Notice Inviting e-Tender

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SUPPLY OF POC (POINT OF CARE) TEST KIT FOR SYPHILIS

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 68/2018	Dated-12.03.2018

Amendment – I

Section IV: Schedule of Requirements

TECHNICAL SPECIFICATIONS

Technical Specifications for Rapid POC (Point of Care) Kit for Syphilis

Sl. No.	Name	Unit	Quantity
1.	**Treponemal-specific Rapid POC (Point of Care) Diagnostic Test Kit for Syphilis**	Kit	25311 [each kit box contains 25 tests (cards)]

- The assay should have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens.
- The assay may be based on any of the rapid test principles: Immunoconcentration/dot blot immuinoassay (vertical flow).
- The assay should qualitatively detect total anti-treponemal antibody (IgG and IGM) in whole blood for serological diagnosis of syphilis in all stages of infection.

- The assay should have an in-built control band for testing the validity of the test kits.
- The kit should have 5/6th of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
- 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.
- 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).
- 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 centers approved by CDSCO.
- The assay should have sensitivity of 99% 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.
- 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.
- The manufacturer should ensure the following:
    - ❖ The test should be packed such that there is a provision to conduct single test at a time.
    - ❖ The pack size of test kits should be in 25 tests (cards) per kit box.
- The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2°C to 30°C.
- Total procedure time should not be more than 30 minutes.
- The test kit should be supplied with capillary pipette one for each test (card) for collection of whole blood sample from prick site to transfer the sample to the test site. Each kit box will contain 25 (twenty five) capillary pipettes.
- The test kit should be supplied with sterile auto retractable disposable lancet one for each test (card). Each kit box will contain 25 (twenty five) such lancets.
- Alcohol soaked swab should be supplied with one for each test (card). Each kit box will contain 25 (twenty five) such swabs.
- The test should be card based single use rapid test kit specifically designed to be used by the lay tester. The card should have a well for transferring whole blood sample and buffer, a result interpretation window having control or test domain and reactive domain so that results can be clearly interpreted based on the appearance of test plus minus reactive bands
- Since the kits to be procured will be utilized at field level, the temperature sensitivity should be like that it can withstand temperature minimally up to 30 degree centigrade.

Labelling

The kit should have a label/sticker on it with the following information:

a. Procured by: WBMSCL

Procured by WBMSCL in the year 2018
'' WEST BENGAL GOVERNMENT SUPPLY ''
NOT FOR SALE

b. Batch Number:
c. Mfg Date:
d. Expiry date:
e. Address:

Inspections and Tests

a) The Vendor shall get the Goods inspected in the manufacturer's works by a competent authority and submit a test certificate and also a guarantee / warranty certificate that the Goods conform to laid down specifications.

b) WBMSCL or its representative may inspect and / or test any or all item of the Goods to confirm their conformity to the Contract.