

साकेत नगर भोपाल (मध्यप्रदेश) - 462020 Saket Nagar, Bhopal (M.P.) – 462020

Ref: RC/AIIMS BPL/2024-25/Micro/RVL Project/PAC -166(i) /1223,

Dated29/08/2024

NOC for Web Challenge

Sub: Proposal for the procurement of **QIAstst DX System (Multiplexing Platform for Syndromic testing),** for the Regional Virology Laboratory Project under Department of Microbiology, AlIMS Bhopal on proprietary Basis through **QIAGEN India Pvt. Ltd, New Delhi** Inviting Comments thereon.

A request received from the **Department of Microbiology**, **AIIMS Bhopal for the procurement of QIAstst DX**System (Multiplexing Platform for Syndromic testing), under the project, funded by ICMR on proprietary basis.

A notice is being uploaded for general Information of aspirant **Manufacturer/Dealer/Distributor** to submit their objections/proposal, if any, on proprietorship of these items.

In case, the product of any Manufacturer/ Authorized distributor/ dealer conforms to the enclosed specifications, they may submit their proposal for the supply same item along with the following: -

- (i) Details of the required product brochure.
- (ii) Point-by -point compliance of the enclosed specifications, along with all relevant documentary evidence.

The objection/proposal should be sent in sealed cover to, The I/c Administrative Officer, Room No:137, Research Cell, 1st Floor, Sardar Vallabh bhai Patel Bhawan, (Medical College Building), AIIMS Bhopal, Saket Nagar, Bhopal (462020) so as to reach on or before 05/09/2024 up to 17:00 Hrs., (if there is any holiday on the last submission day, the next working day will be accepted as due date) failing which it will be presumed that no any other vendor is interested to offer comments/protest and case will be decided accordingly on its merit.

The reference number: RC/AIIMS BPL/2023-2024/Micro/RVL Project/PAC-166(i)/1223, due on: 05/09/2024 should be super scribed on sealed envelope.

-Sd/
Your Faithfully
I/c Administrative Officer
Research Cell AIIMS Bhopal

Enclosed:

- 1. proprietary Certificate of OEM
- 2. Authorization Letter
- 3. Schedule of Requirement with Specification



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Proprietary Certificate



27.10.2023

INDIA

PROPRIETARY CERTIFICATE

To Whom it May Concern,

QIAGEN INDIA Pvt. Ltd., Corporate One, Plot No. 5, District Centre, Jasola-110025, New Delhi, is a subsidiary of QIAGEN GmbH, Qiagen Strasse 1, 40724, Hilden, Germany. Therefore, QIAGEN India is authorized representative to bid, negotiate, sell, and conclude the contract in regard to business in India.

QIAGEN is the legal manufacturer of these listed items. The mentioned products are only being manufactured by QIAGEN worldwide and are a proprietary product.

S. No.	Material code	Product Name	
1	9002814	Qiastat-Dx Analytical Module	
2.	9002813	Qiastat-Dx Operational Module	
3.	9002824	Qiastat-Dx Analyzer	
4.	691411	Qiastat-Dx Gastrointestinal Panel	
5.	691214	Qiastat-Dx Respiratory Panel	
6.	691611	Qiastat-Dx Meningitis (ME) Panel	

For, M/s Qiagen India Pvt. Ltd.

Thanks & Regards.

Ganesh Singh Bisht

Ganeshsingh.bisht@qiagen.com

NEW DELH

Dr. DEBASIS BISWAS

Principal Investigator Regional Virology Laboratory All India Institute of Medical Sciences AllMS, Saket Nagar, Bhopal-462020

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CIN: U74900 DL 2009 PTC 196804



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Authorization Letter



24th May 2024

To, The Director All India Institute of Medical Sciences (AIIMS) Bhopal Bhopal, MadhyaPradesh

Sub: Authorization letter for Science House Medicals Pvt Ltd Ref: SHBPL-QSTATDX-001-24.05.24 Dated: 24.05.24

Dear Sir

This is to confirm that we **QIAGEN India Pvt Ltd** are the OEM of **QIAstat Dx system** quoted with above referred proposal.

