OFFICE OF THE MISSION DIRECTOR
NATIONAL HEALTH MISSION, ASSAM
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No. NHM/18018/2/2021-PROC-NHM/ECF-170018/30-P **DATE: 10-08-21**

CORRIGENDUM NO.1

This is with reference to TENDER NO: NO: NHM/18018/2/2021-PROC-NHM/ECF-170018/13868, Date: 27.7.2021.

The following amendments in the tender may be taken note of prior to submission of bids.

1. **Amended Provisions:ANNEXURE– XIII-A may be read as ANNEXURE– XIII-A (Rev)**

ANNEXURE– XIII-A (Rev)

(Item wise specification in details)

1. **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 (1).

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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.

2. Hepatitis B Virus

Hepatitis B Surface Antigen(ELISA)

1. Microplate ELISA coated with monoclonal antibodies covering all subtypes and variants ofHBsAg

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 eách 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. 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 equal to 99% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature11. The assay should have analytical sensitivity of detecting ≤ 0.2IU/ml.

General Specifications

1. The manufacturer /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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 theprogram

3. HBV & HCV-RTPCR Kit

1. Closed HCV and HBV nucleic acid extraction and Viral Load Platform using human whole blood derived serum/plasma.

Or

HCV and HBV nucleic acid extraction and detection(quantitative) kits using human whole blood derived serum/plasma compatible with real time pcr systems.

2. Technology platform should be based on real time PCR chemistry like TaqMan,molecular beacon probes,SYBR Green and all other fluorescent dye based chemistries and should be calibrated for multiple dyes.

3. The Assay should be CE-IVD marked. The quoted test shall be licensed to bidder in India by DCGI(I).

4. The limit of detection must be-

HCV RNA : 15 IU/ml or lower for 0.5 mi input.

HBV DNA:20 IU/ml or lower for 0.5 mi input.

5. Dynamic range of the quoted assay shall be

HCV : 15- 1x108 RJ/mL or better

HBV: 20- 1.7 x 108 RJ/ml or better

6. Specificity of the assay shall be 100%.

7. Genotype Coverage : Assay shall cover HCV genotypes 1 to 6 & HBV genotypes A to H plus Pre-Core Mutants.

8.The Assay shall have inclusion of reagents/enzymes(either built in or external addition) to remove the carry over contamination by degrading of Nucleic Acid templates amplified in previous runs.

9. Capable of completing a cycle of extraction and testing within 8 hrs.

10. Automated sample extraction and the testing should have a througput of minimum12 sample and above.

11. The platform shall have barcode system for specimen tube identification.

12. Also HCV and HBV nucleic acid extraction and detection(quantitive) kits using human whole blood derived serum/plasma compatible with real time PCR systems. The assay should be CE-IVD MARKED and licensed by DCGI,

General Specification

1. The bidder will provide installation qualifications, operational qualification and performance qualification at the time of installation with all certificates and log book for maintenance of the equipment at no extra cost.

2. The agency shall provide an EQAS on a 6 monthly basis provided by any ISQ 17043 approved provider which should be part of the package with two sets of proficiency testing panels for HBV DNA and HCV RNA.

3. Yearly preventives manitainence and calibration shall be the responsibility of the bidder as per requirement quoted system/essay. Timely upgradation of the facility with respect to hardware/software/reagent/workflow shall be provided free of cost.

4. The manufacturer should provide 95% uptime of the HCV & HBV viral load testing facility.

5. The bidder shall provide free of cost replacement of the viral load platform in case new model or upgraded version is released by the manufacturer.

6. The bidder shall submit the details of engineer and application support team.

7. The bidder shall be responsible for training of laboratory staff on operation of equipment at the time of installation and subsequently every year for optimal utilization of the equipment at the time of installation and subsequently every year for optimal utilization of the equipment. The cost of refresher

trainings will be borne by the government but the technical aspects will have to be dealt with by the vendor.

8.The bidder shall set up the operational facility as per the requirement of proposed system and assay such as refrigeration(4/-20/-80 degree Celsius)centrifuge, air conditioner, biosafety cabinets, HEPA filters, Pipettes or any other equipment /consumables required for running of quoted assay. The same shall be calibrated by the bidder as per requirements of NABL.

9.Compatible(5 to 10KVA)UPS for nucleic acid extraction and testing equipment with back up to compete one cycle at least.

10.Electrical Requirement:

a.Output voltage:220 volts+/-10% volts 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 desirable downtime.

12. Satisfactory report from at least three government sites which have the equipment installed in last three years.

The committee approved that 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.

4. 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 centersapproved by the DCG and Medical Device Rule 2017.

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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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

5. The kit will be evaluated on the above parameters by the centers approved by the program

5. Anti-HAV IgM (Rapid Test)

1.Assay should be based on the principle of "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 witheach 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 of discharge of consignees.

8. The total procedure time shall not be more than 30mins.

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 more than or equal to 97% and specificity of more than or equal to 98% as claimed by the manufacturer in the kit literature.

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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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 forvalidation, 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

6. HBsAg (Rapid Test)

1.Should be coated with monoclonal antibodies covering all subtypes and variants of HBsAg.

2. The assay should detect 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 competentauthority/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 theport/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 beprovided 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 immunoglobulinand 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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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 forvalidation, 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.

7. 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.

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 shouldbe 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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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.

8. Anti-HCV Antibody (Rapid Test)

1. Should utilize recombinant and/or synthetic peptide antigens for core, NS3, NS4 and NSS.

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 competentauthority/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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8° 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

9. 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(1) .

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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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

10. 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(1)

7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act (1940) and Medical Device Kule 2017

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 /importer should ensure maintenance of cold chain during storage and transport of kits at 2-8°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 start date & last date of Bid submission will be extended in view of this Corrigendum.
New dates are as bellow:

1. Bid submission **start date** will be extended from **10/8/2021** (from 2.00 pm) to 1**6/08/2021** (from 2.00 pm).
2. Bid submission last date will be extended from **16/08/2021** (up to 2.00 pm) to **21/08/2021** (up to 2.00 pm).
3. The Bid opening date will be **21/08/2021** at 4.00am at NHM-SHQ, Saikia Commercial Complex, Christanbasti, Guwahati-5, Assam.

All other terms and conditions of the above referred TENDER NO: NHM/18017/33/2020-PROC/ECF 142502/11192, Dated.08/07/2021will remain same.

Sd/-
Mission Director, NHM, Assam