Technical Specifications of Testing Kits 2018

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

27th September 2018

Three Meetings of the Technical Committee to Review Specifications of ELISA and Rapid testing kits for use in Blood Banks were held on 13th August 2018, 30th August 2018 & 27th September 2018. Venue of meeting was Room No. 439 (A Wing), Nirman Bhawan, MoHFW, New Delhi under the chairmanship of Dr. A.K Gadpayle, Addl. DGHS.

The following members attended the meetings as detailed below:

Members	13th August 2018	30th August 2018	27th September 2018
Mr. Sella Senthil M, Asst. Drugs Controller, CDSCO, New Delhi	No	Yes	Yes
Mr. Yogesh Shelar, Asst. Drugs Controller, CDSCO, New Delhi	No	No	Yes
Dr. Madhuri Thakar, Scientist F & HOD, NARI, Pune	Yes	No	No
Dr. Manjula Singh, Scientist E, ICMR HQ, New Delhi	No	No	Yes
Dr Reba Chhabra, Scientist I, DD QC I/C (Diagnostics), NIB, NOIDA	Yes	Yes	No
Mr. N Nanda Gopal Scientist Grade III, NIB Noida	No	No	Yes
Dr. Sumati Muralidhar, Professor & Consultant, Apex STD Lab, VMCC, New Delhi	Yes	Yes	No
Dr Sandhya Kabra, Addl. Director, NCDC & I/C National Hepatitis Programme	Yes	Yes no change	No
Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New	Yes	Yes	No
Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	Yes	Yes	Yes
Dr. Ekta Gupta, Associate Professor, ILBS, Delhi	No	Yes	Yes
Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	Yes	Yes	Yes
Dr. Bhawna Rao, Deputy Director, NACO	No	No	Yes
Dr. YaavarShafi, MO, NBTC/NACO	No	No	Yes
Mr. Jolly J Lazarus, PO(VBD), NBTC	Yes	Yes	Yes

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Discussions were held in all three meetings amongst all members and the representatives from the manufacturers invited for the second meeting. All members were represented in at least one out of three meetings. Specifications were finalized in the third meeting based on discussions held in all three meetings and minuted as detailed below:

Point wise Meeting Agenda:-

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

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 and antibody to HIV 1 p24.
2. The assay should detect HIV I and II antibodies and HIV I p24 antigen.
3. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2 and p24 Antigen, 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 under the provisions of Drugs & Cosmetics Act and rules and / or Medical Devices Rules 2017 in India.
6. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and rules and or Medical Devices Rules 2017 issued by the competent authority defined under Drugs and Cosmetics Act, 1940.
7. The kit should have minimum remaining shelf-life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive (for both antibody as well as antigen) and non-reactive controls with each kit.
9. The assay should have sensitivity level of100% 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^{0}C – 8^{0}C. The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every pack of kits.
11. The pack size should be 96 tests/ kit.

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

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 and antibody to HIV 1 p24.
2. The assay should detect HIV I and II antibodies and HIV 1 p24 antigen in plasma, serum or whole blood.
3. Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2 and p24 Antigen, 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 under the provisions of Drugs & Cosmetics Act andRules and/or Medical Devices Rules 2017 in India.
6. In case of indigenous manufacturers should be licensed under the provisions of Drugs & Cosmetics Act and Rules and/or Medical Devices Rules 2017& also be evaluated by the centers approved by DCG (I).
7. The kit should have minimum shelf-life of 5/6thor 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 100% 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(both antigen and antibody 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^{0}C – 8^{0}C. The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every pack of kits.

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

The following technical specifications were mentioned:

1. Microplate ELISA coated with recombinant/synthetic peptide antigens for core, NS3, NS4, and NS5 and antibody to HCV core Antigen.
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 5/6th or 12 months (whichever is more) at the port of discharge of consignees
7. The assay component should include reactive (for both antibody and antigen) and non-reactive controls
8. The assay should have a sensitivity more than or equal to 100% 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 2^0C – 8^0C. The cumulative time temperature indicator technology used should be pre-qualified by WHO and placed on every pack of kits.
10. The pack size should be 96 tests/ kit.

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

The committee did not recommend specifications for IV generation HCV (Rapid) testing kits as they did not find clear cut 4th generation specifications indicating both antigen and antibody detection in available kit inserts.

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

The committee did not recommend specifications for IV generation Hepatitis B Surface Antigen (ELISA) Testing Kits they did not find clear cut 4th generation specifications indicating both antigen and antibody detection in available kit inserts.

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

The committee did not recommend specifications for IV generation Hepatitis B Surface Antigen (Rapid) Testing Kits they did not find clear cut 4th generation specifications indicating both antigen and antibody detection in available kit inserts.

Agenda Item No 7: Technical Specifications of cumulative time temperature indicator

1. Cumulative time/temperature indicator should indicate the exposure to high temperature above 8 degree C
2. The cumulative time-temperature indicator technology used should be prequalified by WHO
3. The indicator should change color uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters.
4. The color change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.
5. Should be mounted on card with clear instruction of interpretation
6. The card should be self adhesive and placed on each kit box to monitor heat exposure during transit and storage of the kits till its expiry
7. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8° C.

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S No	Name and Designation of Members	Signature
1	Mr. Sella Senthil M, Asst. Drugs Controller, CDSCO, New Delhi	
2	Mr. Yogesh Shelar, Asst. Drugs Controller, CDSCO, New Delhi	
3	Dr. Madhuri Thakar, Scientist F & HOD, NARI, Pune	
4	Dr. Manjula Singh, Scientist E, ICMR HQ, New Delhi	
5	Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida	
6	Mr. N Nanda Gopal Scientist Grade III, NIB Noida	
7	Dr. Sumathi Murlidhar, Consultant, Microbiologist, Apex Center, Safdarjung Hospital New Delhi	
8	Dr. Sandhya Kabra, Addl. Director, NCDC, New Delhi	for 13/8/18 only
9	Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi	
10	Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	
11	Dr. Ekta Gupta, Associate Professor, ILBS, Delhi	
12	Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	
13	Dr. Bhawna Rao, Deputy Director, NACO	
14	Dr. Yaavar Shafi, MO, NBTC/NACO	
15	Mr. Jolly J Lazarus, PO(VBD), NBTC / NACO	
	Chairperson	**Signature**
	Dr. A.K Gadpayle, **Addl. Director General of Health Services**	