We hereby authorize M/S. Science House Medicals Pvt Ltd C-65, Gautam Nagar, Govindpura, Bhopal (M.P.) – 462023 to quote and supply our Quoted Products with respect to the above referred QIAGEN proposal: SHBPL-QSTATDX-001-24.05.24.

We shall notify the above tendering authority if there is any change in the agreement between M/S. Science House Medicals Pvt Ltd C-65, Gautam Nagar, Govindpura, Bhopal (M.P.) – 462023 and us regarding authorized distributorship of our products and further undertake to supply the items quoted by the distributor on my / our behalf at the quoted in the tender enquiry in case of such a change of agreement.

QIAGEI Pradia PVILtd

Dr. DEBASIS PISWAS
Principal Investigator
Regional Virology Laboratory
All India Institute of Medical Sciences
AllMis, Sahot Negar, Bhopal-462020

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Schedule of Requirement

Sr. No	Name of Item	Required Qty
01	QIAstst DX System (Multiplexing Platform for Syndromic testing),	01 Nos.



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Technical Specifications with terms and conditions

Specification for Multiplexing Platform for Syndromic testing

- 1. System should be modular with option of scalability and can work in any clinical/laboratory setting without need of classical 3 room molecular biology set up.
- 2. The system should use prefilled cartridges with predefined assay protocols, via displayed step-by-step instructions, offering an intuitive touch screen interface.
- 3. The system should able to process direct dry swab or liquid transport medium directly in cartridge without any pretreatment manual steps by real time multiplex PCR technology.
- 4. The system should have multiplex capability Up to 48 plex.
- 5. The system should take less than a minute of hands on time prior to start run and post that complete walkaway.
- 6. Run time should not be more than 60-70 min.
- 7. The system should be US FDA, CE IVD approved.
- **8.** Respiratory panel should have 22 pathogens including SARS CoV2, other respiratory virus and bacterial. There should be provision to use dry swab also for the testing.
- Gastrointestinal panel with 22 pathogen including Virus, Bacteria & Parasite. Assay should report toxin content of STEC (stx1 and/or stx2) also.
- 10. Meningitis panel should have 14 pathogens including Virus, Bacteria & Fungi
- 11. Viral Vesicular Panel should have minimum 7 pathogens including MPXV clade 1, MPXV clade 2, Herpes simplex virus 1, Herpes simplex virus 2, Human herpesvirus 6, Enterovirus, Varicella zoster virus
- **12.** System should have full process internal control and single sample can be processed with complete confidence.
- **13.** The system should be able to process respiratory panel including SARS-CoV-2 to support efforts to provide accessible testing to meet the demands of the COVID-19 outbreak. Assay performance should not be affected with new SARS CoV2 variant.
- **14.** The cartridges should contains on board all necessary reagents and should be stored in room temperature.
- **15.** The system has provision of visual check of the sample through inspection window to confirm that the liquid sample has been loaded.
- 16. The analyzer should have inbuild barcode scanner for samples and cartridges.
- **17.** Detected amplification signals should be interpreted by the integrated software and are reported via an intuitive user interface.
- **18.** The cartridges should also contain individually packaged transfer pipettes for dispensing liquid sample.
- **19.** The system should able to deliver diagnostics actionable information by reporting CT values along with amplification curves.
- 20. System should have in build touch screen and separate computer/laptop should not be needed to process the samples.
- System should be LIS compatible to integrate Laboratory/Hospital LIMS system with bidirectional connectivity.
- **22.** System should have ability to for cloud based connectivity to have remote access to system, results, epidemiological data reporting, remote technical support etc.
- 23. Manufacture should have pipeline to develop mire assays in coming years.
- **24.** The instrument should work on electrical supply of 220 volt and provided Indian type of electrical plugs/Switches



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- **25.** Installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and in-house calibration certificates should be provided.
- **26.** System should be provided with 5 years warranty and followed by 5 years CMC; the cost of year-wise CMC should be quoted separately along with the bid. The equipment should be certified by BIS/CE/USFDA/ISO as applicable.