



**Bihar Medical Services & Infrastructure Corporation
Limited**
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CORRIGENDUM-III

Short Tender for rate contract and supply of POC Kits (Point of care test Kits for Syphilis) for different healthcare facilities of State of Bihar for the year 2019-21

Notice Inviting Tender Ref No.:-BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03,Dated:-25-10-2019
(Only through E- Tender on website: -www.eproc.bihar.gov.in)

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) invites E-Bids from the interested parties for "**Short Tender for rate contract and supply of POC Kits (Point of care test Kits for Syphilis) for different healthcare facilities of State of Bihar for the year 2019-21**", vide Notice Inviting Tender No.- BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03 Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website www.eproc.bihar.gov.in.

All the suggestions /queries received from the prospective bidders during and after Pre-Bid meeting and the technical aspects were reviewed by the Technical Specification Committee (TSC) in its meeting dated 04-10-2019. The Minutes of the TSC meeting is attached here with along with this Corrigendum-III. The floated bid document is amended hereby in accordance with the attached minutes of the TSC meeting.

In order to give sufficient time and to ensure wider participation of the bidders the Tender Schedule is being revised as follows:-

Revised Tender Schedule

Tender Reference No.	BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03
Date and time for downloading of bid document	Upto 11th November 2019 till 1500 Hrs.
Last date and time of submission of online bids	Upto 13th November 2019 by 18:00 Hrs.
Last date and time for submission of original bid documents with EMD and Tender Fees	Upto 15th November 2019 till 14:00 Hrs.
Date, Time and Place of opening of Technical Bid	Upto 15th November 2019 (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**

Annexed- Minutes of the TSC meeting dated 04-10-2019.

Note-I:- In case of any query/doubt one can contact DGM(Drugs) on Mobile No- 7008050665 or Manager(Drugs) on Mobile No- 9471009193 or may contact through e-mail on Contact2bmsicl@gmail.com.

**Sd/-
GM (Procurement)
BMSICL**

Minutes of the Technical Specification Committee Meeting for Finalization of Technical Specification of POC Kits (Point of care test kits for Syphilis) floated vide tender no.- BMSIC/MEDICAL DEVICES/CONSUMABLE/19-03 (Tender for rate contract & supply of POC kit for different healthcare facilities of state of Bihar for the year 2019-21).

Date: 4th October 2019

Venue: BMSICL Conference Hall.

The Technical Specification Committee Meeting for finalization of the specification of **POC Kits (Point of care test kits for Syphilis)** floated vide tender no.- BMSIC/MEDICAL DEVICES/CONSUMABLE/19-03 was held on 4th October 2019 under the Chairmanship of Dr. Shiva Chandra Bhagat, Director in Chief, Department of Health, GoB. The other committee members present in the meeting were:

1. Sh. Khalid Arshad, Administrative Officer, SHS Bihar.
2. Sh. Rajani Kant, CGM (Supply Chain), BMSICL.
3. Dr. S. N Singh, Department of Pathology, PMCH.
4. Sh. Sunil Kumar Singh, GM (Procurement), BMSICL.
5. Dr. Biswaprakash Pradhan, DGM (Drugs), BMSICL.
6. Sh. Ravi Kiran Rakesh, Manager (Drugs), BMSICL.

During and after pre-bid meeting held on 30-09-2019, various suggestion from prospective Bidders were received. All the received suggestion and technical aspects were discussed in today's meeting. After due deliberations on all the aspects, it was unanimously decided to recommend to make certain amendments and clarifications as given in annexure-A and Annexure- B of this minutes of the meeting.

The meeting was thus concluded with a vote of thanks.

Sd/-

(Ravi Kiran Rakesh)

Manager (Drugs), BMSICL, Patna.

Sd/-

(Dr. Biswaprakash Pradhan)

DGM (Drugs), BMSICL, Patna.

Sd/-

(Sunil Kumar Singh)

GM (Procurement), BMSICL, Patna

Sd/-

(Dr. S. N Singh)

Department of Pathology, PMCH Patna

Sd/-

(Sh. Rajani Kant)

CGM (Supply Chain), BMSICL,
Patna.

Sd/-

(Khalid Arshad)

Administrative Officer, SHSB.
Patna.

Sd/-

(Dr. Shiva Chandra Bhagat)

Director in Chief, Health Dept. Govt. of Bihar.

ANNEXURE- A				
BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03				
Clarification in the light of queries/suggestions received from various firms during and after Pre-Bid Meeting held on 30/09/2019				
S. N.	Name of the Firm	Bidders Queries	Present Clause	Clarification/Amendment
1	M/s Mediclone Biotech Pvt. Ltd.	<p>1. The Assay maybe based on Rapid Test Principles- Reg :- Please do update if the Assay is Immunochromatographic Assay Based As well.</p>	<p>1. The assay may be based on any of the rapid test principles: (Immunoconcentration /Dot blot immunoassay (vertical flow), dip stick and comb assay.</p>	<p>The assay may be based on any of the rapid test principles: (Immunoconcentration / Immunochromatographic/ Dot blot immunoassay (vertical flow/ lateral flow), card/ cassette based)</p>
		<p>2. Positive and negative Controls- Reg :- The Controls can be Provided as requested for 10% of the Tests to be performed, but we would like it to be separately shipped as they are 2°C to 8°C products, packing them separately would also have little space occupancy in the Warehouse Cold-storage, as the Rapid cards as kits with controls occupy much space and the cards are usually kept at Room-Temperature.</p>	<p>2. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size). The manufacturer / importer should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C.</p>	<p>2. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size). 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.</p>

	<p>3. The Assay Sensitivity and Specificity Statements and Certificate from NIB :- The Assay sensitivity and specificity statements to be enclosed with In-House Test Reports or NABL Accredited Test Reports.</p>	<p>3. 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.</p>	<p>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.</p>
	<p>4. Transportation of Kits - Reg :- The Rapid cards and the accessories mentioned are usually transported in Normal Temperature. As the Products are being packed in Silica Gel to protect from Moisture. The maximum Temperature the Products can be safely stored is 30°C. Hence, request to amend the necessity of Cold-chain Transportation.</p>	<p>4. The assay should have an in-built positive and negative control for testing the validity of the test kits.</p>	<p>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.</p>
	<p>5. Accessories - Reg :- Please request to amend the Auto retractable lancets to Sterile single use Lancets.</p>	<ul style="list-style-type: none"> • The test kit should be supplied with sterile auto retractable disposable lancet one for each test (card). Each kit box will contain 50 (fifty) such lancets. 	<p>No Change</p>

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)	<ul style="list-style-type: none">• The assay may be based on any of the rapid test principles: (Immunoencentration / 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 imported rapid kit should	<p>The manufacturer/ importer should ensure the following:</p> <ul style="list-style-type: none">• 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 with sterile auto retractable disposable lancet one for each	2500000KITS

	<p>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).</p> <ul style="list-style-type: none"> • 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. 	<p>test (card). Each kit box will contain 50 (fifty) such lancets.</p> <ul style="list-style-type: none"> • 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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Sd/-
GM (Procurement)
BMSICL