica Gel Packs	50	Indicating Silica Gel Sachets 1gm complete with opaque non gas permeable bag
	Flexible Packaging	1	Zip locked Bag 150 x 180mm (approx.),Printed Flexible Non Gas Permeable Bag with contents description, quantity, Packer and distributor's name and contact details.
4	Humidity	5	Tropically packed Humidity Indicator Card

	Indicator Cards		with 6 blue circles indicating percentage humidity changes
5	Sterile Alcohol Swipes	20	Single use Alcohol Pad saturated with 70% Isopropyl Alcohol
	Flexible Packaging	1	Zip locked Bag 100 x 85mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
6	Gauze Swabs	20	Gauze 8 ply 50 x 50mm(approx.),
	Flexible Packaging	1	Zip locked Bag 100 x 150mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
7	Zip lock Bags	5	Opaque Low Gas Permeable double Zip locked Bag 150 x 180mm(approx.),
	Flexible Packaging	1	Zip locked Bag 150 x 180mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
8	Powderless Gloves	30	Latex Examination Glove, powder free, Medium
	Flexible Packaging	15	Zip locked Bag 100 x 80mm (approx.),with one pair of gloves
	Flexible Packaging	1	Zip locked Bag 200 x 250mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
9	Auto retractable Lancets 2mm Blade	20	Auto retractable Lancet with 2mm blade
	Flexible Packaging	1	Zip locked Bag 100 x 150mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
10	Cardboard Box	1	White Printed Corrugated box with Tuck in Lid. Colour Printed NACO Logo and list of contents 250 x 250 x 160mm(approx.),with

			expiry date of product with least expiry clearly mentioned.
11	Fabric Bandages	10	Individually wrapped Fabric Adhesive Bandage 72 x 20mm(approx.),
	Flexible Packaging	1	Zip locked Bag 100 x 80mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
12	Drying Rack	1	Drying Rack, disposable, to accomodate10 DBS cards and to stand vertically with compliance to sample provided in pre-bid meeting. It should be white, complete with folding instructions
	Flexible Packaging	1	Zip locked Bag 200 x 250mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
13	Biohazard Bag	1	Polypropylene Autoclavable Biohazard Bag 400 x 650mm (approx.),with orange biohazard symbol
	Flexible Packaging	1	Zip locked Bag 150 x 250mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
14	DBS Instructions	1	Colour Printed Step by Step Guide 1-14 DBS Instructions with pictures, to be shown in pre-bid meeting.
15	Biohazard Stickers	5	Biohazard sticker 2.5 x 2.5cm. (approx.),Red with black biohazard symbol
	Flexible Packaging	1	Zip locked Bag 100 x 80mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
16	Envelopes (plain)	5	A5 Brown Envelope, self sealing, in gm/sq mt. To be specified in pre-bid meeting.
	Flexible Packaging	1	Zip locked Bag 200 x 250mm (approx.),Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.
17	Envelopes (lined)	5	White bubble lined envelope 300 x 220mm, (approx.), self sealing, specify gm/sq mt.

	Flexible Packaging	1	Zip locked Bag 250 x 350mm (approx.), Printed Flexible packaging with contents description, quantity, Packer and distributor's name and contact details.

Whole Blood (WB) Collection Kits (for 10 samples):

S.No.	Components of Whole Blood Collection Kit	Quantity/Kit
1	Butterfly winged infusion set (23G)	10
2	Vaccum collection tube holder	1
3	Luer adapter	10
4	EDTA evacuated vacuum tubes 3 ml	10
5	EDTA evacuated vacuum tubes 0.5 ml.	20
6	Syringe 2ml with needle 22-23 gauge	10
7	Safety lancet/Auto-retractable lancet (2 mm depth blade type)	20
8	Powderless gloves(gloves)	15 Pairs
10	Sterile alcohol swipes	20
11	Sterile gauze pads	20
12	Biohazard Bag (autoclavable)	1
13	Biohazard Stickers	15

* **All these contents will be in a white card board box**

Laboratory Consumable Bundle for HIV-1 DNA PCR testing (one bundle for 10 kits of 96 tests each):

