Rajasthan Medical Services Corporation Limited

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Ref. No.:- F.02(256)/RMSCL/PROCUREMENT/DRUG/NIB-22/2018/1311 Dated: 6/12/2018

Corrigendum – 1

Subject:- Amendments in BOQ

Ref.:-Pre bid meeting dated 05.12.2018 and NIB No. F.02(256)/RMSCL/PROCUREMENT /DRUG /NIB-22/2018/1276 Dated: 19.11.2018 (Technical bid opening due on dated – 21.12.2018)

<table>
<tr><th>S. No</th><th>Existing condition / technical specification/Packing Unit/Quantity (clause no.)</th><th>Amended condition / technical specification/ Packing Unit/Quantity/Shelf Life/Date Extension (clause no.).</th></tr>
<tr><td>1</td><td>Annexure-VIII and BOQ:-</td><td>Annexure-VIII and BOQ :- Add the following drugs in the bid
<table>
<tr><th>Code No.</th><th>Name of item with specification</th><th>Packing Unit</th><th>Minimum labelled Shelf Life (In Months)</th><th>Estimated Bid Qty.(No. of tabs, Caps, ampoules, bottles, injections, etc.)</th></tr>
<tr><td>NE3</td><td>Treponemal-Specific Rapid (Point of Care) Diagnostic Test for Syphilis</td><td>50 Tests per Kit (Rate should be quoted for one kit which contains 50 tests)</td><td>As per Annexure 'A'</td><td>1000000</td></tr>
<tr><td>NE4</td><td>Whole Blood Finger Prick Test kit for HIV (Rapid)</td><td>50 Kits (Rate should be quoted for 50 Kit)</td><td>As per Annexure 'B'</td><td>1400000</td></tr>
<tr><td>NE6</td><td>Urine Albumin & Sugar Strip</td><td>Pack of 100 Strips</td><td>As per Annexure 'C'</td><td>1500000</td></tr>
</table>
BOQ: - One drug has been added in the bid. The BOQ is replaced with new BOQ. Please ensure that financial bid is submitted in new BOQ only.
<u>(Total Drugs in Bid 81)</u></td></tr>
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Note:-

- **It may be noted that if any type of amendments required than further corrigendum will be published and informed.**
- **Rest terms and conditions will remain the same.**

Executive Director (Proc.)
RMSC

Technical Specifications of Treponemal-specific Rapid (Point-of-Care) Diagnostic Test for Syphilis (Item code NE3)

1. The assay may be based on any of the rapid test principles: (immunoconcentration/ immunofiltration/immunochromatography).
2. The assay should quantitatively detect total anti-treponemal antibody (IgG and IgM) in whole blood, serum or plasma for serological diagnosis of syphilis in all stages of infection.
3. The assay should have an in-built procedural control in form of bend or dot for validation of the test kits.
4. The assay should have reactive and non-reactive controls with each kit in ad
5. equate volume (minimum 10% of pack size).
6. The kit should have $5/6^{th}$ of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
7. Adequate literature detailing the principle, components, methodologies, validity criteria, bio-safety, performance characteristics, storage conditions, limitation of assay, manufacture and expiry dates and methods of disposal should be provided with each kit.
8. The imported rapid kit should have approval of the statutory authority in its country of origin. The imported kits should have been registered and licensed in India by the Central Drugs Standard Control Organization (CDSCO).
9. In case of indigenous manufacturers they should have a valid license issued by the competent authority defined under Drugs and Cosmetics Act, 1940, after appropriate evaluation by the centres approved by the CDSCO.
10. The assay should have sensitivity of 90% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences.
11. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from the manufacturer.
12. Test procedure should be user friendly (can be performed with few simple steps with minimum training)
13. The manufacturer should ensure the following:
    - Test should be equipment free. Result should be visualised with nacked eye.
    - The test should be packed such that there is a provision to conduct single test at a time.
    - The pack size of test lots should be in 50 (for peripheral health levels) and 100 tests per kit (for secondary and tertiary health care level) but not more than 100 tests per kit.
14. The manufacturer should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C in form of transtracker on every kit.
15. Total procedure time should not be more than 30 minutes.
16. Quantity 18000 Pkt (50 Units per Packet)

Annexure - B

(Item code NE4)

Technical Specifications of HIV (Rapid) Whole Blood Finger Prick Test Kits

1. The indigenous HIV antibody rapid test kits should have a valid license by the competent authority defined under Drugs & cosmetics Act, 1940 after appropriate evaluation by the centres approved by DCG (I). The imported rapid test kits should have the approval of the statutory authority in the country of origin/manufacturer and should satisfy the requirements of Drugs & Cosmetics Act in India. The imported kits should also get evaluated in our country.
2. The assay should be able to detect antibodies of HIV1 & HIV2 and all the subtypes by detection of antibodies by the agglutination/ Enzyme Immuno Assay or any other Principle.
3. The assay should have sensitivity of 99.5% or more and specificity of 98% or more as per data from an identified national reference laboratory.
4. The assay should have solid phase/ particles coated with synthetic and/ or recombination or both types of antigen of HIV1 & HIV2.
5. Total procedure time should not be more than 30 minutes.
6. The manufacturers should ensure that:
   a) The test kit should be packet 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 conducing 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.
7. The kit should able to perform with whole blood finger prick sample.

Term and Conditions:

1. Shelf life of the kits has to be defined as 60% of residual life or a shelf-life of 12 months at the time of dispatch to the consignee, whichever is more.
2. The supplier should have the facility to store kits at 2°C to 8°C. The cumulative time temperature indicator technology used should be pre qualified by WHO.
3. The supplier should supply Kits for at least 600 tests free of cost from each lot for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocols for each batch to be attached.
4. The kit should not be using the comb device as the feasibility study reported by NARI Pune has difficulty in performance using the comb test in field conditions.

Annexure - C

(Item code NE6)

Technical Specifications of Urine Albumin & Sugar Strip

Visual Urine Strips with 12 parameters:

Urine test strips to determine pathological changes in the urine in standard Urinalysis. A standard urine test strip should comprise of up to 12 different chemical pads or reagents which react (change colour) when immersed in, and then removed from, a urine sample. To achieve better results each strip width should be 6mm & test to be read between 60 and 120 seconds after dipping. Following parameters should be provided in each Strip: Leucocytes, Nitrite, Urobilinogen, Protein, PH, Blood, Specific Gravity, Ascorbic Acid, Ketone, Bilirubin Glucose, Micro albumin.

Urinalysis strips must be resistant to interference from ascorbic acid (vitamin C) to avoid interference and give false- lower or false- negative results. Should be Easy to Use with Rapid Results in 30 seconds to 2 minutes depending on the tests & each bottle should have High Quality Colour Chart for accurate analysis. The strip bottle should have 2 year shelf Life if un-opened. Pack of 100 strips each.