All India Institute of Medical Sciences
Jodhpur

Admn/Prop/22/2020-AIIMS.JDH

Dated: - July 13, 2020

Subject: Purchase of IHC fully Automated Slide Preparation System for the Extramural Research Project at Research Section, AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of IHC fully Automated Slide Preparation System for Extramural Research Project at Research Section, AIIMS, Jodhpur from M/s Ventana Medical Systems, Inc., 1910 E. Innovation Park Drive, Tucson, AZ 85755 USA on proprietary basis. The proposal submitted by M/s Ventana Medical Systems, Inc., USA and PAC certification by user are attached.

The above documents 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/22/2020-AIIMS.JDH. The comments should be received by office of Dean (Research), Research Section at AIIMS, Jodhpur on or before August 03, 2020 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.

Dean (Research)

Enclosed: Related documents enclosed.

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

26 June 2020

Proprietary Certificate

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.

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 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, AZ 85755 USA

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 approved as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib)
- 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.

- 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.

  These products are intended for in vitro diagnostic (IVD) use.

Sincerely

Ventana Medical Systems, Inc.

By: DocuSigned by: Christoph Majewski 0BAFE5804BCE447...

Christoph Majewski

VP and LCL, CDx

Roche Legal: DS

IHC autostainer

Technical specifications of the equipment to be supplied and its standards:

1. Fully automated complete walk-away slide stainer with option of delay start for IHC, FDA approved DISH Her2/Neu, ISH and FITC.
2. Automation of all slide preparation steps -From Baking to Counter staining should be on-board.
3. Third party primary antibodies should be able to perform as a titration method (Manual dispensing).
4. Should be compatible for paraffin (dewaxed), frozen sections and cytology smears.
5. Should be capable of running more than 4 staining protocols in a single run.
6. Should have throughput of at least 20 slides at a time.
7. IHC run time should not be more than 3.5 hour.
8. Unattended overnight runs should also be possible.
9. Antibody and micro-reagent Consumption per slide should not be more than 100µl.
10. It should be able to perform test as well as control on the same slide in the same run without any extra consumption of reagents.
11. Should have latest liquid cover slip technology and air vortex mixer technology for homogeneous binding of the Antibody across the entire slide.
12. The system should have built-in Antigen Retrieval System and not a separate module system.
13. Instrument should have both low pH and high pH for Antigen Retrieval.
14. Instrument should be able to perform enzyme pre-treatment.
15. Should have a Slide Labelling System (Bar code printer) to print labels before staining.
16. Should have facility of Individual programming for 20 slides with different protocols.
17. Should have humidity and temperature regulation for operation between 37°C -100 °C and 10-90% humidity.
18. Should be compatible for use with standardized protocols or user defined protocols.
19. Should come with compatible computer and software.
20. The software should be upgradable at no extra cost to the user.
21. The reagent rack should hold at least 25 ready-to-use reagent containers.
22. UPS back up for at least 1 hour should be provided along with the system.
23. Instrument should be able to do FDA approved ALK (D5F3), Her-2/neu and PD-L1 Assay etc.
24. Instrument should be able to perform FDA approved Dual-ISH for Her-2/neu and Chr 17.
25. Instrument should be able to perform Alkaline Phosphatase Fast Red-chromogen for tissue samples like, Melanin pigment.
26. Instrument should have the capability to run both DAB & Red detection at the same time in a single run.
27. Instrument should have the capability to perform dual stain, single stain in a single run.
28. Price of detection kits and reagent consumables should be sealed up to the contract periods.

29. Company should provide operators' training, Instrument qualification, operation qualification, performance qualification, training certificate, Free of cost.
30. Should be modular. Future attachment and upgradation of modules for higher workloads should be possible.
31. The equipment should be US-FDA / European CE approved.