

All India Institute of Medical Sciences Jodhpur

Admn/Prop/69/2021-AIIMS.JDH

Dated: - 26th October, 2021

Subject: Purchase of New Born Screening (NBS) System for Extramural Research Project at

AIIMS Jodhpur on proprietary basis - <u>Inviting comments thereon.</u>

The Institute is in the process of purchasing New Born Screening (NBS) System for

Extramural Research Project at AIIMS Jodhpur on proprietary basis from M/s Bio-Rad Laboratories

(India) Private Limited and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection,

comments, if any from any manufacturer regarding proprietary nature of the equipment within 21

days of issue giving reference Admn/Prop/69/2021-AIIMS.JDH. The comments should be received

by office of Deputy Director (Administration), Medical College at AIIMS, Jodhpur on or before

15th November, 2021 upto 03:00 PM failing which it will be presumed that any other vendor is

having no comment to offer and case will be decided on merits.

Deputy Director (Administration)

Enclosed: Related documents enclosed.



Bio-Rad Laboratories, Inc. Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 – 1803 Telephone 510 724 7000 Fax 510 741 5824

PROPRIETARY CERTIFICATE

This is to certify that the VARIANT™ nbs Newborn Screening System (Catalog number: 250-3010) is a product of Bio-Rad Laboratories, Inc., 4000 Alfred Noble Drive, Hercules, California 94547 USA. The system and integral spare parts are manufactured for Bio-Rad Laboratories, Inc., by the contract manufacturer, OEM SYSTEMS Co. Ltd, located at 84 MEKAWA MAKISHIMA-CHO, UJI-SHI, Kyoto Japan 6110041. Bio-Rad Laboratories, Inc. is the sole legal manufacturer and distributor for this product worldwide.

Only Bio-Rad proprietary reagent kit VARIANT™ NBS Sickle Cell Reorder Pack (Catalog number: 250-3000) and required consumables must be used in conjunction with the VARIANT™nbs Newborn Screening System (Catalog number: 250-3010).

Bio-Rad Laboratories India Pvt. Ltd is a direct subsidiary of Bio-Rad Laboratories, Inc., and is the sole entity responsible for importing, promoting and marketing the VARIANT™ nbs Newborn Screening System (Catalog number: 250-3010), VARIANT™ NBS Sickle Cell Reorder Pack (Catalog number: 250-3000) and its associate spare parts, reagent kits and consumables in India.

Authorized Signatory:

Jackie Buckley

Regulatory Affairs Manager

7-15-2019

Date:

Submitted by: Raizada Associates

*Note: Variant NBS sickle cell program is based on the principles of cation-exchange high performance liquid chromatography (H.P.L.C.).

Enclosed- Complete Technical Brochure and S.O.P. document is enclosed for your kind perusal.

New Born Screening (NBS) System

- 1) Automated, HPLC based system for screening of Hb F, HbA, HbS, HbD, HbE and HbC and some thalassemia conditions in neonates.
- 2) The system should be able to accept samples of neonatal blood collected by heel stick method on filter paper.
- 3) The system should have two dual piston pumps with a maximum pressure of 4000 psi & a precision of + 1%
- 4) The system should be capable of testing greater than 250 samples in a day.
- 5) The sample testing time should be less than 4 minutes to enable high throughput screening.
- 6) The company should have an installation base in India and should be able to provide the relevant product and service support in India.
- 7) Complete ready to use reagent kit for at least 1500 tests with one HbA2/F control should be provided with buffers in plastic tanks to view the levels of buffers, columns, primers, calibrators and sample vials.
- 8) The system should have alarms, for overflow of waste tank, as well as built in alarms for calibration and equipment failures.
- 8) Software should have customized reporting format, giving info on the subtype and quantity of hemoglobin detected. Also the software should enable result storage of minimum 5000 chromatograms.
- 9) The software provided should allow for real time viewing of the analysis of the sample
- 10) The system with the aid of software should be able to print customized reports.
- 11) The system should have a Barcode reader for easy sample identification.
- 12) Desktop monitor computer with 21 inch, i7 Processor, HDD 1 TB/ SDD 512 MB, RAM 8 GB, Operating system windows 10 with Inbuilt Microsoft office.
- 13) The system should have been used in at least one newborn sickle cell screening programs in India and should have more than 10 installations worldwide.
- 14) A Punching kit for DBS Collection
- 15) 2 KVA Online UPS
- 16) Instrument should come with an ultrasonicator (minimum capacity 12 lit, frequency $40 \pm 3 \text{ kHz}$)
- 17) Instrument should come with 5 years' warranty

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