9. Compatible (5 to 10 KVA) UPS for nucleic acid extraction and testing equipment with back-up to complete one cycle atleast..
10. Electrical Requirement:
    a) Output voltage:220 volts +/- 10% volts.Input voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
    b) Electrical safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
11. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and provide alternative to ensure uninterrupted testing services. Punitive actions shall be taken in case of failure to maintain the desirable downtime.
12. Satisfactory report from atleast three government sites which have the equipment installed in last three years.

The committee approved the technical specifications of the quantitative viral load testing platform for HBV and HCV and agreed for procurement of the same under reagent rental model wherein the kits procured for HBV DNA and HCV RNA would be compatible with the platform.

22. WATER PURIFICATION SYSTEM

23. THERMAL CYCLER

Due to paucity of time, the committee felt the technical specifications of Equipment at S.No.22&23 will be deliberated in the next meeting

Agenda 2: ***The committee deliberated on the kit specifications for use in the program and finalised the technical specifications of kits for use in the NVHCP and other related programs.The committee approved the specifications for the following kits:***

Hepatitis A Virus

Anti-HAV IgM (ELISA)

1. Assay should be based on the principle of "IgM capture/Indirect ELISA"
2. The assay should detect IgM anti HAV antibodies.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) and Medical Devices Rule 2017
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
9. All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
10. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.

Agenda 2 The committee deliberated on the kit specification to be used under the program and finalized the following specifications for test kits

Technical specifications for test kits

1) Anti-HAV IgM (Rapid Test)

1. The assay should detect IgM anti HAV antibodies
2. Should be compatible with plasma and serum both.
3. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and 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 manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
7. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
8. The total procedure time shall not be more than 30 minutes.
9. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).
10. The assay should have sensitivity ≥97% and specificity of ≥ 98% as claimed by the manufacturer in the kit literature as per kit inserts from manufacturers subject to modification by the program
11. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specification of Anti HAV IgM (rapid test)

2) HBsAg (Rapid Test)

1. Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg
2. The assay should be able to detect surface antigen to Hepatitis B virus.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
8. The kit should have minimum shelf life of 60% or 12 months(whichever is more) at the port/place of discharge of consignees.
9. The total procedure time shall not be more than 30 minutes.
10. The assay components should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit.
11. The assay should have sensitivity of 100%and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC(65) dated 13/6/2017
12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except lateral flow technology

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specification of HBsAg (rapid test)

13. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Hepatitis B Surface Antigen (Rapid Test)

Hepatitis B core (HBc) IgM Antibody(ELISA)

1. Assay should be based on the principle of "IgM capture/Indirect ELISA"
2. The assay should detect IgM antibodies to Hepatitis B core antigen
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940)* and also be evaluated by the centers approved by the DCG(I)* and Medical Device Rule 2017 24/8/18
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
9. All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
10. The assay should have sensitivity more than or equal to 98% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with ELISA reader and washer.
3. 4 kits should be supplied along with the procurement lot of which two kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and two kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Hepatitis B core (HBc) IgM Antibody (ELISA)

24/8/18 24/8/18 27/8/18 24/8/18

Hepatitis B Virus

Hepatitis B Surface Antigen(ELISA)

1. Microplate ELISA coated with monoclonal antibodies covering all subtypes and variants of HBsAg
2. The assay should be able to detect surface antigen to Hepatitis B virus.
3. Should be compatible with plasma and serum both.

4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) & Medical Devices Rule 2017
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
9. All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
10. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature
11. The assay should have analytical sensitivity of detecting ≤0.2IU/ml

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with ELISA reader and washer.
3. 4 kits should be supplied along with the procurement lot of which two kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and two kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Hepatitis B Surface Antigen (ELISA)

Hepatitis C Virus

Anti-HCV Antibody Kits (ELISA)

1. Microplate ELISA coated with recombinant/synthetic peptide antigens for core, NS3, NS4 and NS5.
2. The assay should detect total anti HCV antibodies.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I).
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) and Medical Device Rule 2017 24/8/18
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
9. All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
10. The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The kit size should be 96 tests/kit(in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with ELISA reader and washer.
3. 4 kits should be supplied along with the procurement lot of which two kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and two kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Anti-HCV Antibody Kits (ELISA)

4) Anti-HCV Antibody (Rapid Test)

1. Should utilize recombinant and /or synthetic peptide antigens for core, NS3, NS4 and NS5.
2. The assay should detect total anti HCV antibodies
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
9. The total procedure time shall not be more than 30 minutes.
10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)which may be provided along with the kits if not a part of the kit.
11. The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No 29/Misc./4/2016-DC(65) dated 12/7/2017
12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

<u>The committee approved the specification of Anti HCV antibody (rapid test)</u>

11. The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature
12. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Anti-HCV Antibody Kits (Rapid test)

Hepatitis E Virus

Anti HEV IgM Antibody (ELISA)

1. Assay should be based on the principle of "IgM capture/ indirect ELISA"
2. The assay should detect IgM anti HEV antibodies.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) and Medical Device Rule 2017 24/8/18
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
9. All the assay components provided in the kit including positive and negative controls should be sufficient for at least 4 runs for the 96 tests provided.
10. The assay should have sensitivity more than or equal to 99% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^{0}C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with ELISA reader and washer.
3. 4 kits should be supplied along with the procurement lot of which two kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and two kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

The committee approved the specifications for Anti HEV IgM Antibody (ELISA)

24/8/18 24/8/18 24/8/18

5) Anti-HEV IgM(Rapid Test)

1. The assay should detect IgM anti HEV antibodies
2. Should be compatible with plasma and serum both.
3. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and 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 manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017
7. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
8. The total procedure time shall not be more than 30 minutes.
9. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)which may be provided along with the kits if not a part of the kit.
10. The assay should have sensitivity more than or equal to 97% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literatureas per kit inserts from manufacturers subject to modification by the program
11. The control dot/band should be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be supplied to program and four kits will be retained for evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters
4. The kit will be evaluated on the above parameters by the centers approved by the program

<u>The committee approved the specification of Anti HEV IgM (rapid test)</u>