भारत सरकार/Government of India

स्वास्थ्यऔर परिवारकल्याणमंत्रालय/ Ministry of Health and Family Welfare प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSSY

अखिलभारतीयआयुर्विज्ञानसंस्थान/All India Institute of Medical Sciences agiri.edu.in मंगलगिरि, आंध्रप्रदेश/Mangalagiri, Andhra Pradesh

www.aiimsmangalagiri.edu.in

Ref: AIIMS/MG/MICRO/Non DPR/Fully Automated Multiplex Film Array Syndromic System/2023-24/05

Date: 21-11-2024

Call for Objection

Subject: Inviting comments/objection, if any before declaring proprietary article for procurement of "Fully Automated Multiplex Film Array Syndromic System" for the Department of Clinical Microbiology AIIMS Mangalagiri.

Clinical Microbiology Department, AIIMS Mangalaigiri has to procure 'Fully Automated Multiplex Film Array Syndromic System' through Proprietary Article basis.

The proposal submitted by M/s. Biomerieux India Pvt Limited, New Delhi who is authorized wholly owned subsidiary in India and M/s. Biofire Diagnostics, LLC USA which is a company of biomerieux S.A., France who is sole manufactures of this item along with Proprietary Article Certificate are attached & uploaded on Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days (i.e. 02/12/2024) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in Annexure -I, if any Firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, Room no: 2151, Logistic block at AIIMS Mangalagiri in a sealed envelope with above reference on or before 02/12/2024 up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

AAO (Procurement) AIIMS Mangalagiri

PAC CERTIFICATE

P-3 Form

(To be attached with P-2 form for Proprietary items)

AllMS, Mangalagiri

PROPRIETORY ARTICLE CERTIFICATE

It is certified that the item <u>FULLY AUTOMATED MULTIPLEX FILM ARRAY SYNDROMIC SYSTEM</u> required should be purchased from BIOMERIEUX INDIA PVT. LTD. To the best of my knowledge BIOMERIEUX INDIA PVT. LTD. are the sole Dealer/agents of the sole manufacturer.

Similar items manufactured by other finm(s) shall not be suitable for our purpose as it is a closed system. The consumables and reagents of same company has to be used to provide appropriate reliable results.

(Signature indenter)

Date: 04/12/2023s, MD(Microbiology), DNB, MNAMS
Assistant Professor

Designation:

Department of Microbiology

I India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh

Department:

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Signature of Heads Miles and Section MD(Gold Medalist) PDCC Infectious Diseases)

N.B. Department of Ministry Mistally lead above certificate should satisfy himself that the article is genuinely of propagatory, natural manufactured under patent laws.

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Dated: 18 Aug. 2023

PROPRIETARY ARTICLE CERTIFICATE

This is to certify that FILMARRAY® Instrument (an automated in vitro diagnostic (IVD) device intended for use in combination with assay specific reagent pouched to detect multiple nucleic acid targets contained in clinical specimens) is a proprietary product of BIOFIRE® Diagnostics, LLC, USA which is a company of bioMerieux S.A.,

The following BIOFIRE® Kits/Panels/reagents are used along with our above-mentioned system, are also proprietary

- Meningitis/Encephalitis (ME) panel - Blood Culture Identification 2 (BCID 2) Panel

- Gastrointestinal (GI) Panel

- Respiratory Panel 2.1 (RP2.1)

- Pneumonia Panel PLUS

- Joint Infection Panel

While distributed and marketed in India by its wholly owned 100% subsidiary bioMerieux India Pvt. Ltd., New Delhi and through its authorized set of distributors only.

The above features are unique and there are no other manufacturers in the world.

Sincerely Yours,

For bioMérieux India Pvt. Ltd.

Bivash

Bivash CHAKRABORTY

CHAKRABORT Head - Public Business, Regulatory Affairs &

Quality (Authorized Signatory)

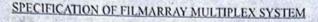
Digitally signed by BIVASH CHAKRABORTY

Date: 2023.08.18

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bloMerleux India Pvt. Ltd.

MD(Gold Mcdallst) PDCC (Infectious D
Professor & Head
Toll Free No.: 18001027791 – customercare India@blomerleux.com
Professor & Head
Professor & He



- System should be based on film array technology.
- The detection should be based on dye hybridization and melt curve analysis. Reports should be generated automatically without setting any threshold or manual adjustment.
- Workstation should comprise of complete solution for nucleic acid extraction, amplification and detection in a single go without manual intervention.
- Should be able to do testing for upper & lower respiratory infections, gastro intestinal
 pathogens, identification of blood culture pathogens and meningitis/encephalitis infection.
- System should be very compact and should not require molecular infrastructure or real time
 PCR setup (pre, post and amplification areas) for testing.
- 6. System should do the multiplex syndrome based testing for above infections.
- 7. System should be modular.
- Should have minimum hands on time less than 5 minutes and results should be available in not more than 60 minutes.
- GI panel should detect bacteria, viruses as well as protozoa, especially V cholera, Shigella,
 Diarrheagenic E.coli, Rota virus, Entamocba, cryptosporidium etc directly from stool samples.
- 10. Blood culture ID should detect most common gram positive, gram negative bacteria and Candia sp, with antibiotic resistance genes.
- 11. Respiratory panel should combine viral and bacterial targets directly from sample.
- 12. Meningitis / encephalitis should combine viral, bacterial and fungal targets directly from CSF.
- 13. One supplier must be capable of supporting entire workstation for requested infectious diseases.
- Company should provide details of the kit U.S FDA/DCGI/CE-IVD approval certificate and should quote price of the kits available.
- 15. Reagents and consumables for 125 tests for respiratory panel, 50 tests for Blood culture ID panel and 25 tests for Meningitis panel to be provided.
- 16. Warranty: 5 years from the Date of Satisfactory Installation. Warranty period should include preventive maintenance and calibration of equipment every 6 months.
- 17. CMC: 5 years after expiry of warranty [i.e 6th to 10th year].

18. Breakdown assistance: The breakdown calls should be attended in maximum of 48 hours after documented communication or complain log.

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Dr. SUMIT RAI

Adalist), PDCC(Infectious Diseases)

Professor & Head

Professor & Head

All Microbiology

Little of Medical Sciences

Manga Liri (Andhra Pradesh)

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SPECIFICATIONS

Objection should be submitted in following format:

S. no	Item specification as given	Specification offered by firm	Deviation if any	Remarks

