All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Reference No: J-11077/(29)/S&P/2023-24/Vol-13/ **Dated: 07/12/2023**

Sub: Procurement of IHC Fully Automated System "Ventana Benchmark GX" for the Department of Pathology (Project) at AIIMS, BBSR on Proprietary basis - Inviting Comments thereon.

The user department at AIIMS, Bhubaneswar has requested for Procurement of IHC Fully Automated System "Ventana Benchmark GX" from Roche Diagnostics India Pvt. Ltd, a member of Roche Group and affiliate of Ventana Medical Systems on a proprietary basis.

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer (I/C), AIIMS, Bhubaneswar (Odisha) – 751019 or through e-mail to:-

(i) **spo@aiimsbhubaneswar.edu.in**,
(ii) **so@aiimsbhubaneswar.edu.in**
(iii) **stokee_debashish@aiimsbhubaneswar.edu.in**

so as to reach on or before **date: 17-12-2023** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no.– **J-11077/(29)/S&P/2023-24/Vol-13** dt: 02-12-2023, due on dated: 17-12-2023 should be superscripted on sealed envelope.

Enclosure:

1.Proprietary Article Certificate from Indenting Officer-**Annexure-I**
2. PAC of M/s. Ventana Medical Systems & OEM authorization of Certificate M/s Roche Diagnostics India Pvt. Ltd **- Annexure-II**
3. Latest Price Quotation **- Annexure III**
4. Technical Specification-**IV**

Sr. Procurement-cum-Stores Officer (I/C)

Copy to: -

1. Indenting Officer : for information please
2. Accounts Officer : for information please
3. IT Cell : for hoisting in the website.

uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Annexure - I (16)

AIIMS, BHUBANESWAR

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	IHC Fully Automated System "Ventana Benchmark GX"
2	Forecast of quantity /annual requirement	1 Qty
3	Approximate estimated value for above quantity	Rs. 41,30,000/-
4	Maker's name and address	Ventana Medical Systems, Inc. A member of the Roche Group 1910 E. Innovation Park Drive Tucson. AZ 85755 USA
5	Name(s) of authorized dealers/ stockists	M/s. : Roche Diagnostics India PVT LTD
6	I perceive 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	Yes
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	
6 (c-2)	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 **The following assays are proprietary to Ms. Ventana Medical Systems and run on Benchmark GX instruments. (A) Ventana ALK (D5F3), (B) Ventana MMR IHC, (C) Ventana PDL 1 (SP263) Assay, (D) Ventana PDL-1 (SP142) Assay.**	Yes
7	Reference of concurrence of finance wing to the proposal :	Fund available Accounts Officer (Research) AIIMS, Bhubaneswar-751019 29/06/2023

History of PAC Purchase 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

Signature of the Indenting Officer

31/1/23

Dr. Pritinanda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS, Bhubaneswar-751019

Signature of Approving Authority

15/11/23

डॉ. आशुतोष बिश्वास
Dr. Ashutosh Biswas
कार्यकारी निदेशक / Executive Director
एम्स, भुवनेश्वर
AIIMS, Bhubaneswar-751019

Date

Designation of Officer

Annexure-II (7)

Roche

DocuSign Envelope ID: 46924698-47BC-4142-A7A4-5DDE24DA4DC8

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)

31/07 Prityanda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS, Bhubaneswar-751009

- 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.

31/8/22

Dr. Srinanda Mishra
Additional Professor
of Pathology & Lab Medicine
Bhubaneswar-751019

Roche

- 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: Christoph Majewski

Christoph Majewski

VP and LCL, CDx

Roche Legal:

21/1/23

Dr. Pritinanda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS,Bhubaneswar-751009

Annexure - III

(11)

Date	03-01-2023
Ref No.	Roche/02/2022-23

To

The Director
All India Institute of Medical Science
Bhubaneshwar

Kind Attention: Dr. Susama Patra, Prof & Head, Department of Pathology.

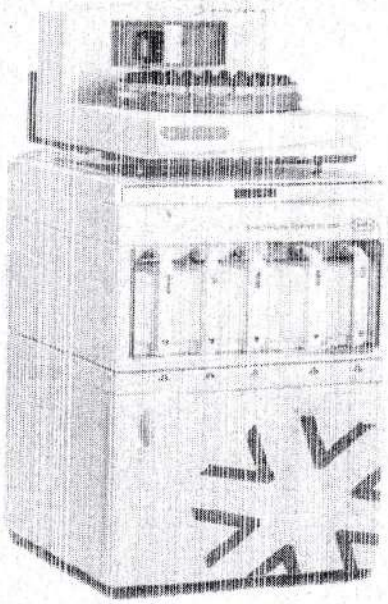
Sub: Quotation for IHC Fully Automated System "Ventana Benchmark GX"

Dear Sir/ Madam,

This has reference to the discussions regarding Roche Ventana BenchMark system please find the details for quote for our fully automated IHC system Ventana Benchmark GX are as follows.

