ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

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Admn/Prop/48/2022-AIIMS.JDH Dated: -20th September 2022.

Subject: Purchase of Hybrid Capture (HC2) System the Department of Pathology at AIIMS, Jodhpur on proprietary basis-

Inviting comments thereon.

The Institute is in the process to Hybrid Capture (HC2) System for the department of Pathology at AIIMS, Jodhpur from M/s QIAGEN India Pvt. Ltd., Samyak Tower 39, Pusa Road, Karol Bagh, New Delhi - 110001 on proprietary basis. The proposal submitted by M/s QIAGEN India Pvt. Ltd., New Delhi and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/48/2022-AIIMS.JDH. The comments should be received by office of Deputy Director (Admin), Medical College at AIIMS, Jodhpur on or before 11th October 2022 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 (Admin)

Enclosed: Related documents enclosed.

QIAGEN

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

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CIN : U74900 DL 2009 PTC 196804

QIAGEN

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

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Technical Specification for Hybrid Capture (HC2) System for HR-HPV DNA testing.

1. The instrument should be a benchtop, computer- controlled instrument.
2. The HPV DNA test should be able to detect a minimum of 13 high-risk types.
3. Use of whole genome probe technology for the detection of high-Risk types without hampering by insertions, deletions and mutations of genomes.
4. Detection Technology should use signal amplification technique (rather than target amplification technique).
5. Test has no need of stringent molecular diagnostics laboratory setup.
6. System should have all accessory parts/ instruments for complete processing of samples from sample to result.
7. Test kits and sample collection device should also be available with the instrument manufacturer.
8. Collected samples should be stable at room temperature for at least 2 weeks. Kits which ensure longer shelf life of collected sample materials will be preferred.
9. The HPV DNA test should support both manual and automated processing of samples.
10. The instrument should be a luminometer for automation of amplified chemiluminescent signal detection and result reporting for HC2 assays, including the HC2 High-Risk HPV DNA Test.
11. The instrument should be able to measure and analyze the light produced by the glow-type chemiluminescence used in HC2 technology.
12. The instrument should be able to measure light in the visible spectrum (300–650 nm) and Chemi-luminescence from opaque microplates.
13. The dynamic range should be around 10 to 5 x 106 RLU.
14. Crosstalk should be less than 4.0 x 10–5 RLU.
15. This system should be supported by published data in peer reviewed journals to support primary screening.
16. Long term longitudinal data to support screening using this technology in Indian population to be made available.
17. Acceptable median sensitivity for the HPV DNA test to detect high grade cervical disease should be a minimum of 94% and acceptable specificity should be a minimum of 90%.
18. Both sensitivity and specificity data should be supported by published data from multicentric studies in peer reviewed journals.
19. Negative Predictive Value should be more than 98.9%.
20. HPV DNA test be registered in India.
21. Assay must be CE IVD approved for self-sampling.
22. HPV DNA system should be CE IVD and US FDA approved.
23. A list of reference customers and existing users of HPV DNA test in India is required with the bids.