S.No.	Laboratory Consumables		Product Description
1	Aerosol Resistant Pipette Tips (200-1000ul)	3200	Universal Filter Tip Clear, Pre-Sterilized and Racked 1000ul
2	Aerosol Resistant Pipette Tips (50-200ul)	8160	Universal Filter Tip Clear, Pre-Sterilized and Racked 200ul
3	PCR Reaction Tubes	1200	0.2ml Thin Wall PCR Tube with flat cap. Ultra-thin and consistent wall thickness for precise thermal transfer. Manufactured from 99.9% virgin polypropylene
4	2.0 mL skirted base cryovials with knurls	2200	2ml Screw Cap Microtube, conical, skirted polypropylene, sterile with printed writing space and graduation. Autoclavable

			121°C. Maximum centrifugation speed 20000xg
5	Sterile polypropylene tube	75	Sterile Polypropylene Graduated 50ml Centrifuge tubes with screw cap.
6	Powderless Latex Gloves	800	Latex Examination Gloves, Powder Free, Single Use Only. Packed in waterproof plastic insulated box with manufacture and expiry dates and lot numbers
7	Disposable zip-locked bags	50	Opaque Low Gas Permeable double Ziploc Bag 150 x 180mm (approx.)
8	Reagent Reservoir	200	White Trough Type Reagent Reservoir Polystyrene for multi channel pipette reagent handling. Dimensions : 14.5 x 6.6 x 2.5mm(approx.)
9	Biohazard Bags (Small)	200	Polypropylene Autoclavable Biohazard Bag 400 x 650mm with orange biohazard symbol
10	Disposable lab coats	30	Sterile Disposable long-sleeve Laboratory Gown with polypropylene fabric and Towel which makes the coat water/bodyfluid or blood repellent. Elasticated wrists and tie-backs at rear
11	Punching Card	100	Blotting Paper BF4 150 x 200mm. Basis weight 550 g/m2 and thickness 1.3mm
12	Fine Tipped Waterproof Permanent Lab Marking Pens, Black	5	Water Resistant, quick drying super fine black Special Laboratory Marker
13	Pipette tips non filter (200-1000 ul)	1000	-
14	Pipette tips non filter (50-200 ul)	1000	-

The mode of packaging must be in line with demonstration pack of DBS collection kit as shown in pre-bid meeting.

Agenda Item No. 2: **Review of Technical Specifications of HIV (ELISA) Kits**

The committee approved the technical specifications of HIV (ELISA) Kits as follows:

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 60% or more of the shelf life at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls with each kit.
9. The assay should have sensitivity of ≥ 99.8% and specificity of ≥ 98%.
10. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C
11. The pack size should be 96 tests/kit.

Agenda Item No. 3: **Review of Technical Specifications of HIV (Rapid) Kits**

The committee approved the technical specifications of HIV (Rapid) Kits as follows:

By principle of Enzyme Immune Assay

1. Should be solid phase 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 60% or more of the shelf life at the port of discharge of consignees.
8. The time required for performing the test should not be more than 30 minutes.
9. The control dot/band should be able to detect the presence of human immunoglobulins and should not be just a "procedural control" or meant for merely checking the flow of reagents or integrity of the antigen.
10. The assay should have sensitivity of ≥ 99.5% and specificity of ≥ 98%.
11. The manufacturers should ensure that:
    1. The test kit should be packed such that there is a provision to conduct single test at a time;
    2. The assay components should include HIV positive and negative serum controls sufficient for conducting 20 % of the tests (10% negative and 10 % positive controls); and
    3. The pack size of HIV rapid test kits should not be more than 50 tests per kit.
12. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C

By principle of Agglutination

1. Should be solid particle coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies by agglutination.
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 Centers approved by the DCGI.
7. The kit should have minimum 60% or more of the shelf life at the port of discharge of consignees.
8. The time required for performing the test should not be more than 30 minutes.
9. The test kit should be packed such that there is a provision to conduct single test at a time;
10. The assay components should include HIV positive and negative serum controls sufficient for conducting 20 % of the tests (10% negative and 10 % positive controls); and
11. The pack size of HIV rapid test kits should not be more than 50 tests per kit.
12. The assay should have sensitivity of ≥ 99.5% and specificity of ≥ 98%.
13. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C

