Bihar Medical Services & Infrastructure Corporation Limited
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Hospital Road, Shastri Nagar, Patna 800023
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CORRIGENDUM-III

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 DEVICE/CONSUMABLES/22-03
Dated: - 07/07/2022

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

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) has invited 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 DEVICE/CONSUMABLES/22-03**. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions is available on the website **www.eproc.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 product specification as well as deletion of certain items from the tendered product list and rationalization of the tendered quantity of certain products as mentioned in Annexure I of this Corrigendum-III.

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

Revised Tender Schedule

Tender Reference No.	**BMSIC/MEDICAL DEVICE/CONSUMABLES/22-03**
Date and time for downloading of bid document	**Upto 13th July 2022 till 18:00 Hrs.**
Last date and time of submission of online bids	**Upto 14th July 2022 by 18:00 Hrs.**
Last date and time for submission of original bid documents with EMD and Tender Fees	**Upto 15th July 2022 till 14:00 Hrs.**
Date, Time and Place of opening of Technical Bid	**Upto 15th July 2022 (at 15:00 Hrs.) on the website of www.eproc.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.eproc.bihar.gov.in**
Validity of Tender	**180 Days**
Cost of the tender document	**Rs. 10,000/- (Ten Thousand only) Non-refundable.**
Bid Processing Fee	**Rs 1180/-(One thousand one hundred eighty only) Non-refundable.**

Sd/-
GM (Procurement)
BMSICL

Annexure-I

S.N.	Composition of the Drugs/Kits	Estimated tendered quantity
1	HIV (Rapid) Kits - 1st Antigen	4000 Kits
2	HIV (Rapid) Kits - 2nd Antigen	3000 Kits
3	HIV (3rd kit)	3000 Kits
4	Whole Blood Finger Prick HIV Test Kits	1000000 Kits
5	POC Kit for HIV & Syphilis	300000 Kits
6	ELISA Kit Syphilis	400000 kits
7	Triple Blood bag with SAGM (350 ml)	100000 Bags
8	Single Blood bag (350 ml)	300000 Bags
9	Pediatric Bag	2000 Bags
10	Malaria Antigen Testing Kit	300000 Kits
11	Antisera A (Monoclonal, IgM)- 10 ml Vial	3000 Vial
12	Antisera B (Monoclonal, IgM)- 10 ml Vial	3000 Vial
13	Antisera D (Monoclonal, IgM)- 10 ml Vial	3000 Vial
14	Antisera D (Polyclonal, IgM)- 10 ml Vial	3000 Vial
15	Antisera D (Monoclonal IgM + IgG Blend)- 10 ml Vial	3000 Vial
16	Coomb's Card (AHG Card) for cross matching	300 Card

Note- I :- Deletion of total 09 products i.e. (i) RPR Test Kits, (ii) DBS Card, (iii) DBS Kit (Dried Blood Spot Collection Kit), (iv) ELISA KITS Anti HIV I & II (Antibody) IVth generation, (v) ELISA KITS Anti-HCV (antibody) IVth generation, (vi) ELISA KITS HbSAg IVth generation, (vii) Malaria ELISA Kit, (viii) Transfer Bag & (ix)Typing Card (Kell Duffy Kidd Lutheren) from Tendered product List.

Note- II :-

Please refer to the Annexure-I of this corrigendum for Revised product list in the price bid before submission of the bid.

Note- III :-

Those bidders who have already submitted their bids shall also have to Resubmit their bids accordingly otherwise their bid will be summarily rejected.

(1) Technical Specifications of HIV (Rapid) Test kits- 1 By the Principal Dot Immune Assay:

1. Should be solid phase coated HIV 1 & 2 recombinant and/ or synthetic peptide antigens.
2. The Assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 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 statuary authority from the country of origin.
5. Imported kits, it should be registered and licensed by the DCG (I).
6. Indigenous manufacturer should be licensed by the competent authority defined under Drugs & Cosmetics Act 1940 & Rule 1945 and/ or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The control dot/ band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:

a. The test kit should be packed such that there is a provision to conduct the single test at a time.

b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls).

c. The pack size of HIV rapid test kits should be not more than 50 tests per kit.

