अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स), गुवाहाटी
All India Institute of Medical Sciences, Guwahati
स्वास्थ्य और परिवार कल्याण मंत्रालय,भारत सरकार के तत्वावधान में एक वैधानिक निकाय
(A statutory body under the aegis of Ministry of Health and Family Welfare, GoI)
Changsari, District- Kamrup, Assam, PIN-781101

WEB CHALLENGE NOTICE

Ref. No. 4-125/2023-24/AIIMS/GHY/PROC-Pathology/1889 Date: 08.12.2023

The notice is being uploaded on the web site www.aiimsguwahati.ac.in, and CPPP.

Sub : Verification and Justification of proprietary nature through 21 days Web- Challenge on the official website of AIIMS, Guwahati and CPPP before Procurement of **IHC Fully Automated System "Ventana Benchmark GX" -Roche** on proprietary basis against proprietary article certificate of the Original Equipment Manufacturer (O.E.M)- Inviting Comments thereon.

Department of Pathology, AIIMS, Guwahati intends to buy the subject equipment**, (**make by M/s Ventana Medical Systems, Inc., 1910 E, US), from M/s Roche Diagnostics India Pvt. Ltd. on proprietary basis. M/s Roche Diagnostics India Pvt. Ltd., having its registered office in 501 B, Silver Utopia, Cardinal Gracious Road, Chakala, Andheri East, Mumbai – 400069, India, a member of the Roche Group and affiliate of M/s. Ventana Medical Systems, Inc. USA, is responsible for the sales & service of the equipment including its spare parts.

The notice is being uploaded for general information of prospective Manufacturer/Authorized Distributor/Dealer to submit their objection/comments, if any, on proprietorship of **IHC Fully Automated System Ventana Benchmark GX" -Roche** Make: M/s Ventana Medical Systems, Inc., 1910 E, US, they may submit their proposal along with specifications, supported by all documentary evidence and a price quotation.

The objection/proposal/comments, if any should be sent in sealed cover to the office of Chairperson, Procurement Cell, AIIMS, Guwahati, District- Kamrup (Assam), Pin-781101. Or through email to procurement@aiimsguwahati.ac.in so as to reach on or before dated on 28.12.2023 failing which it will be presumed that no other firm is interested to offer comments/ proposal/objection and case will be decided on its merits.

The Ref. No 4-125/2023-24/AIIMS/GHY/PROC-Pathology/1889, due on 28.12.2023 (before 5:00 PM) should be superscripted on sealed envelope.

Enclosures:

1) Proprietary Certificate of Manufacturer M/s Ventana Medical Systems, Inc., 1910 E, US.
2) Authorization provided by the OEM to M/s Roche Diagnostics India Pvt. Ltd., Andheri East, Mumbai - 400069.
3) Technical specification of the equipment namely **IHC Fully Automated System Ventana Benchmark GX" - Roche**.

Note from pre-page

Copy to:

1) Indenting Officer : For kind information please.
2) PS to ED : For kind information please.
3) FIC Website : For kind information please.

Sd/-
Administrative Officer
AIIMS, Guwahati

Ventana Medical Systems, Inc.
A member of the Roche Group
1910 E. Innovation Park Drive
Tucson, AZ 85755, US

15 February 2022

Proprietary Certificate – BenchMark GX

Dear Sir/Madam,

This is to certify M/s Ventana Medical Systems, Inc, a member of the Roche Group, is the legal manufacturer and/or distributor for below listed products.

Ms Roche Diagnostics India Pvt Ltd, having its registered office in 501 B, Silver Utopia, Cardinal Gracious Road, Chakala, Andheri East. Mumbai-400069, India, a member of the Roche Group and an affiliate of M/s Ventana Medical Systems, Inc., is responsible for the sale & service of the equipment including its spare parts, accessories etc.

Product name	Gmmi no	Physical Manufacturer
Benchmark GX	5894662001	M/s Ventana Medical Systems, Inc., 1910 E. Innovation Park Drive Tucson, Arizona 85755, US

The following assays are proprietary to Ms. Ventana Medical Systems and run on Benchmark GX instruments. Ms. Ventana Medical Systems has not validated the performance of these assays on instruments other than Ventana's Benchmark instruments.

VENTANA ALK (D5F3)

Intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained on BenchMark IHC/ISH instruments including **BenchMark GX** automated staining instrument.

- Indicated and eapproved as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib), & is proprietary to Ms. Ventana Medical Systems.

VENTANA anti-BRAF V600E (VE1) Mouse Monoclonal Primary Antibody (VENTANA anti-BRAF V600E (VE1) antibody)

- Intended for the qualitative detection of BRAF V600E protein in formalin-fixed, paraffin-embedded tissue sections.
- Ready to use on **BenchMark GX** instruments with the OptiView DAB IHC Detection Kit and ancillary reagents.
- Part of the VENTANA MMR IHC Panel.

