

Department of Medicine ALL INDIA INSTITUTE OF MEDICAL SCIENCES New Delhi 110 029

Date: 6th Sep, 2018

(Reference Medicine/ Proprietary/ M&E / 2018-19

Subject: Purchase of TB Lamp Assay for the Department of Medicine AIIMS, New Delhi on proprietary basis- inviting comments thereon.

The Department of Medicine needs to TB Lamp Assay from M/s. HUMAN Gesellschaft for Biochemica und Diagnostica mbH Germany proprietary basis. The proposal submitted by M/s. HUMAN Gesellschaft for Biochemica und Diagnostica mbH Germany and PAC Certification are attached & uploaded on website.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/items within 15 days from the date of issue/uploading of the notification giving reference Medicine/ Proprietary/ M&E / 2018-19.

The comments should be sent to professor & Head Department of Medicine Room No. 3094A 3rd floor teaching block at AIIMS, New Delhi on or before 25th Sep, 2018 up to 5.00 pm failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on Merits.

Thanking you

Sincerely

Dr. Naval K. Vikram

Officer in-charge

Department of Medicine

Instrument specifications for (TB LAMP assay)

The equipment should be a programmed incubator with visual fluorescence detection system, Sample Lysis and Amplification Incubation Chambers

Minimum Tests per run

16

Time per run

< 1h

Sample volume

Maximum 60 μl (sixty microlitre)

Test positions

Upto 16

System should have two incubation Chambers with following features:

Sample lysis Wells

Temperature

90°C

Time

5 minutes

2. Amplification Incubation Chamber

Temperature

67 °C (preinstalled, fixed) isothermal reaction

80 °C (preinstalled, fixed) enzyme inactivation

Time

40 min (preinstalled, fixed) isothermal reaction

5 min (preinstalled, fixed) enzyme inactivation

Temperature

Accuracy

± 0.5 °C (for reaction)

± 1.0 °C (for sample lysis & enzyme inactivation)

Result analysis

Visual reading of fluorescence, Qualitative

Light source

LED

Wavelengths

450~500 nm (465~470 nm)

Applicable dye

Calcein

Wavelength filter

1

Electrical requirements

100V-240 V~ ±10%; 50Hz/60HZ, 240 W

Warranty

5 Years

Quality Management

System

EN ISO 9001(ISO 9001: 2015)



Gesellschaft für Biochemica und Diagnostica mbH

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To whom it may concern

Proprietary Certificate HumaLoop T Cat.-Ref. 961000

We.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Max-Planck-Ring 21, 65205 Wiesbaden, Germany

declare that the above mentioned HumaLoop T instrument (incubator for sample processing, amplification and visual result reading), used for TB LAMP Test is a proprietary product within the framework of an OEM supply agreement between Eiken Chemical Co. Ltd. and HUMAN Gesellschaft für Biochemica und Diagnostica mbH.

The above mentioned product will be supplied by Biohouse Solutions Pvt. Ltd, 409, Palm Springs Plaza, Golf Course Road, Gurugram 122002, India through HUMAN Gesellschaft für Biochemica und Diagnostica mbH.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Wiesbaden, August 27, 2018

Dr. Torsten Börchers Vice President Quality Assurance and Regulatory Affairs

Human

Gesellschaft für Biochemica und Diagnostica mbH Max-Planck-Ring 21 65205 Wiesbaden-Delkenheim Germany