

Annexure- B

TENDER NO. BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03

Amended Technical Specification and Estimated Quantity of POC Kit

S.N.	Name of the Product	Specification / Strength	Pack Size	Estimated Quantity for 2019-2021
1	POC kits (Point of Care test kits for Syphilis)	• The assay may be based on any of the rapid test principles: (Immunochromatographic/ Dot blot immunoassay (vertical flow/ lateral flow), card/ cassette based) • The assay should have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens. • 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. • The assay should have an in-built positive and negative control for testing the validity of the test kits. • The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size). • 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 manufacturer/ importer 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 50 test/kit (Each kit should contain 50 strips (card/ cassette based) along with buffer/ diluent in five small containers/ bottles (each container/ bottle must contain the buffer/ diluent for 10 tests)) • The manufacturer/ importer should ensure maintenance of cold chain of the control reagents during storage and transport at 2°C to 8°C. The POC kit containing the required accessories as per the mentioned specification excluding the control reagents may be shipped at ambient temperature. • 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 50 (fifty) capillary pipettes. • The test kit should be supplied	2500000KITS

		• 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 the 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/Independent NABL Accredited Test Reports along with In-House Test Reports. • 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.	with sterile auto retractable disposable lancet one for each test (card). Each kit box will contain 50 (fifty) such lancets. • Alcohol soaked swab should be supplied with one for each test (card). Each kit box will contain 50 (fifty) 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.	
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