Bihar Medical Services & Infrastructure Corporation Limited
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CORRIGENDUM-I

Tender for rate contract and supply of Medical Devices/Consumables for different healthcare facilities of state of Bihar

Notice Inviting Tender Ref No.: -BMSIC/MEDICAL DEVICES/CONSUMABLES/24-05
Dated: - 15-07-2024

(Only through E- Tender on website: -www.eproc2.bihar.gov.in)

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) invites E-Bids from the interested parties for "**Tender for rate contract and supply of Medical Devices/Consumables for different healthcare facilities of state of Bihar**", vide Notice Inviting Tender No.- **BMSIC/MEDICAL DEVICES/CONSUMABLES/24-05**. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website www.eproc2.bihar.gov.in**.**

After considering the suggestion/queries received from the prospective bidders & after due deliberation on all aspects, certain amendments have been made in the Technical Specification in Annexure- I of the standard bid document in this Corrigendum-I.

In order to ensure wider participation of the bidders the tender schedule revised as follows: -

Revised Tender Schedule

Tender Reference No.	**BMSIC/MEDICAL DEVICES/CONSUMABLES/24-05**
Last date and time of submission of online bids	**26th July 2024 by 17:00 Hrs.**
Last date and time for submission of EMD and Tender Fees	**29th July 2024 till 14:00 Hrs.**
Date, Time and Place of opening of Technical Bid	**29th July 2024 (at 15:00 Hrs.) on the website of www.eproc2.bihar.gov.in in the office of BMSICL**
Date and time of opening of Financial Bids	**To be announced later on www.bmsicl.gov.in and www.eproc2.bihar.gov.in**
Validity of Tender	**180 Days**
Cost of the tender document	**Rs. 11,800/- (Eleven Thousand Eight Hundred only) Non-refundable.**

Sd/-
GM (Procurement)
BMSICL

Annexure- A

Technical Specification of HBsAg (Rapid Test) – Whole blood

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 whole blood.
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 Rules, 2017.
8. The kit should have minimum shelf life of 12 months 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 of **more than 98%** 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 13/06/2017.
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°C.
2. The pack size should not be more than 50 tests, wherein each test is individually packed.

The committee approved the specification of HBsAg (rapid test) on whole blood samples.

Annexure-B
Technical Specification of Anti-HCV Antibody Kits (Rapid Test)- Whole blood

1. Should utilize recombinant and/or synthetic peptide antigens for core, NS3, NSA and NS5.
2. The assay should detect total anti HCV antibodies.
3. Should be compatible with whole blood.
4. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assay, manufacturing and expiry dates should be provided in each kit.
5. The kit should have approval of the statutory authority form the country of origin.
6. In case of imported kits, it should be registered and licensed by the DCG (I).
7. Indigenous manufactures should be licensed by the competent authority/Licensing authority, defined under Drugs and Cosmetics Act (1940) and Medical Device Rules, 2017.
8. The kit should have minimum residual shelf life of 12 months 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 12/07/2017.

12. The control dot/band should be visible to the naked eye and 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°C.
2. The pack size of kit should not be more than 50 tests, wherein each test is individually packed.

The committee approved the specification of Anti HCV antibody (rapid test) on whole blood samples.

Annexure- C
Technical Specification of HIV- 4th Generation ELISA Kits

1. Kit needs to detect antibodies against HIV 1+2 and p24 Ag against HIV-1.
2. Kit needs to have specificity of more than 99.5% for both Antigen as well as Antibody without compromising the assay sensitivity
3. Kit needs to have reactive and non reactive controls with separate positive control for Antigen and Antibody.
4. The analytical Sensitivity of p-24 Ag detection needs to be less than 50 pg/ml or 1.0 IU/ml of WHO Standard
5. Kit needs to have colour coded reagents (Optional).
6. OD norms for reagents verification on automation as well as manual procedure.
7. Kit needs to detect all the three classes of antibodies to HIV i.e. IgM, IgG and IgA simultaneously providing highest early sero-conversion sensitivity.
8. Total Incubation time needs not to be more than 2 hrs.
9. Sample volume needs not to be more than 100 µl without any predilution step.
10. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.
11. Product needs to be CE approved and Certificate of Analysis should be provided for each batch of the product.
12. Kit needs to be programmable & compatible for automated / semi-automated systems.

Annexure- D
Technical Specification of HCV- 4th Generation ELISA Kits

1. Needs to detect both Ab and Ag against HCV
2. Sensitivity needs to be **more than 98%** and Specificity needs to be more than 99.5% for both Ag as well as Ab without compromising the Assay sensitivity.
3. Principle needs to be Streptavidin-Biotin based sandwich Elisa
4. Monoclonal Abs against capsid proteins, and recombinant protein or antigens for NS3, NS4 and Capsid need to be coated on the solid phase.
5. 2 separate conjugates for Ag as well as Ab detection need to be present.
6. Kit needs to have colour coded reagents (Optional).
7. OD norms for reagents verification on automation as well as manual procedure.
8. Kit need to have separate positive controls for Ag and Ab
9. Total Incubation time needs not be more than 2.5 Hrs.
10. Kit needs to be programmable & compatible for automated / semi-automated systems.
11. Product needs to be CE approved and Certificate of Analysis should be provided for each batch of the product.
12. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.

Annexure- E
Technical Specification of Hep B 3rd Generation ELISA Kits

1. Kit needs to have a minimum analytical sensitivity of 0.060 ng/ml or 0.05 IU/ml for WHO Standard.
2. Specificity of the Kit needs to be more than 99.5%.
3. Kit needs to be able to detect all known major subtypes - adr, adw, ayr, ayw as well as most of the mutants.
4. Kit needs to be based on one step sandwich Elisa.
5. Kit needs to use combination of monoclonal & polyclonal antibodies on solid phase and in the conjugate to enable best coverage of all the subtypes.
6. Kit needs to have colour coded reagents (Optional).
7. OD norms for reagents verification on automation as well as manual procedure.
8. Total incubation time of the assay needs not to be more than 2 Hrs.
9. Kit needs to be programmable & compatible for automated / semi-automated systems.
10. Sample volume need not to be more than 100 µl without any predilution step.
11. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.
12. Product needs to be CE approved and Certificate of Analysis should be provided for each batch of the product.

Annexure- F
Technical Specification of Syphillis ELISA Kit

1. Detection of total Antibodies (Ig M, Ig A & Ig G) against Treponemapallidum in Human serum/plasma.
2. Solid phase microplate coated with mixture of recombinant Treponemal Antigens.
3. Ready to use reagents.
4. Assay procedure Time should not be more than two hour thirty min.
5. Specificity 99%.
6. Sensitivity 99%.
7. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.

Annexure- G
Technical Specification of Malaria ELISA Kit

1. Detection of Antigen of all four species of plasmodium in Human Whole Blood.
2. Assay procedure Time should not be more than two hour thirty min.
3. Incubation at 37ºC.
4. All reagents are ready to use.
5. Specificity 99%.
6. Sensitivity more than 98%.
7. Supplier needs to provide the Certificate of Analysis/Quality from NIB/NARI for each supplied batch.

Note:- Demonstration of all the mentioned Kits in Annexure-I of Standard Bid document will be performed upon requirement at Patna.

Sd/-
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