

Technical Specifications of Testing Kits

Minutes of the Meeting of the Technical Committee to Review Specifications of Testing Kits for use in Blood Banks

15th February 2017

A Meeting of the Technical Committee to Review Specifications of Blood Bags for use in Blood Banks was held on 15th Feb 2017 at 11:00 AM in Room No. 439 (A Wing), Nirman Bhawan, MoHFW, New Delhi under the chairmanship of Dr. B.D. Athani, Special DGHS.

The following members attended the meeting:

1. Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi
2. Dr. Ravi Kant Sharma, Asst. Drugs Controller, CDSCO, New Delhi
3. Dr. Manjula Singh, Scientist D, ICMR HQ, New Delhi
4. Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida
5. Dr. Manjubala, Consultant & Professor, Safdarjung Hospital
6. Dr. Bharat Singh, Director SBTC, New Delhi
7. Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi
8. Dr. Abhijit Kadam, Scientist B, NARI
9. Dr. Meenu Bajpai, Addl. Professor, Transfusion Medicine, ILBS
10. Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO
11. Dr. Shanoo Mishra, PO (QC), NBTC/NACO

Point wise Meeting Agenda:-

1. Review of Technical Specifications of HIV (ELISA) Testing Kits.
2. Review of Technical Specifications of HIV (Rapid) Testing Kits.
3. Review of Technical Specifications of HCV (ELISA) Testing Kits.
4. Review of Technical Specifications of HCV (Rapid) Testing Kits.
5. Review of Technical Specifications of Hepatitis B Surface Antigen (ELISA) Testing Kits.
6. Review of Technical Specifications of Hepatitis B Surface Antigen (Rapid) Testing Kits.
7. Review of Technical Specifications of RPR (Rapid Plasma Reagin) Testing Kits.
8. View of Technical Committee on up gradation of III Generation ELISA and Rapid Test Kits to IV Generation.
9. View of Technical Committee on use of Rapid Test Kit for Malaria.

The bottom of the page contains several handwritten signatures in blue ink. From left to right, they include: a signature that appears to be 'Kiran', a signature that reads 'Vanshree', a signature that reads 'Ravi Kant', a signature that reads 'Manjula', a signature that reads 'Reba', a signature that reads 'Manjubala', a signature that reads 'Bharat', a signature that reads 'Abhijit', a signature that reads 'Meenu', a signature that reads 'Shobini', and a signature that reads 'Shanoo'. There is also a small signature that reads 'M.C.L.' and another that reads '112'.

Technical Specifications of Testing Kits

Agenda Item No 1: Review of Technical Specifications of HIV (ELISA) Testing Kits

The following technical specifications were approved by the Committee:

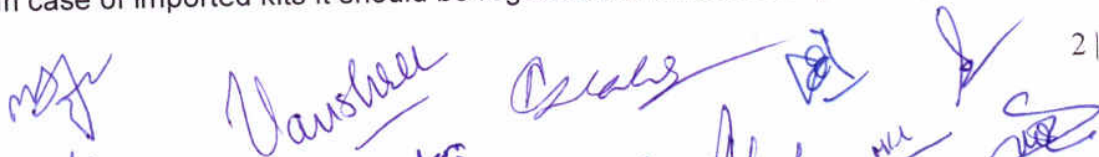
1. Should be solid phase micro plate coated HIV I & II recombinant and/or synthetic peptide antigens.
2. The assay should detect HIV I and II antibodies.
3. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority in its country of origin
5. In case of imported kits it should be registered and licensed in India by DCG (I).
6. 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).
7. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) 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 level of more than or equal to 99.5% and specificity level of more than or equal to 98%.
10. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage and transport the kits at 2°C – 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.
11. The pack size should be 96 tests/ kit

Agenda Item No 2: Review of Technical Specifications of HIV (Rapid) Testing Kits

The following technical specifications were approved by the Committee:

(By Principle of Enzyme Immuno Assay, Agglutination, or any other principle):-

1. Should be a Solid phase coated HIV I & HIV II recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV I and II antibodies in plasma, serum or whole blood.
3. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, 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 DCG (I).



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6. In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act, 1940, also be evaluated by the centers approved by DCG (I).
7. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) 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 more than or equal to 99.5% and specificity of more than or equal to 98%.
11. The manufacturers should ensure that:
 - a. The test kit should be packed such that there is a provision to conduct single test at a time;
 - b. The assay components should include HIV positive and negative serum control sufficient for conducting 20% of the tests (10% negative and 10% positive controls); and
 - c. 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°C – 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Agenda Item No 3: Review of Technical Specifications of HCV (ELISA) Testing Kits

The following technical specifications were approved by the Committee:

1. Microplate ELISA coated with recombinant/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 to be procured should have approval of the statutory authority in its country of origin
4. In case of imported kits it should have been registered and licensed in India by DCG (I).
5. 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).
6. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) at the port of discharge of consignees
7. The assay component should include reactive and non-reactive controls

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8. The assay should have a sensitivity more than or equal to 99 % and specificity of more than or equal to 98%.
9. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2°C – 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.
10. The kit size should be 96 tests/ kit.

