



क्रमांक: AIIMS/R/CS/Bio/19/03-176/PAC

दिनांक: 13-09-2019

### NOTICE

**Sub:-** PAC purchase of consumable “**D10 Hemoglobin Analyzer with Accessories**” for Department of Biochemistry at AIIMS, Raipur on Proprietary basis- **Inviting Comments Thereon.**

The institute is in the process to purchase through PAC consumable item “**D10 Hemoglobin Analyzer with Accessories**” for Department of Biochemistry at AIIMS Raipur from **M/s Bio-Rad Laboratories India Pvt. Ltd. Mumbai** and Company on proprietary basis. The local agent for above item is **M/s. Scientific Traders, Raipur**. The proposal submitted by department of Biochemistry at AIIMS, Raipur and PAC Certifications is attached which is to be upload 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 Consumables/ items within **10 days** from the date of issue/ upload of notification by reference no. AIIMS/R/CS/Bio/ 19/03-176/PAC. The comments should be sent to Stores Officer, AIIMS, Raipur on or before **23-09-2019** up to **3.00 pm**. failing which it will be presumed that any other vendor having no comment to offer and case will be decided on merits.

Encl:-

01. Certificate for Purchase of Proprietary Article.
02. Technical Specification

  
भंडार अधिकारी  
अखिल भारतीय आयुर्विज्ञान संस्थान (छत्तीसगढ़)  
**Stores Officer (C.G.)**  
एम्स, रायपुर (छ.ग.)  
**AIIMS Raipur (C.G.)**



**स्वामित्व प्रमाण पत्र**  
**Proprietary Article Certificate**

फाइल संख्या और संदर्भ File Number and Reference				
1	सामग्री का विवरण Description of article	The equipment is required for the testing of parameters in the Clinical Service Lab (2nd floor, room no.2214) in the Department of Biochemistry.		
		S. no.	Complete Description of items (Specification Model, Catalog No)	Qty. Req.
		1	D10 Hemoglobin Analyzer with Accessories, (Complete description is enclosed as annexure-I)	01 Nos
2	पूर्वानुमानित मात्रा/वार्षिक आवश्यकता Forecast of quantity/Annual requirement	As mentioned in above table		
3	उपरोक्त मात्रा हेतु अनुमानित मूल्य Approximate estimated value for above	<b>Total Amount ₹ 23,18,700.00</b>		
4	निर्माता का नाम एवं पता Maker's Name and Address	<b>M/S Bio-Rad Laboratories India Pvt. Ltd.</b> Fatima Villa, Behind Atlanta Arcade Charch Road, Andheri (east) Mumbai-400059 Tel: +91-22-29254437/66989015, 32946441, Email: <a href="mailto:sales.india@bio-rad.com">sales.india@bio-rad.com</a>  <b>Registered Office:</b> Plot No.1270 Basement, Lal Dora, Village Kapashera, Opp. Fun-Food Village, New Delhi-110037, Tel: +91-11-25065913 Contact: Mr. Lalit Dhoble (09975728990)		
5	अधिकृत डीलर/स्टॉकिस्ट का नाम Name(s) of authorised dealers/stockists	<b>M/S Scientific Traders</b> H.O.30/162, Tatyapara, Badaipara Road, Raipur-492001, (Chhattisgarh) Tel: 0771-2535351, 2225373, Email: <a href="mailto:admin@scientifictraders.in">admin@scientifictraders.in</a> Contact: Mr. Chetan Wadher (9826124489) <a href="mailto:chetan.wadher@scientifictraders.in">chetan.wadher@scientifictraders.in</a>		
6	मैं पीएसी के आधार पर उपरोक्त खरीद को स्वीकार करता हूँ। और यह प्रमाणित करता हूँ कि: नोट- (बी) (सी-1) या (सी-2) में से केवल एक को बनाए रखने के लिए टिक करें जो भी लागू हो और दूसरों को काट दें। कृपया ए टिक कर पुष्टि करें इसके बिना पीएसी प्रमाण पत्र अवैध होगा। I approve the above on PAC basis and certify that:- Note: Tick to retain only one out of (b) (c-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it-without which PAC certificate will be invalid.			
6(a)	यह एकमात्र फर्म है जो इस मद का निर्माण/संग्रहण कर रहा है। और This is the only firm who is manufacturing / stocking this item. AND	✓		
6(b)	किसी अन्य फर्म द्वारा समरूप मद निर्मित/विक्रय नहीं किया जाता है जिसका उपयोग इसके बदले किया जा सकता है। अथवा A similar article is not manufacturing /sold by any other firm, which could be used in lieu OR	✓		
6(c-1)	कोई अन्य मेक/ब्रांड निम्नलिखित कारणों (जैसे ओईएम/वारंटी के) के लिए उपयुक्त नहीं होगा। अथवा no other make/brand will be suitable for following tangible reasons (like OEM/warranty spares) OR	✗		
6(c-2)	कोई अन्य मेक/ब्रांड निम्नलिखित कारणों से उपयुक्त नहीं होगा (अगर पीएसी पिछले खरीद में भी दिया गया था, तो कृपया इसके बाद से अधिक स्रोतों का पता लगाने के लिए प्रयास करें)। तथा No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources): OR	✗		
7	प्रस्ताव के लिए वित्त भाखा की सहमति का संदर्भ (कार्रवाई भंडार और लेखा विभाग द्वारा की जायेगी)			