VENTANA MMR IHC

Includes VENTANA anti-BRAF V600E (VE1) antibody, VENTANA anti-MLH1 (M1) Mouse Monoclonal Primary Antibody, VENTANA anti-PMS2 (A16-4) Mouse Monoclonal Primary Antibody, VENTANA anti-MSH2 (G219-1129) Mouse Monoclonal Primary Antibody and VENTANA anti-MSH6 (SP93) Rabbit Monoclonal Primary Antibody.

- Indicated and approved for the detection of mismatch repair protein deficiency as a test for the identification of individuals at risk for Lynch syndrome in patients diagnosed with colorectal cancer (CRC), and, with BRAF V600E status, as an aid to differentiate between sporadic and probable Lynch syndrome CRC in the absence of MLH1 protein expression.

VENTANA PD-L1 (SP263) Assay

- Intended for the qualitative detection of the programmed death ligand 1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), urothelial carcinoma (UC) and other tumor tissues stained with OptiView DAB IHC Detection Kit.
- Indicated as an aid in identifying patients for treatment with KEYTRUDA® (pembrolizumab) & may be associated with enhanced survival from OPDIVO® (nivolumab). VENTANA PD-L1 (SP263) Assay is intended for identifying Urothelial Carcinoma patients who may benefit from IMFINZI™ (durvalumab).

VENTANA PD-L1 (SP142) Assay

- Intended for the immunohistochemical assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor-infiltrating immune cells in formalin-fixed, paraffin-embedded (FFPE) tissues

indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit, stained on BenchMark IHC/ISH automated staining instruments including **BenchMark GX.**

- Indicated as an aid in identifying patients for treatment in therapy TECENTRIQ in urothelial carcinoma, Trip Negative Breast Carcinoma (TBBC) & Non Small Cell Lung Cancer (NSCLC).

VENTANA ROS1 (SP384)

- Intended for laboratory use in the qualitative detection of ROS1 protein in formalin-fixed, paraffin-embedded tissue stained with VENTANA BenchMark IHC/ISH instruments including **BenchMark GX**.

VENTANA pan-TRK (EPR17341) Assay

- Intended for the immunohistochemical detection of the C-terminal region of the tropomyosin receptor kinase (TRK) proteins A, B and C, which is known to be conserved across wild-type and chimeric fusion proteins, in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues stained with BenchMark IHC/ISH instruments.
- These products are intended for *in vitro* diagnostic (IVD) use.
- Test results of all the above product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

Sincerely,

DocuSigned by:
Laura Apitz
57074E2D931C498...

Laura Apitz
Lifecycle Leader, Oncology Assays
Ventana Medical Systems, Inc.

Technical specifications of fully automated, walk away IHC staining system "Ventana Benchmark GX" - Roche.

1. Fully automated complete walk-away slide Stainer for IHC. FDA-approved DISH Her2/Neu, ISH, and FISH. The system should be FDA-approved to run FDA-approved ALK (D5F3) assay, MMR panel. PD-L1 (SP263). PD-L1 (SP142) assay, and HER-2 DISH assay
2. Baking to counter staining should be on board.
3. Compatibility for paraffin (dewaxed), frozen sections, and cytology smears.
4. Should be capable of running 4 or more staining protocols.
5. Should have a throughput of at least 20 slides at a time.
6. IHC run time should not be more than 3.5 hours.
7. Antibody & micro reagent Consumption per slide should not be more than 100 microliters.
8. It should be open for third-party primary antibodies.
9. It should be able to do tests as well as control on the same slide without any extra consumption of reagents.
10. Level sensors for the reagents on board the system.
11. The system should have a built-in Antigen Retrieval System & not a separate module system.
12. The system should have liquid cover slip which will be able to control evaporation and protect tissue integrity on each slide.
13. Should have a Slide Labelling System. (Bar code reader and Printer).
14. The system should be able to recognize Slide Specific Barcode/QR code labels, which would provide automatic programming, and patient and case identification.
15. It should be compatible and integrative with the LIS system.
16. There should not be any pre-staining manual steps involved to cover the slides.
17. Should have the facility of Individual programming for each slide with any protocol.
18. Should have humidity and temperature regulation for operation between 35 °C - 100 °C and 10-90% humidity.
19. Should be compatible for use with standardized protocols or user-defined protocols.
20. The reagent carousel holds at least 25 ready-to-use reagent containers.
21. The instrument should be able to run both DAB and red detection simultaneously in a single run.