12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8° C. The cumulative time temperature indicator technology used should be pre- qualified by WHO.

(2) Technical Specification of HIV (Rapid) Test kits- 2 (Principal Agglutination)

1. Should be solid phase coated HIV 1 & 2 recombinant and/ or synthetic peptide antigens.
2. The Assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 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 statuary authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG (I).
6. Indigenous manufacturer should be licensed by the competent authority defined under Drugs &

   Cosmetics Act 1940 & Rule 1945 and/ or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The control dot/ band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:

    a. The test kit should be packed such that there is a provision to conduct the single test at a time.

    b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls).

    c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8° C. The cumulative time temperature indicator technology used should be pre- qualified by WHO.

(3) Technical Specification of HIV (Rapid) Test kits- 3 (Principle excluding Agglutination and (Dot Immune Assay)

1. Should be solid phase coated HIV 1& 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 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 statuary authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and/ or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.

8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:
    a. The test kit should be packed such that there is a provision to conduct the single test at a time.
    b. The assay component should include HIV positive & negative serum controls, Sufficient for conducting 20% of the test (10% negative & 10% positive controls)
    c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2- 8° C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

(4) <u>Technical Specification of Whole Blood Finger Prick test kit for HIV</u>

1. The assay should be able to detect antibodies to HIV 1 & HIV 2, including all the subtypes by the rapid test in whole blood/ and serum/ plasma.

2. The assay should have sensitivity of 100 % and specificity of ≥98%.

3. The clinical data to determine the performance characteristics of the kit on whole blood sample should be made available by the manufacturer.

4. The assay should have solid phase/particles coated with synthetic and or recombination or both types of antigens of HIV 1 and HIV 2.

5. Total procedure time should not be more than 30 minutes.

6. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.

7. The Control dot/ band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.

8. Adequate documents detailing the principal component, detail of antigen for antibody detection of HIV 1 & 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.

9. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8° C. The cumulative time temperature indicator technology used should be pre – qualified by WHO.

10. Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act 1940 & Rule 1945 and/or Medical device rule 2017.

11. The imported rapid test kits should have the approval of the statutory authority in the country of Origin/ manufacturers and should satisfy the requirements of Drugs & Cosmetics Act in India. The imported kits should also get evaluated in our country.

12. 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 controls sufficient for conducting 20% of the test (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.

(5) <u>Technical Specification of POC Kit for HIV & Syphilis</u>

One step, rapid Immunochromatographic test for the qualitative detection of antibodies specific to HIV-1 including subtype O, HIV-2 and syphilis (Treponema pallidium) in human serum, plasma or whole blood.

(6) <u>Specifications for ELISA test Kits</u>

a. Kits should have ready to use reagents.

b. Kits should have near 100% sensitivity and 100% specificity.
c. Adaptable to all makes of ELISA processor.
d. Adequate literature detailing the components, methodologies, and validity criteria and performance characteristics of the product should be provided with each kit.
e. The kits to be procured should have approval of the statutory authority in the country and should satisfy the requirements of Drugs & cosmetic Act (IP2014).
f. At the time of supply QC report, from NIB (National Inst. of Biological),New Delhi/any other designated Lab. by Central /State govt. for the same, is to be submitted.
g. The Kits should have reactive and non-reactive controls with each kit.
h. The supplier/ local agent or manufacturer should have an import/ manufacturing licence issued by the competent authority for the brand name of the Kit offered on the date of bid opening.
i. The manufacture/- authorized agent should ensure maintenance of cold chain during storage and transport at 2 to 8°C.
j. The kit should have a shelf life of minimum 18 months at 2-8^0 C at the time of supply.

(7) Technical Specifications of Triple Blood Bag-350 ml with Additive Sol. (SAGM/ ADSOL).

