HITES
HLL INFRA TECH SERVICES LTD

For and on behalf of

ALL INDIA INSTITUE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029
(Mother & Child Block)

Ref: HITES/PCD/MCH-AIIMS/24-25/Prop-06

Date: 27-01-2025

Subject: **Proposal for Procurement of 'Ventana Automated IHC' related to Mother and Child Hospital Block, AIIMS New Delhi-110029 on PAC basis and invitation of comments/objections against such procurement, if any, thereof.**

HLL Infra Tech Services Ltd. for and on behalf of Mother and Child Hospital Block, AIIMS, New Delhi is in the process of procuring of 'Ventana Automated IHC' (Mfg: M/s. Ventana Medical Systems, USA *thru'* M/s. Roche Diagnostics, India) on proprietary basis. The Proprietary Article Certificate submitted by OEM in this regard along with Departmental PAC certification are attached herein.

The above documents are being uploaded for open intimation to all principal manufacturers or their authorised distributors with the intention to invite comments and/or objections with regards to the proprietary nature of the aforesaid product, if any.

The comments/objections if any should be received in the office of **The Head (PCD), HLL Infra Tech Services Ltd. B/14 A, Sector-62, Noida, Uttar Pradesh-201301** within 15 days of issue of this advertisement with contact details and ref no. **HITES/PCD/MCH-AIIMS/24-25/Prop-06**, failng which it will be presumed that no other bidder/manufacturer/vendor is having any comments/objection against the proposition and the case will be decided purely on merit.

AVP (PCD)

HLL Infra Tech Services Ltd., Noida

Enclosures:

- PAC by User Department
- Letter for Authorisation
- PAC from Manufacturer

Proprietary Article Certificate

(Refer Para 4.6.1 of Procurement of Manual of Goods, 2017)

File Number and Date Reference		
1	Description of article	Ventana Automated IHC
2	Forecast of quantity/annual requirement	01 No.
3	Approximate estimated value for above quantity	Rupees Ninety Lakhs only (Rs. 90,00,000/-)
4	Maker's name and address	M/s Ventana Medical Systems, USA
5	Name(s) of authorised dealers/ stockists	M/s Roche Diagnostics, India
6	I approve the above purchase on PAC basis and certify that: -- Note- Tick to retain only one out of (b), (c-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it – without which PAC certificate will be invalid.	
6(a)	This is the only firm who is manufacturing/stocking this item. AND	✓
6(b)	A similar article is not manufactured/sold by any other firm, which could be used in lieu OR	✓
6(c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ warranty spares): OR FDA approved for ALK(D5F3) assay, MMR panel PDL1 (SP263), PDL1 (SP142) assay & Her-2 DISH assay.	✓
6(c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources): OR (Any other details)	✓ ☐
7	Reference of concurrence of finance wing to the proposal:	

History of PAC purchases of this item for past three years may be given below			
Name of the Supplier			
Order/ Tender Reference& Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any
3/01/2023 ~~NA~~	5	90 lakhs/unit	Nil.

Signature of Approving Authority

Date: 06.09.2024

Name & Designation of Officer: Dr. Sandeep Mathur, Professor, Dept of Pathology

Dr. Sandeep Mathur, MD
Professor
Department of Pathology
All India Institute of Medical Sciences

Technical specifications of fully automated, walk away IHC staining system: Bench Mark Ultra on Proprietary basis (01 in number, approximate cost: 90 lakhs)

1. The system must be walk away fully Automated Slide Staining System to process slides for Immunohistochemistry (IHC), In Situ Hybridization, Immuno Fluorescence. 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. System should have 30 independent slide drawers to add slide at any time and customize each individual protocol.
3. Should have Automated IHC/ISH platform which manages immediate requests with no impact on ongoing processing of slides.
4. The system must be fully automated to do baking, deparaffinization, antigen retrieval and staining within the same system.
5. Up to 7 different bulk solutions can be changed "on the fly" without process interruption.
6. The System should be open for Primary antibodies.
7. System should have throughput of at least 30 slides at a time and have throughput of 90 slides in 8-hour shift.
8. It should be able to do test as well as control on same slide without any extra consumption of reagents.
9. The system must have individual Slide heaters for all the slide position; slide temperature should be individually controlled.
10. The system should have liquid cover slip which will be able to control evaporation and protect tissue integrity on each slide
11. The reagents and the antibody should get mixed through air whirlpool and no mechanical part should be involved for mixing the reagents and antibodies.
12. System should have dispenser technology to dispense the critical reagents to avoid cross contamination.
13. Should have a Slide Labeling System, Bar code/QR code reader and Printer for each machine separate.
14. Should have facility of Individual programming for each slide with any protocol.
15. Only 100 micro liter of Primary antibody must be required to cover the whole slide, irrespective of the size and number of the tissue sections on the slide
16. The system should be able to recognize Slide Specific Barcode/QR code label, which would provide automatic programming, patient and case identification.
17. It should be compatible and integrative with LIS system.
18. There should not be any pre staining manual steps involved to cover the slides.