Reference of concurrence of finance wing to the proposal (Action will be taken by Stores and Account Department )

पिछले तीन सालों में इस मद की पीएसी खरीद का इतिहास नीचे दिया जा सकता है (यदि कोई हो)  
History of PAC purchase of this item for past three years may be given below (if any)

प्रदायक का नाम Name of the supplier	आदेशित मात्रा quantity ordered	आदेश पर मूल दर Basic rate on order (Rs.)	प्रतिकूल प्रदर्शन रिपोर्ट अगर कोई हो adverse performance reported if any
आदेश/निविदा संदर्भ और दिनांक order/tender reference & date			

अनुमोदन करने वाले प्राधिकारी का हस्ताक्षर .....  
Signature

*[Handwritten Signature]*  
27/04/19

दिनांक .....  
Date -----

अधिकारी का पदनाम .....  
Designation of Officer -----



## Detail specifications for D10 Hemoglobin Analyzer, Make: Bio-Rad

SL.	Item Description
1	Automated HPLC system, must be dedicated to HbA1c testing and Thalassaemia and Haemoglobinopathy testing and Screening.
2	The system should be able to screen and quantitate haemoglobins Hb A2, Hb A, HbA1c and Hb F and detect the most commonly occurring abnormal hemoglobins like Hb S, Hb D, Hb E, Hb C, Hb Q- India, Hb D-Iran, Hb Lepore, Hb Saurashtra and other rare abnormal hemoglobins in both homozygous and in single and double heterozygous conditions.
3	The system should have the provision of presumptive identification of Hb Barts and Hb H and various alpha chain variants like Hb J Meerut, Constant Spring etc.
4	The company must have an installation base of minimum 1000 in India for doing Thalassaemia and Haemoglobinopathy of which there should be atleast 30 installation in NABL or CAP accredited Laboratories and should be able to provide the relevant product and service support
5	The company must have at least 15 years of presence in India with availability of system & reagents for thalassaemia and haemoglobinopathies testing. And must have users for Haemoglobinopathies for a minimum of last 10 years.
6	A minimum of 10 customer satisfaction certificate should be provided.
7	The system should have dual performance of HbA1c estimation and Hemoglobin Testing for thalassaemia and hemoglobinopathies using a single kit so as to avoid any change of kit or reagents for each test, thus reducing the loss of buffers and reagents. The change from one test to another should just happen with a click of button and should estimate A1c in not more than 3 mins and A2/F estimation in not more than 6.5mins.
8	The system should have automatic barcode positioning facility.
9	The system should have continuous or batch wise sample analysis with random access and sample bar code sensor
10	The system should have the facility of primary tube sampling and direct dilution of the samples without manual intervention.
11	The system should have Tube Venting Capabilities so that there is no resistance caused while pulling blood from the tube which can impact the repeatability of results.
12	Complete ready to use reagent kit must be provided with buffers in plastic tanks to view the levels of buffers. Columns, primers, calibrators and sample vials must be within the kit as a single kit thus making it easy to calculate cost per test.
13	All reagents required should be of the same lot for reliability of result and cost calculation per test.
14	The system should have an inbuilt system check facility which checks that all the system parameters (eg, cartridge, buffer, reagent, waste etc) are ready before the sample analysis.
15	The buffers must be provided with in plastic tanks to view the levels of buffers during the run. Also there should be a system which monitors liquid volume and an alarm is generated by Software if the buffer reduces than the set volume.
16	The system should be able to detect correct A1c values in presence of abnormal hemoglobin variants like HbD, HbE, HbS & HbC
17	The System should be NGSP (National Glycohemoglobin Standardisation Program) Certified and traceable to IFCC reference method.
18	The system should offer both NGSP & IFCC value reporting on the same patient report, control & calibrator report.
19	The required item must be USFDA or European CE approved product (authentic documents must be submitted along with the offer).
20	The HPLC system should have better precision, CV less than 2.5%.
21	The system should have in-kit external standards for instrument calibration ensuring accurate quantitation of results. The calibration should not be more than 2 point calibration.
22	It should have an sufficient data hard disk approx. 80GB hard drive and a remote data access feature when connected to LAN or Intranet.