(1) All specification of single blood bag
(2) As per NBTC guidelines there should be provision of Diversion pouches in addition to the three bags.
(3) 49 ml. CPD (Anti-Coagulant), certificate from Govt. Recognized companies for progency testing of Anti-coagulant. The anti-coagulant must be as per IP or USP.
(4) Two transfer bags of 350 ml. Capacity.
(5) Additive solution SAG-M/ ADSOL.
(6) Break off value: should have big break off valve to help in smooth flow of component and thereby reduce processing time. Uniform break force of the click tip ensure breakability.
(7) Platelet storage bags should store platelet for at least 5 days storage, with permeability characteristic. pH of the platelet should be maintained at 6.8 to 7.2 during 5 days storage. Platelet count also should not be reduced during 5 days storage
(8) Shelf life of the bag should be minimum two years.
(9) Customer satisfaction feedback from institution of repute should be submitted.

(8) Technical Specifications of Single Blood Bag- 350 ml with CPDA/CPDA- I Anti-Coagulant.

(1) Blood Bags should be Flexible, pre-sterilized & Pyrogen Free and made of Non-Toxic, non-haemolytic, bio-compatible material with no risk of contamination or air-embolism (closed system) with leak proof seals.
(2) Slits on both sides should be enough to accommodate 4-5 pilot tube segments.
(3) The capacity of the bags should be enough to prevent any ballooning/rupture of the bags from the seam when filled with the requisite amount (350 ml.) of Whole Human Blood.
(4) Tubing- Flexible, non-kinking, transparent, leak-proof with the same ID number as on the bag. The ID numbers should be printed at multiple places over the tubing.
(5) Needle-should be 16 G with sharp margin, bevel tip design and ultra thin walled for painless vein puncture with tightly fixed with hub covered by protective sterile guard (cap) to prevent leakage of anticoagulant, which should be easily removable. It should be hermetically sealed.
(6) External port-should be easily accessible, tamper-proof and shouldn't be recapped.
(7) Packaging-protective dual packaging (individual and Aluminium) eliminating microbial contamination on the surface and the contents of the bag. It should be easy to handle.
(8) Anti-coagulant and preservative solution-CPDA-1 (49 ml. i.e. 14 ml. /100 ml. of blood) as per IP. It should be clear, Colourless and sterile. There should be no discolouration on storage at room temperature.
(9) Label-Non-peel off, heat sealed label, which should remain attached between room temp. 4^o C and 80^o C. Date of Manuf. & Date of Expiry should be clearly written.
(10) Shelf life of the bag should be minimum two years.

(9) Technical Specifications for Pediatric Bag 100 ml.

Description: Plastic collapsible, non-vented, sterile containers complete with collecting tube outlet port, integral needle, containing 14 ml of CPDA IP anticoagulant solution for the collection & storage of 100 ml whole blood (Human).

Specifications

1. Design of Blood Bags:

1.1 **General**: The bags permit the collection of blood with a minimal hazard of contamination by microorganisms.

1.2 **Needle**:

i) Triple Bevel Design, sharp point and smooth internal surface.

ii) Can withstand without working loose from the assembly, a tensile force of 20N applied along the longitudinal axis of the tubing for 15 sec.

iii) Needle exposed length 35 – 37 mm. Diameter 1.65 mm (16G).

iv) Tamper evident PVC needle cover.

1.3 **Blood Bag Sheet**:

i) Made of heat extruded medical grade DEHP plasticized PVC.

ii) The sheet of blood bag withstands storage at- 80° C for 24 hrs. & subsequent immersion in water at 37±2° C for 60 minutes.

iii) High Frequency RF Welding is used for sealing the bag so that it eliminates leakage during centrifugation.

1.4 **Donor tube length**: Min1000 mm with 12 segment markings.

1.5 **Tamper evident port protector**: The outlet ports are covered with extended blood bag sheet which is hermetically sealed with RF & is tamper evident to maintain sterility of the internal surface.

2. Physical requirements:

2.1 **Peel resistant label**: The heat sealed label is made from the pure unbleached medical grade paper. The label has hot melt polymer coating, which do not permit the growth of Micro-organisms during the storage of blood. The high frequency RF welding is used for fixing of labels on the bags to render it non peelable.

