TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-03						
Check list - I: Evaluation sheet to be used for preliminary evaluation of technical bids						
Company Name - RAPID DIAGNOSTIC PRIVATE LIMITED **Total Number of Pages Submitted in bid - 1 TO 118**						
Sl. No	**SBD clause serial No**	**Descrption of the Clause/ Technical Eligibility Criteria as per SBD as mentioned in the Check List**	**Document/ fees submission status (Yes/ No)**	**Page number**	**Do the provided documents meet the eligibility criteria ? (Yes/ No)**	**Remarks**
1	3. (a)	**Tender Fee (Non –Refundable) of Rs 10,000/- in form of Demand Draft** drawn in Favor of "Managing Director, Bihar Medical Services and Infrastructure Corporation Limited" payable at Patna. This fee is payable only once for one tender irrespective of items contained therein.	YES	109	YES	-
2	3.(b)	Bidder are required to submit **Earnest Money Deposit in the form of Demand Draft / Bank Guarantee of Rs 1,00,000/- (one lakh)** drawn in favor of Managing Director, Bihar Medical Services and Infrastructure Corporation Limited from any Scheduled/Nationalized bank payable at Patna	YES	105-108	YES	-
3	3.(c)	Documentary evidence of the **constitution of the company/ firm/ Proprietorship such as Memorandum and Articles of Association, Partnership Deed** etc. should be submitted with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted.	YES	13-35	YES	-
4	3.(d)	The **details of Bidder** Name, Address, Telephone Number, Fax. Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in Annexure-V.	YES	100	YES	-
5	3.(e)	**Power of Attorney or Resolution of Board** by which the **authorised signatory** has been authorised by bidder firm to sign the documents. As per Clause 3(e) of the NIT.	YES	36-37	YES	-
6	3.(l)	Copies of the **Audited Balance Sheet and Profit and Loss statement** showing details of their annual average turnover not less than **5 Crores** for any three of the last four consecutive financial years (Auditor/CA certificate of turnover will not be accepted). **Self-attested copies** are to be submitted.	YES	–	YES	Copies of the Audited Balance Sheet and Profit and Loss statement found in Original Document.

7	3.(m)	Copy of **Income Tax Return for any three of last four Consecutive Assessment years** should be submitted **(self-attested).**	**YES**	**110-113**	**YES**	-
8	3.(p)	**Copy of PAN Card of the bidder company should be submitted (self-attested).**	**YES**	**114**	**YES**	-
9	3.(q)	**Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).**	**YES**	**115-117**	**YES**	Along with GSTIN Number,Copy of Nature of Business of Bidder must be attached with these Documents.

Archana Singh
3/2/22

TENDER NO. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-03						
Check list - II: Evaluation sheet to be used for preliminary evaluation of technical bids						
Company Name: -M/s Rapid Diagnostic Private Limited, B-82, G.T. Karnal Road Industrial Area, Delhi-110033 Total Number of Pages Submitted in bid documents: -118						
Sl. No	**SBD Clause serial No**	**Descrption of the Clause/ Technical Eligibility Criteria as per SBD, as mentioned in Check List**	**Document/ fees submission status (Yes/ No)**	**Page Number**	**Do the provided documents meet the eligibility criteria ? (Yes/ No)**	**Remarks**
1	3.(d)	The **details of Bidder** Name, Address, Telephone Number, Fax. Number, e-mail address of the bidder and of the Managing Director / Partners / Proprietor should be submitted in Annexure-V.	Yes	100	Yes	
2	3.(e)	**Power of Attorney or Resolution of Board** by which the **authorised signatory** has been authorised by bidder firm to sign the documents.	NA			
3	3.(f)	Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate as applicable.	–	–		
		Approved product list as per the license issued for quoted product for minimum three years as applicable.	–	–		
		Manufacturing License along with approved product list must be valid till the last date of the submission of tender.	–	–		
		Market standing certificate & Manufacturing certificate issued by the Licensing Authority as a Manufacturer for each quoted product for the last 3 years (Certificate should be enclosed with list of items) (where ever applicable).	–	–	–	
		Bidders shall submit self-attested copies of required manufacturing license and approved product list (as applicable) in support of above-mentioned condition and they are required to specify the quoted product in their approved product list by highlighting it.	Yes	61-67	Yes	