23	The system must have a software for real time viewing of the analysis of the sample
24	It should have an offline CD-ROM and an online chromatogram library which should be a searchable database with more than 400 chromatograms of fully classified abnormal haemoglobins and thalassaemias along with their clinical and molecular classification.

27/02/19

SL.	Item Description
25	The HPLC system must be used in govt. thalassaemia screening programs in India and a minimum of 15 Govt user list of the thalassaemia HPLC kit should be provided.
26	The system should have an on board QC Menu capable of storing the quality control data and printing the standard deviation and Coefficient of Variation values.
27	The company should provide normal and abnormal third party controls for Hb A2, Hb F and Hb S and provide External Quality Assurance Scheme (EQAS) to help compare results with similar users worldwide.
28	The system software should give information on the subtype and quantity of hemoglobin detected along with viewing of full chromatogram on the system. Also the software should enable result storage of minimum 10000 chromatograms without the need for an additional computer or software. It should also have a builtin DVD Drive to update kit parameters – calibrator values, integration parameter, lot number, expiry details of reagent etc.
29	The result from the machine should be presented in a symmetrical order (vertical) with proper description of date, time of injection, sample ID, age, sex, total area count, different fractions of haemoglobins along with their quantity with flagging for out of range values and the chromatogram with each peak marked with their respective retention time for easy viewing of the result.
30	It should have a built in vacuum-based degassing system, automatic equilibration and wash procedures and have built in column thermostat for reproducibility.
31	The system must be capable of holding 10 samples at a time and should have the facility of expanding it to 50 samples along with a rack loader so that it can be used for at least 50 samples at a time.
32	The system should have a polyethylene waste tank which has a sensor to detect a 95% full tank and gives an alarm when sensor is tripped, as well as built in alarms for calibration and control failures for equipment.
33	The waste tank should be sufficiently big (atleast 5 liters) so that it reduces user interference with the machine and help in smooth running of large volume of samples without interruption.
34	The reagent containers should have a capacity of more than 1.5 liters so that the user does not need to change buffers regularly.
35	The system must have a dual Piston Pump to give a continuous and a precise buffer gradient.
36	The company must have feature of capillary collection kit for remote sample collection with sample stability at 2-8 C for 14 days
37	The company must provide a support of factory trained engineers, application specialist and thalassemia expert for the technical and chromatogram interpretation related issues.
38	Standardization: Traceable to the Diabetes Control and Complications Trial (DCCT) reference methods and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).
39	The manufacturer should be ISO 13485 certified.
40	The HPLC system should have flexibility to use various samples tube sizes of 13x75mm, 13x100 mm micro capillary tubes (Micro cuvette startstedt), Micro capillary tubes brands (other than Micro cuvette startstedt) defined as sample vials 1.5ml sample vials.
41	The HPLC system should have touch screen LCD display operation with resistive colour touch screen, simple to use, user friendly and with menu driven facility. The software should be able to show not just the values and run process but also full chromatogram.
42	The HPLC system should have built in thermal printer.
43	The instrument provider should also provide training to the concerned doctor for working, quality control, testing, evaluation and interpretation.
44	The instrument should be supplied with all the standard accessories.
45	Suitable Online UPS to provide 25-30 mins backup during power failure should be supplied along with the system.
46	The vendor must provide three months reagents for testing of HbA1c (4500tests) or HbA2/F (2200tests) along with the instrument. Suitable control for three months should also be provided for both the parameters.
47	The system should be provided Warranty for 03 years followed by CMC for next 03 years on all the parts, accessories and UPS.