By any other principle excluding Agglutination and EIA

1. Should be solid phase /particle coated with 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 60% or more of the shelf life at the port of discharge of consignees.
8. The time required for performing the test should not be more than 30 minutes.
9. The control dot/band should be able to detect the presence of human immunoglobulins and should not be just a "procedural control" or meant for merely checking the flow of reagents or integrity of the antigen except in kits using "lateral flow through" technology.
10. The manufacturers should ensure that:
    1. The test kit should be packed such that there is a provision to conduct single test at a time;
    2. The assay components should include HIV positive and negative serum controls sufficient for conducting 20 % of the tests (10% negative and 10 % positive controls); and
    3. The pack size of HIV rapid test kits should not be more than 50 tests per kit.
11. The assay should have sensitivity of ≥ 99.5% and specificity of ≥ 98%.
12. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C

Agenda Item No. 4: **Review of Technical Specifications of HCV (ELISA) Kits**

The committee approved the technical specifications of HCV (ELISA) Kits as follows:

1. Microplate 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 60% or more of the shelf life at the port of discharge of consignees.
7. The assay component should include reactive and non-reactive controls.
8. The assay should have sensitivity of ≥ 99.8% and specificity of ≥ 98%.
9. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C
10. The pack size should be 96 tests/kit.

Agenda Item No. 5: **Review of Technical Specifications of HCV (Rapid) Kits**

The committee approved the technical specifications of HCV (Rapid) Kits as follows:

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 60% 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 reactive and non-reactive controls sufficient for conducting individual testing.
9. The assay should have sensitivity of ≥ 99.0% and specificity of ≥ 98%.
10. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C
11. The pack size should not be more than 50 test wherein each test is individually packed .

Agenda Item No. 6: **Review of Technical Specifications of Hepatitis B Surface Antigen ELISA Kits**

The committee approved the technical specifications of Hepatitis B Surface Antigen ELISA Kits as follows:

1. Microplate ELISA coated with monoclonal antibodies to HBsAg

2. The assay should be able to detect surface antigen to Hepatitis B virus .
3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing &expiry dates should be provided with each Kit.
4. The Kit should have approval of the statutory authority from 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 60% or more of the shelf life at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls.
9. The assay should have sensitivity of ≥ 99.8 % and specificity of ≥ 98%.
10. The assay should have analytical sensitivity of detecting ≤0.2 ng/ml.
11. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C
12. The pack size should be 96 tests/kit.

Agenda Item No. 7: **Review of Technical Specifications of Hepatitis B Surface Antigen Rapid Kits**

The committee approved the technical specifications of Hepatitis B Surface Antigen Rapid Kits as follows:

1. Should be solid phase/ particle coated with monoclonal antibodies to HBsAg
2. The assay should be able to detect surface antigen to Hepatitis B virus .
3. Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance

characteristics, storage conditions, limitation of assays, manufacturing &expiry dates should be provided with each Kit.

4. The Kit should have approval of the statutory authority 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 60% or more of the shelf life at the port of discharge of consignees.
8. The time required for performing the test should not be more than 30 minutes.
9. The assay component should include reactive and non-reactive controls sufficient for conducting individual testing.
10. The assay should have sensitivity of ≥ 99.0% and specificity of ≥ 98%.
11. The assay should have analytical sensitivity of detecting ≤0.5 ng/ml.
12. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8^0 C
13. The pack size should not be more than 50 tests wherein each test is individually packed.

S.No.	Name & Designation	Signature
1	Dr. Manjula Singh, Scientist C, ICMR H.Q, New Delhi	
2	Director, National AIDS Research Institute, Pune	Comments received from NARI
3	Dr.K.Bangarurajan DDC, Representative from Drug Controller General of India, MOH & FW	
4	Dr.G.R.Soni, Scientist Gr I, National Institute of Biologicals, Noida	
5	Dr. Sandhya Kabra, ADG (BS & LS), NACO	

6	Dr. Lalit Dar, Professor, Department of Microbiology, AIIMS, New Delhi	
7	Dr. Anita S.Desai, Addl. Prof, Dept. of Neurovirology, NIMHANS, Bangalore	24/8/12
8	Dr. Rajiv Thakur, Professor, Department of Microbiology, IHBAS, New Delhi	24/8/12
9	Dr. Namita Singh, Consultant, CHAI, New Delhi	24/8/12

Dr. Mohd. Shaukat 24/8/12
ADG (CST), NACO
as Member Secretary

24/8/12
(Dr. B. D. Athani)
Addl. DGHS &
Medical Superintendant,
Safdarjung Hospital, New Delhi
as Chairman