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4	3.(g)	In case of Importer, the bidder (importer) firm must have minimum three years old valid import License of the quoted product. All Quoted products should be accompanied by their invoices, statement and import License showing that the quoted product is being imported and sold in India by the bidder (Importer) firm minimum for Last three years. Import license must be valid on the last date of submission of tender.	Yes	61-63 64-67 68-69	Yes	
5	3.(h)	Bidder must have Market Standing Certificate (in India) of minimum three years issued by the concerned Licensing Authority from Drugs Control Department for the quoted product (where ever applicable). Self-attested copies are to be submitted.	Yes	57,58	Yes	
6	3.(i)	Non-ConvictionCertificate (NCC) issued by the concerned Licensing Authority from Drugs Control Administration of the state for last three years should be submitted (where ever applicable). It should be not more than one year old. Self attested copies are to be submitted.	No	–	No	Not Submitted
7	3.(j)	WHO-GMP/GMP (Good Manufacturing Practice) as per revised Schedule-'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department(where ever applicable). The GMP certificate must not be older than one year from the last date of submission of tender. Self-attested copies are to be submitted.	Yes	94 95	Yes	EC ISO 13485: 2016 for M/s Hangzhou Biotest Biotech Co. Ltd.
8	3.(k)	Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority form Drugs Control Department highlighting the quoted product section (where ever applicable). Self-attested copies are to be submitted.In case of Importer An affidavit (With Stamp) sworn before first class magistrate/Notary stating the batch production capacity of the firm and also that said production (Importing) capacity shall be adequate for requirement laid in NIT. Importer will have also to submit Invoices/Evidence of import in items of said product with quantity details	No	–	No	Not Submitted
9	3(n)	The tenderer should give an affidavit (with stamp) sworn before first class magistrate / Notary stating that the firm & its quoted product is not black listed currently (as on the date of submission of the tender) by Central Government / Central Government agencies/any state government or any of the state government agencies / or any Drug procurement agencies or by BMSICL asper **Annexure-II.**	Yes	96-97	Yes	

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10	**3.(o)**	**List of item quoted in prescribed format as per Annexure-III duly signed.**	**Yes**	**38-40**	**Yes**	
11	**5.(j)**	An Affidavit (with stamp)regarding acceptance of tender conditions to be submitted by the bidding firm as per Annexure-IV.	**Yes**	**98-99**	**Yes**	
12	**5.(k)**	Filled check list as per given Annexure-VI to be submitted at the time of uploading the bid.	**Yes**	**9-11**	**Yes**	
13	**7.(c)**	Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm should sign the documents in cases where person other than the Managing Director/Managing Partner or sole Proprietor signs the document.	**Yes**	**37**	**Yes**	
14	**10.(c)**	If a particular document/Certificate to be uploaded as specified in bid, is not applicable for a bidder, the bidder shall attach a scanned copy of declaration in the letter head stating that the specific document is not applicable/exempted for the bidder in connection to this tender.	**NA**			
15	**2 (C)**	The price quoted by the bidders must not exceed the ceiling price as fixed by NPPA (National Pharmaceutical Pricing Authority) as per the provisions of "Drugs Price Control Order" and the quoted rate should be at least 20% less than its MRP, where ever applicable.In extraordinary case the Managing Director has discretion to take decision. Explanation- In order to ensure procurement of the tendered products at the most appropriate and competitive rate, the bidders are directed to quote their lowest price as compared to the Rates provided to their respective Distributors/Dealers/ Wholesalers/Carrying and Forwarding Agents/Authorized depot sales point in the State of Bihar. A Notarized affidavit to this effect on a Rs 100/- Non-Judicial Stamp Paper should be submitted with the Bid."	**No**	–	**No**	**Not Submitted**
16		**Note:** The bidders have to submit the Valid Pollution Control Clearance Certificate in accordance with Water [Prevention and control of Pollution] Act, 1974 & Air [Prevention and control of Pollution] Act, 1981 and Hazardous Wastes (Management, Handling & Trans Boundary Movement) Rules 2008 (Self Attested Copy of Certificate to be enclosed).	**No**	–	**No**	**Not Submitted**