27/2/09



Bio-Rad Laboratories

Diagnostics Group  
4000 Alfred Nobel Dr.  
Hercules, CA 94547 - 1803  
Telephone 510 724 7000  
Fax 510 741 5824

**TO WHOMSOEVER IT MAY CONCERN**

This is to certify that the D-10™ Hemoglobin Testing System is a registered trademark of Bio-Rad Laboratories USA used as analysis and monitoring of HbA<sub>1c</sub>, Thalassemia and Hemoglobinopathy..

As per our knowledge there is no other manufacturer in the world for this kind of integrated HPLC testing system meant for the analysis and monitoring of HbA<sub>1c</sub>, Thalassemia and Hemoglobinopathy.

**Sallent features of the system are:-**

1. Primary tube sampling.
2. Automated bar code reading.
3. Bidirectional LIS
4. Over 10,000 direct storage of chromatograms.
5. Accurate identification and detection of correct A<sub>1c</sub> values in presence of abnormal hemoglobin variants like HbD, HbE, HbS & HbC.
6. Unique Dual program with a special feature for HbA<sub>1c</sub> (in 3 mins) and Thalassemia & Hemoglobinopathies testing in 6.5 mins without the change of cartridge or reagents. It quantitates Hb A<sub>2</sub> and Hb F accurately for the monitoring of thalassemia and detects structural hemoglobin variants like Hb S, Hb C, Hb D, Hb E, Hb Lepore, Hb D Iran etc and alpha chain variants like Hb Q India and combination of hemoglobinopathies and thalassemia like Hb S-β thalassemia, Hb D- β thalassemia, Hb E- β thalassemia are also detected.
7. Calibration for HbA<sub>1c</sub>, Hb A<sub>2</sub> & F.
8. Offline Library of variants.
9. Real time viewing of sample analysis.
10. Dual reporting units for HbA<sub>1c</sub> in NGSP unit as % and IFCC unit as mmol/mol.
11. Market leading accuracy & reproducibility.

These products are also proprietary to Bio-Rad Laboratories Inc.USA.

Catalog No.

Description

2200101  
2200201

D-10™ Hemoglobin A1c Reorder Pack  
D-10™ Dual Program Reorder Pack

Stin Amal  
27/07/19

For and on behalf of  
Bio-Rad Laboratories (India) Pvt Ltd.

*[Signature]*

11 June 2019

Authorized signatory

Original forwarded to SO  
27/07/19



TRUE COPY ATTESTED.

*[Signature]*  
RAJESH KUMAR AGRAWAL  
NOTARY/ADVOCATE  
RAIPUR, (C.G.) INDIA

25 JUL 2019