ALL INDIA INSTITUTE OF MEDICAL SCIENCES

BILASPUR (H.P)

Ref. No. Pathology/2023-196. **Dated: 15.11.2023**

Subject: Procurement of Hybrid Capture (HC-2) on proprietary basis- Inviting Comments thereon

A demand received from **Pathology Department AIIMS Bilaspur (H.P)** for the procurement of above cited item **(Hybrid Capture (HC-2))** on proprietary basis. The product is proprietary product of **QIAGEN India Pvt.Ltd.** The PAC certificate from the firm and its authorized suppler are attached and uploaded on website.

The above documents are being uploaded for open information to all, firms to submit the objections, with respect to proprietary nature of the product, if any within 15 days from the date of issue/uploading of the notification, giving reference no. **Pathology/2023-196.** The objections/comments should be sent to storeofficer@aiimsbilaspur.edu.in or Procurement Officer, AIIMS Bilaspur (HP) 174037, on or before 29.11.2023 up to 5:00 PM, failing which it will be presumed that any other vendor is having no comments to offer and the case will be decided on merit.

Faculty In charge
(Procurement)

Encl: Related Documents Enclosed
1) PAC certificate
2) Authorization certificate

(8)

12.09.2022

INDIA

To whomsover it may concern;

QIAGEN develops, manufactures and markets proprietary gene-based diagnostic tests for the screening, monitoring and diagnosis of human diseases. Our primary focus is in women's cancers and infectious diseases. We have applied our proprietary Hybrid Capture® technology to develop a successful diagnostic test for human papillomavirus (HPV), which is the primary cause of cervical cancer and is found in greater than 99% of all cervical cancer cases. Our HPV testing products, which are US Food and Drug Administration (FDA)-approved tests for the detection of HPV, are each a reproducible, objective test for the primary cause of cervical cancer.

Hybrid Capture is a signal amplification technology that combines the convenience of a direct probe test with the sensitivity of an amplification test, requires minimal sample preparation and provides objective test results. The Hybrid Capture system comprises of the HC2 High-Risk HPV DNA Test® kit (the *digene*® HPV test) and the micro plate luminometer DML 3000 along with accessories. Our patented Hybrid Capture RCS platform has been optimized for automated, high-throughput, cost-effective cervical cancer screening applications with the HC2 High-Risk HPV DNA Test kit.

The HC2 HPV test kits use an antibody capture chemiluminescence signal-detection system that involves signal amplification. The HPV DNA reacts with the base pairs of the test solution. This reacted viral DNA is combined with viral-specific RNA probes, creating hybrids. These RNA:DNA hybrids are then combined onto a solid phase coat, with subsequent capture by universal antibodies that are specific for that particular RNA:DNA nucleic acid hybrid. In turn, the RNA:DNA antibody is detected by a signaling antibody conjugated to alkaline phosphatase, resulting in chemiluminescence, which, when amplified, can be measured in relative light units (RLU) on the DML instrument.

The *digene* HPV Test kit uses our proprietary hybrid capture technology and contains individual RNA probes of the thirteen most significant cancer-causing, high-risk HPV types. Our HPV test products use a signal amplification process to detect small amounts of the HPV DNA collected from the cells of the cervix. Each test kit consists of RNA probes to specific HPV types, antibodies, detection reagents and a 96-well microplate coated with antibodies. The detection is carried out on the DML 3000 instrument system.

We manufacture the DML 3000 system and accessories to enable labs to perform the HC2 HPV tests (the *digene* HPV tests). The *digene* HPV tests and associated instrumentation have been approved by US FDA for testing patient samples. The equipment

QIAGEN India Pvt. Ltd.
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Hosur Sarjapur Road Junction | Kormangala 2 B Block | Bengaluru - 560068

CIN : U74900 DL 2009 PTC 196804

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set consists of the following:

- DML 3000™ Instrument and Version 2 Software

Patents and other proprietary rights are essential to our business. We own or have license rights to over 150 patents and patent applications. Our most significant patent rights relate to our Hybrid Capture technology and HPV types. Our Hybrid Capture technology combines two of the most significant technologies in the life sciences industry, DNA/RNA probes and monoclonal/polyclonal antibodies, to allow rapid, standardized gene-based testing in virtually any laboratory setting. In May 2001, we received a United States patent for our Hybrid Capture assay from the United States Patent and Trademark Office.

U.S. Hybrid Capture Patent Nos.

6,228,578B1

We have not out licensed our Hybrid Capture technology to any third party and believe our know-how and the complexity of our technology make it difficult for others to replicate our Hybrid Capture technology.

Our principal trademarks include:

a. digene

b. hc2 high-risk hpv dna test

c. hybrid capture

For, M/s Qiagen India Pvt. Ltd.

Thanks & Regards

QIAGEN INDIA PVT. LTD. NEW DELHI INDIA

Ganesh Singh Bisht
Asst. Manager Regulatory affairs
Ganeshsingh.bisht@qiagen.com

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MANUFACTURER'S AUTHORISATION FORM

Date: - 10/09/2023

To
The 'Executive Director'
All India Institute of Medical Sciences
Bilaspur, Himachal Pradesh-174001, INDIA.

Dear Sir,

Ref: Authority Letter for Hybrid Capture (HC2) System

We, **QIAGEN INDIA Pvt. Ltd.** who are proven and reputable manufacturers Of Molecular Diagnostic Instruments & Kits, having factories at Hilden, Germany and Germantown, US, hereby authorize **M/s Medihealth, 16-A, Calibre Plaza (A.C. Market), Bhadaur House, Ludhiana (Punjab) – 141008** to submit a bid, process the same further and enter into a Rate Contract with you against your requirement as contained in the above for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs. **Medihealth, 16-A, Calibre Plaza (A.C. Market), Bhadaur House, Ludhiana (Punjab) – 141008** is authorized to submit a bid, process the same with you against your requirement as contained in the above goods manufactured by us.

Yours faithfully,
Sanjay Kumar – Account Manager (MDx)
Mob :- 7042895138
Email :- Sanjay.Kumar@qiagen.com

For QIAGEN India Private Limited,

(Authorized Signatory)

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