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

Check list - III: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name: - M/s Rapid Diagnostic Private Limited, B-82, G.T. Karnal Road Industrial Area, Delhi-110033 **Total Number of Pages Submitted in bid documents: - 118**

Sheet to be used for verification of product approval and market standing

Sl. No	NIT Sl. No	Name of the Quoted MEDICAL DEVICES/CONSUMABLE		Specification		Pack Size		Product category	Approval Details			Last 3yrs market standing certificate/ New Drug
		As per NIT	As per Approval	As per NIT	As per Approval	As per NIT	As per Approval	(Drug/Non Drug)	First Approval	Approved Upto	Approved in Brand /Generic Name	
1	1	POC kits (Point of Care test kits for Syphilis)	Syphilis Rapid Test Cassette/Strip	• The assay may be based on any of the rapid test principles: (Immunoconcentration / Immunochromatographic/ Dot blot immunoassay (vertical flow/ lateral flow), card/ cassette based)	Submitted	The manufacturer/ importer should ensure the following:		Drug	01-09-15	06-12-23	Generic	Yes
				• The assay should have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens.	Submitted	• The test should be packed such that there is a provision to conduct single test at a time.	Submitted					
				• 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.	Submitted	• 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)	Not submitted					
				• The assay should have an in-built positive and negative control for testing the validity of the test kits.	Submitted	• 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.	Submitted					
				• The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size).	Not Submitted	• Total procedure time should not be more than 30 minutes.	Submitted					
				• 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.	24 months	• 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.	Not Submitted					
				• 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.	Submitted	• 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.	Not Submitted					
				• 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).	Submitted	• Alcohol soaked swab should be supplied with one for each test (card). Each kit box will contain 50 (fifty) such swabs.	Not Submitted					
				• 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.	NA	• 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.	Not Submitted					
				• 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.	Yes (Page No, 43 & 44)	• 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.	Submitted					
				• 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.	Not Submitted							

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

Check list - IV: Evaluation sheet to be used for preliminary evaluation of technical bids

Company Name: - M/s Rapid Diagnostic Private Limited, B-82, G.T. Karnal Road Industrial Area, Delhi-110033
Total Number of Pages Submitted in bid documents: - 118

Sheet for verification of licence details

Sl. No	NIT Sl. No	Name of the MEDICAL DEVICES/CONSUMABLE as per NIT	Manufacturer		Importer		Validity		GMP/ WHO GMP/ COPP (Import)/BIS/ISI/ISO	
			Forms Number	Manufacturing license Number	Forms Number	Import license Number	From	To	From	To
1	1	POC Kits	–	–	Form 10 MD-15	NCD-204/15 IMP/IVD/ 2018/000040	01-9-15 01-12-18	31-8-18 06-12-23	06-09-17	05-09-20 (ISO 13485:2016-QMS)

Note:- Assisted in technical evaluation in reference to letter no.BMSIC/40010/47-2019 /6405 dt 22.01.2020 on the basis of documents provided by BMSICL as check list II,III & IV. Provided checklist compiled with due deligence and care.Inspite, some inadvertent discreprencies could have been crept in. Humble request to all concerned to bring to the notice in due time if any discrepencies are observed for rectification.

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