

# Kalyan Singh Super Specialty Cancer Institute

कल्याण सिंह अति विशिष्ट कैंसर संस्थान

C.G. City, Sultanpur Road, Lucknow-226002

सी०जी० सिटी, सुल्तानपुर रोड, लखनऊ- 226002

(An Autonomous Institute of the Govt. of Uttar Pradesh)

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

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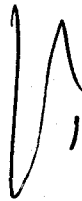
## Notice of PAC (Proprietary Article Certificate) Bid

**Subject:** Purchase of fully automated Immunohistochemistry (IHC) staining, Ventana Benchmark GX System for the use of DIAMOnDS Project, Department of Pathology & Cancer Genetics, KSSSCI, Lucknow-226002 on proprietary basis – inviting comments thereon.

The institute is in the process of Purchasing 1(one) set of fully automated Immunohistochemistry (IHC) staining, Ventana Benchmark GX System for the use of DIAMOnDS Project, Department of Pathology & Cancer Genetics, KSSSCI, Lucknow-226002 from GeM Bid as PAC (Proprietary Article Certificate) Bid. The PAC Certification is attached.

The above documents are being uploaded at KSSSCI website for open information to submit objections, comments if any, from relevant manufacturer regarding proprietary nature of the equipment/item within 10 days from the date of issue of notification by giving GeM Bid No. GEM/2022/B/2032765 Dated: 11-03-2022 for fully automated Immunohistochemistry (IHC) staining Benchmark GX System. The comments should reach KSSSCI Purchase Section at Administrative Block of KSSSCI or Institute's Email Id. i.e., [jdmm.sscih@gmail.com](mailto:jdmm.sscih@gmail.com) on or before 21-03-2022 upto 4:00 PM failing which it will be presumed that any other vendor is having no comments or offer and case will be decided on merits.

**Enclosure:** Related documents enclosed.

  
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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.

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- 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.

DocuSigned by:  
By: Christoph Majewski  
0B4FE9804BCE447...

Christoph Majewski

VP and LCL, CDx

Roche Legal: 



## Roche/Ventana Benchmark GX ,Fully automated, walk away IHC staining system

- Should allow user to Automate all slide preparation steps: baking, deparaffinization (Xylene Free), antigen retrieval , staining and counter staining.
- Fully automated complete walk away slide Stainer with option of delay start for IHC, FDA approved DISH Her 2/Neu, FDA approved ALK D5F3 assay, FDA approved MMR panel along with BRAF, ISH & FITC, FDA approved PD-L1 (SP263) and FDA approved PD-L1(SP142).
  - Minimum 20 individually temperature controlled Slide positions with individual slide Heaters.
  - Should have system throughput to perform baking to counter staining of 20 IHC slides in 3-3:30 hrs.
  - The total Primary antibody consumption / IHC slide should be not more than 100 µL.
  - Should allow user to use 3rd Party Primary antibodies.
  - Should allow user to choose between standardized protocols or should have facility to optimize protocols with flexible options.
  - Should be Compatible to use paraffin (dewaxed), and frozen sections as well as cytology smears as sample.
- Should enable user to perform both Test and control tissue on the same slide in the same run without consuming any additional reagents.
- Should be barcode-driven technology that match protocols and reagents to patient slides to eliminate the potential errors.
- Should Have capacity to hold minimum 25 reagents onboard.
- Should have latest liquid coverslip technology which creates a reaction chamber on the surface of each slide controlling evaporation, protecting tissue integrity.
- Should come with compatible computer and software
- Should have air vortex mixer which enables uniform mixing of reagents dispensed ensuring uniform reaction kinetics across the entire surface of the slide.
- Supplier must upgrade the system software time to time or when available at no extra cost to the user.
- Should have a facility to control multiple staining systems in single control system to enable sharing of reagents and protocols across multiple instruments.
- Supplier must provide a suitable slide labelling system / barcode printing system to print labels for slides before staining.