15/10/23

Dr. Prashant Durgappa Patil M.D.
Assistant Professor
Dept. of Pathology & Laboratory Medicine
All India Institute of Medical Sciences, Guwahati

25/9/23

Dr. Rakesh Baishya M.D/ डॉ. राकेश बैश्य
Assistant Professor/ सहायक आचार्य,
Dept. of Pathology/ विकृति विज्ञान
All India Institute of Medical Sciences,Gowahati
अखिल भारतीय आयुर्विज्ञान संस्थान, गुवाहाटी

Dr.Sinhasan, S. P
Professor & HOD, Dept of Pathology
अखिल भारतीय आयुर्विज्ञान संस्थान, गुवाहाटी

25/9/2023

Bifica S. Lyngdoh
Assistant Professor
Deptt. of Pathology
All India Institute of Medical Sciences, Guwahati

22. Instrument should be able to do FDA-approved ALK (D5F3), Her-2/neu, and PD-L1 assay for targeted drug therapy, MMR etc.
23. Instrument should be able to perform FDA-approved Dual ISH for Her-2/neu and Chromosome 17.
24. Should be modular, future attachment and upgradation of modules for higher workloads should be possible.
25. Should come with a compatible computer and software.
26. The software should be upgradable. The Supplier must upgrade the software with the latest version from time to time at no extra cost.
27. The equipment should be US-FDA / European CE and ISO certified.
28. A suitable online UPS and battery backup sufficient to cover a power outage of 60 minutes should be provided.
29. One commercial-grade RO system which sufficient to run the instrument should be provided along with the instrument. There should be a storage tank. The water quality should be compatible with the special water requirements of the equipment and any additional accessory equipment if required should be provided.
30. Demonstration of equipment is required before financial bidding.

Additional terms and conditions:

1. All installation/service reports and satisfactory performance and servicing reports from a government institute are to be attached.
2. The company should provide operators training, instrument qualifications, operation qualifications, performance qualifications, and training certificates, free of cost.
3. The system or any variants of the system with the same technology should be installed in more than 10 hospital labs across India in both Govt and Private sectors.
4. Technical support should be available for troubleshooting with a maximum response time of 48 hours.
5. The price of all consumables including buffers, reagents, amplification kits, FISH probes, DISH Her2 assay, and reagents necessary for working or servicing/cleaning of machine antibodies, and any consumable machine parts should be quoted.
6. The following information should be provided for each consumable item separately
   a) Pack size

15/10/23

Dr. Prashant Durgapal (M.D.)
अपर -आचार्य /Additional Professor
विकृति विज्ञान एवं प्रयोगशाला चिकित्सा विभाग
Dept. of Pathology & Laboratory Medicine
एम्स ऋषिकेश /AIIMS, Rishikesh

25/9/23

Dr. Pakesh Baishya M.D/ डॉ. ...
Assistant Professor/ सहायक आचार्य,
Dept. of Pathology/ विकृति विज्ञान
All India Institute of Medical Sciences, Guwahati
अखिल भारतीय आयुर्विज्ञान संस्थान, गुवाहाटी

25/9/2023

सिंहासन एस. पि / Dr. Sinhasan S.P.
आचार्य, विभागाध्यक्ष, रोग लक्षण शास्त्र
Professor & HOD, Dept of Pathology
अखिल भारतीय आयुर्विज्ञान संस्थान

25/9/23

... Assistant Professor / सहायक आचार्य
Dept. of Pathology / विकृति विज्ञान विभाग
All India Institute of Medical Sciences, Guwahati

   b) Number of tests per pack size
   c) Unit price of pack

7. Consumable prices should be fixed for five years by means of a rate contract.
8. The hidden cost of all the items that are required but not provided with the equipment should be elaborated.
9. Prices are to be quoted with a five-year on-site warranty and a further 5 years CMC for a total of ten years.

**Exempted from MAKE in INDIA Category as per Sl No. 7. of Ministry of FINANCE list, Govt of India dated 03.04.2023 VALID for all tenders till 31st March 2024.

=====================X=====================

-Specifications vetted and approved as per rules

15/10/23

Dr. ... अपर -आचार्य /Additional Professor
विकृत विज्ञान एवं प्रयोगशाला चिकित्सा विभाग
Dept of Pathology & Laboratory Medicine
एम्स ऋषिकेश /AIIMS Rishikesh

25/9/23

25/9/23
Dr. Pakesh Baishya M.D/ डॉ. ...
Assistant Professor/ सहायक आचार्य,
Dept. of Pathology/ विकृति विज्ञान
All India Institute of Medical Sciences, Guwahati
अखिल भारतीय आयुर्विज्ञान संस्थान, गुवाहाटी

...हासन. एस. पि / Dr. Sinhasan S...
..., विभागाध्यक्ष, रोग लक्षण शास्त्र
...essor & HOD, Dept of Pathology
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All India Institute of Medical Sciences, Guwahati

25/9/23
...ca S. Lyngdoh / डॉ. ...
Assistant Professor / सहायक आचार्य
Deptt. of Pathology / विकृति विज्ञान विभाग
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