19. A single slide run should not consume more reagents per test compared to when run in batches with other slides.
20. System should have a facility to control multiple staining systems in single control system to enable sharing of reagents and protocols across multiple instruments.
21. The reagent carousal should hold 35 ready to use reagent container.
22. One commercial grade RO & Deionized water system should be provided along with the instruments. There should be high capacity (30 Litres) 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.
23. The system should be US FDA certified.
24. The installation and training should be done free of cost.
25. The system should have compatible computer and software of latest technology available during installation. The software should be upgradable free of cost.
26. A suitable online UPS and battery backup sufficient to cover power outage of 60 minutes should be provided
27. The system or any variants of the system with the same technology should be installed in minimum 50 Hospitals Labs across India in both Govt and Private sectors.
28. Technical support should be available for troubleshooting with a maximum response time of 48 hours

29. 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, any consumable machine parts should be quoted.
30. The following information should be provided for each consumable item separately
    a) Pack size
    b) Number of tests per pack size
    c) Unit price of pack
31. Consumable prices should be fixed for ten years by means of a rate contract
32. The hidden cost of all the items that are required but not provided with the equipment should be elaborated
33. Prices to be quoted with five years on-site warranty and further 5 years CMC for a total of ten years.

Roche Diagnostics Asia Pacific
8 Kallang Avenue, #10-01/09
Aperia Tower 1
Singapore 339509

13 September 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.

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 ULTRA	5342716001	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 ULTRA instruments. Ms. Ventana Medical Systems has not validated the performance of these assays on instruments other than Ventana's BenchMark instruments.

VENTANA ALK (D5F3) Assay

- 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 ULTRA** 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 ULTRA** instruments with the OptiView DAB IHC Detection Kit and ancillary reagents

- Part of the VENTANA MMR IHC Panel

VENTANA MMR IHC Panel

- 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 ULTRA.**

- 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)

- Test results of this product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
- This product is intended for in *vitro diagnostic* (IVD) use

Sincerely,

Cesar A. Diaz-Brown
Roche Diagnostics, Asia Pacific
Business Manager – Roche Tissue Diagnostics

Roche

06-Sep-2024

To,

The Director
All India Institute of Medical Sciences
New Delhi, India

Subject: Authorization for supply of Roche reagents & consumables for the fully automated IHC Stainer (Ventana BenchMark Ultra)" for AIIMS Delhi.

Dear Sir,

We are pleased to inform you that we hereby authorize M/s. Merit Medicare (P) Ltd., Office No.2 First Floor, Plot No. 34, Corner Market, Maharishi Dayanand Marg, Malviya Nagar, New Delhi-110017 as our authorized distributor to supply of the reagents & consumables for IHC Staining System "Ventana BenchMark Ultra" , receive orders, collect payments, submit bills and do follow up on other relevant documents with your esteemed organization.

Hence, the orders and the payments against supplies to AIIMS Delhi for the reagents & consumables for IHC Staining System "Ventana BenchMark Ultra" should be made in the name of M/s. Merit Medicare (P) Ltd.

For Roche Diagnostics India Private Ltd.

Satish Katwal
Zonal Manager-Pathology Lab
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Satish.katwal@roche.com

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CIN - U85195MH1988PTC141417

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VENTANA

Roche

Declaration of Relationship

Dear Sir/Madam,

We, **M/s. Ventana Medical Systems, Inc.,** hereby we confirm that Roche Diagnostics India Pvt. Ltd. and Ventana Medical Systems, Inc. are members of the Roche Groups.

Roche Diagnostics India Pvt. Ltd. is directly handling all business transactions in India for Roche's Diagnostics Division.

Yours Sincerely,

Ventana Medical Systems, Inc.
A member of the Roche Group

Fatima Pereira
Regulatory Affairs Director

17-Dec-2020.
Date

ROCHE DIAGNOSTICS INDIA PVT. LTD. NEW DELHI

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