3. Chemical requirements:

3.1 The sheet fulfills the requirements of ISO 3826-1.

4. Biological requirements:

4.1 The blood bags do not adversely affect the therapeutic effectiveness of blood & blood components & not release substances, which may exhibit toxic, cytotoxic, pyrogenic or haemolytic reactions.

5. Packaging requirements:

5.1 The blood bags are individually packed in laminated pouches free of holes.

5.2 The 10 units are packed in the aluminum pouches.

5.3 The 10 aluminum pouches are further packed in a 5 ply corrugated box.

6. Labeling requirements: As per ISO 3826-2.

7. Anticoagulant solution:

7.1 The anticoagulant solution fulfills the requirements given in the Indian Pharmacopoeia (IP)/ US Pharmacopoeia. The volume of the anticoagulant solution is 14 ml for 100 ml of whole blood. The anticoagulant allows the storage of whole blood for 35 days.

8. **Certifications:** ISO 9001:2015, ISO 13485:2016 & CE mark.

(10) Technical Specification of Malaria Antigen Testing Kit

A. RDT (Bivalent) Malaria Kit for both Pv & Pf test (Antigen based).

B. The bidders are directed to ensure the manufacturing the RDT (Bivalent) Malaria Kit for both Pv & Pf test (Antigen based) in accordance with the specification as mentioned in the S.O 1352(E) dated 23.03.18 of Department of Health and family welfare of Ministry of Health and Family Welfare, Govt. of India.

(11) Technical Specification of Anti- A, B & Anti D (IgM) Monoclonal- 10 ml

a. Appearance: No turbidity, precipitate, particles, or gel formation on visual inspection.
b. Specificity: 100% clear cut reaction with cells having corresponding antigen (s), and not reaction with negative control.
c. Potency: Should give +++/C reactions with undiluted sample using 3-5% cell suspension at RT, with minimum Titre of 1:128.
d. Avidity: Macroscopic agglutinate with 50% red cells suspension in homologues serum/ normal saline using slide test 3-4 seconds for anti- A, Anti- B and anti- AB at 28° C.
e. Reactivity: No immune hemolysis, rouleaux formation in saline tube test.

(12) Anti- D Antisera (Polyclonal) 10ml, (IgM)

a. Appearance: No turbidity, precipitate, particles, or gel formation by visual inspection.
b. Specificity: 100% clear cut reaction with cells having corresponding antigen (s), and no reaction with negative control.
c. Potency: Should give +++/C reactions with undiluted sample using 3-5% cell suspension at RT, with minimum Titre of 1:64(after proper incubation)
d. Avidity: Macroscopic agglutinate with 50% red cells suspension in homologous serum/ normal saline using slide test 60 seconds. at 28^0 C.
e. Reactivity: No immune haemolysis, rouleaux formation in saline tube test at room temperature.
f. Titer should be at least not less than in 1:128 dil. with corresponding cells.

(13) Technical Specification of Antisera D (Monoclonal IgM + IgG Blend)

a. Appearance: No turbidity, precipitation, particles or gel formation by visual inspection.
b. Specificity: 100% Clear-cut reaction with cells having corresponding antigen (s), and no reaction with negative control.
c. Potency: Should give +++/C reactions with undiluted sample using 3-5% cell suspension at RT, with minimum Titre of 1:128.
d. Avidity: Visible agglutination with 40% red cell suspension in homologous serum using the slide test in 10 seconds.
e. Reactivity: No immune hemolysis, rouleaux formation or prozone phenomenon.

(14) Technical Specification of Coomb's Card (AHG Card) for cross matching 144T/288T with diluents

A. Micro-tubes prefilled with gel/beads with suitable buffer, containing polyspecific AHG.
B. Micro-tubes pre-sealed with Aluminium foil to prevent drying/degeneration.
C. Free Diluent/LISS, for preparation of red cell suspension.
D. Shelf life minimum of 1 year.

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