Agenda Item No 4: Review of Technical Specifications of HCV (Rapid) Testing Kits:

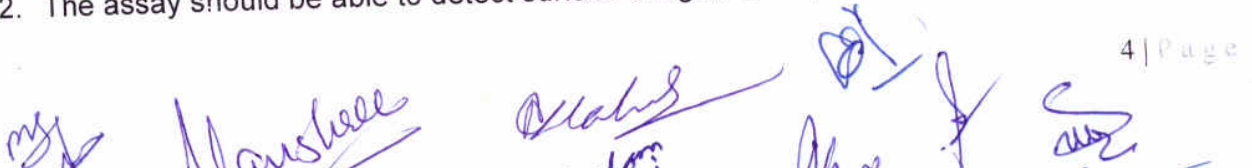
The following technical specifications were approved by the Committee:

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 to be procured should have approval of the statutory authority in its country of origin
4. In case of imported kits it should have been registered and licensed in India by DCG (I).
5. 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. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) at the port of discharge of consignees
7. The total procedure time shall not be more than 30 minutes.
8. The assay component should include Positive and Negative control in each pack of 50 tests.
9. The assay should have sensitivity of more than or equal to 99% and specificity of more than or equal to 98%.
10. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2°C – 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO
11. The pack size should not be more than 50 tests wherein each test is individually packed.

Agenda Item No 5: Review of Technical Specifications of Hepatitis B Surface Antigen (ELISA) Testing Kits:

The following technical specifications were approved by the Committee:

1. Microplate ELISA coated with monoclonal antibodies to HBsAg.
2. The assay should be able to detect surface antigen to Hepatitis B virus.

 Several handwritten signatures in blue ink are present at the bottom of the page, including names like 'Moushree', 'Alab', and others.

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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 to be procured should have approval of the statutory authority in its country of origin.
5. In case of imported kits it should have been registered and licensed in India by DCG (I).
6. 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).
7. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) at the port of discharge of consignees
8. The assay component should include reactive and non-reactive controls.
9. The assay should have sensitivity of more than or equal to 99% and specificity of more than or equal to 98%.
10. The assay should have analytical sensitivity of detecting less than or equal to 0.5 ng/ml.
11. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2°C – 8°C. The cumulative time temperature indicator technology used should be pre-qualified by WHO
12. The kit size should be 96 tests/ kit.

Agenda Item No 6: Review of Technical Specifications of Hepatitis B Surface Antigen (Rapid) Testing Kits:

The following technical specifications were approved by the Committee:

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 to be procured should have approval of the statutory authority in its country of origin
5. In case of imported kits it should be registered and licensed in India by DCG (I).
6. 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).
7. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) at the port of discharge of consignees
8. The total procedure time shall not be more than 30 minutes



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9. The assay component should include Positive and Negative control in each pack of 50 tests.
10. The assay should have sensitivity of more than or equal to 99% and specificity of more than or equal to 98%.
11. The assay should have analytical sensitivity of detecting less than or equal to 0.5 ng/ml
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2^oC – 8^oC. The cumulative time temperature indicator technology used should be pre-qualified by WHO
13. The pack size should not be more than 50 tests wherein each test is individually packed.

Agenda Item No 7: Review of Technical Specifications of RPR (Rapid Plasma Reagin) Testing Kits:

The following technical specifications were approved by the Committee:

1. The indigenous RPR (Rapid Plasma Reagin) kits should have been manufactured under manufacturing license issued by the State Licensing Authority under the Drugs and Cosmetics Act. The imported kits should have been imported under Import License issued by the DCG (I) under Drugs and Cosmetics Act.
2. The assay should allow for qualitative and semi quantitative determination of Reagin antibodies in serum or plasma for sero-diagnosis of syphilis based on flocculation principle using non treponemal antigens.
3. The assay should be suitable to perform with either serum or plasma
4. The assay should have sensitivity of 85% or more in primary syphilis and a specificity of 93% or more.
5. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from manufacturer.
6. The test should be able to yield results within 20 minutes.
7. The pack size of RPR test kit should be less than or equal to 50 tests per kit.
8. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
9. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.
10. The kit should have minimum shelf-life of 60% or 12 months (whichever is more) at the port of discharge of consignees.

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11. The cumulative time temperature indicator technology used should be pre-qualified by WHO
12. Literature, detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each kit.

Agenda Item No 8: View of Technical Committee on up gradation of III Generation ELISA and Rapid Test Kits to IV Generation:


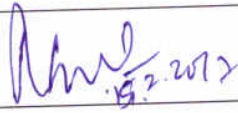


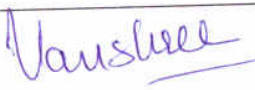


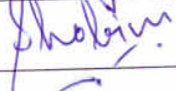
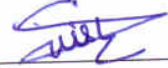
1. The Committee recommended the Up gradation of III Generation ELISA and Rapid Test Kits to IV Generation in light of BTS TRG recommendations dated 12th January 2015.
2. The Committee recommended working out specifications for the same and procurement of IV Gen kits at National Level from the next procurement cycle to maintain good quality and uniform testing standards across the Country.

Agenda item No. 9: View of Technical Committee on use of Rapid Test Kit for Malaria:

The Committee did not recommend for the use of Rapid Test Kits for Testing Malaria at blood banks due to high cost implications and low numbers of positive cases reported.

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S No	Name and Designation	Signature
1	Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi	
2	Dr. Ravi Kant Sharma, Asst. Drugs Controller, CDSCO, New Delhi	
3	Dr. Manjula Singh, Scientist D, ICMR HQ, New Delhi	MS-6 15/2/17
4	Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida	
5	Dr. Manjubala, Consultant & Professor, Safdarjung Hospital	
6	Dr. Bharat Singh, Director SBTC, New Delhi	
7	Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	
8	Dr. Abhijit Kadam, Scientist B, NARI	
9	Dr. Meenu Bajpai, Addl. Professor, Transfusion Medicine, ILBS	
10	Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	
11	Dr. Shanoo Mishra, PO (QC), NBTC/NACO	

Chairperson	Signature
Dr. B.D Athani, Special Director General of Health Services	