Description	Qty	Price* /unit (INR)
Roche / Ventana Benchmark GX System	01	35,00,000.00

Rupees Thirty Five Lacs only
**GST @ 18% will be extra as applicable.*
***Price may vary as per commercial terms & conditions.*



31/1/23
Dr. Pritinanda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS, Bhubaneswar-751009

ROCHE DIAGNOSTICS INDIA PVT. LTD.
Regional Office:
Unit - 1002, Media Acropolis,
1858/1, Rajdanga Main Road,
East Kolkata Township,
Kolkata, West Bengal-700 107
Tel.: +91 (33) 4015 3700
Fax: +91 (33) 4015 3701
Regd. Office
501-B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400099
Tel.: +91 (22) 6697 4000
Fax: +91 (22) 6697 4949
www.roche-diagnostics.co.in

(10)

Roche

Instrument Features

Flexible Automation
The New Generation of Productivity for the Histology Laboratory

Flexibility

- Process IHC, ISH, SISH and FITC tests independently or simultaneously
- Optimize protocols with flexible options, including extended incubation times and varying temperature controls.
- Choose your own primary antibody or one of over 260 antibodies available from Ventana.
- Automate any or all slide preparation steps: baking, deparaffinization, cell conditioning, and staining.
- Extended incubation time with varying temperature setting at 37 or 42 deg.
- Dual Staining can perform on the same run.
- US-FDA approved Companion Diagnostics Assay for the detection of ALK IHC can be performed for NSCLC patients who might benefit from treatment with Xalkori (crizotinib) from Pfizer.

Automation

- Completely automate the processing of your IHC, ISH, SISH, and FITC slides.
- Baking.
- Deparaffinization (solvent free)
- Cell conditioning
- Staining
- Eliminate manual errors

Sample Throughput & Protocols

- Process the baking through staining of up to 40 IHC slides per 8-hour shift
- Run BenchMark GX unattended overnight and report up to an additional 70 results in the morning
- Reduce repeats with standardized baking through Staining
- Protocols are INDEPENDENT on slide positions
- Cases are kept together WITHOUT any need for sorting

31/1/23
Dr. Prityananda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS, Bhubaneswar-751009

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U51909MH2007PTC174417

Regional Office:
Unit - 1002, Merlin Acropolis
1858/1, Rajdanga Main Road,
East Kolkata Township,
Kolkata, West Bengal - 700 107
Tel. : +91 (33) 4015 3700
Fax: +91 (33) 4015 370.

Regd. Office:
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400099
Tel.: +91 (22) 660 4300
Fax: +91 (22) 660 4300
www.roche-diagnostics.co.in

Roche

Air Vortex Mixers

- Blend the aqueous layer under the Liquid Coverslip, mixing reagents and ensuring uniform reaction kinetics across the entire surface of the slide.
- No covertiles required
- Uniform mixing

Liquid Coverslip

- Creates a reaction chamber on the surface of each slide controlling evaporation protecting tissue integrity.

Thermoflex Pad

- 20 unique slide heaters provide highly precise, INDIVIDUAL slide heating for Synchronized IHC, ISH and FITC protocols
- Slides' temperature are individually controlled

Dispensing Reagent Volume

- 100uL of antibody dispensing is only required for FULL slide coverage
- No Dead Volume required

Usage of Detection Kits

- Every slide is 100uL dispense. No wastage. User can FULLY utilized the test kit From 1 to 250 tests as indicated (250 tests/kit)
- No Dead Volume required

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1998PTC114417

Regional Office:
Unit - 1002, Merlin Acropolis,
1858/1, Rajdanga Main Road,
Kasba, Kolkata Township
Kolkata, West Bengal-700 107

Tel.: +91 (33) 4015 9700
Fax: +91 (33) 4015 9701

Regd. Office:
901 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400099

Tel.: +91 (22) 6897 4900
Fax: +91 (22) 6897 4999
www.roche-diagnostics.co.in

Dr. Pritinanda Mishra
Additional Professor
of Pathology & Lab Medicine
Bhubaneswar-751009

(8)

Terms & Conditions:

1. **Warranty:** Standard one year from the date of satisfactory installation.
2. **CMC:** 5% p.a. + service tax for next 5 years after warranty period.
3. GST will be extra on above quoted consumables & reagents price.
4. **Quoted price for instrument & consumables may varies as per commercial terms & conditions.**
5. **Delivery:** 60 days from the date of order.
6. **Installation & Training:** Free of Cost at site.
7. **Payment terms:** As per tender terms & conditions.

For Roche Diagnostics India Pvt. Ltd.

Biswajit Bhattacharya

ROCHE DIAGNOSTICS INDIA PVT. LTD. Roche KOLKATA

Biswajit Bhattacharya
Zonal Manager -Pathology Lab East
biswajit.bhattacharya@roche.com
Mob: +91 9331297360

31/1/23
Dr. Prttinanda Mishra
Additional Professor
Dept. of Pathology & Lab Medicine
AIIMS,Bhubaneswar-751009

Annexure-IV

TECHNICAL SPECIFICATION OF THE FULLY AUTOMATED IMMUNOHISTOCHEMISTRY STAINING SYSTEM

Sl. No.	Specification
1.	Fully automated complete walk away slide stainer for IHC, FDA approved DISH Her2/Neu, ISH and FISH
2.	Baking to counter staining should be on-board.
3.	Compatibility for paraffin (dewaxed), and frozen sections as well as cytology smears.
4.	Should be capable of running 4 or more staining protocols.
5.	Should have throughput of at least 20 slides at a time.
6.	IHC run time should not be more than 3.5 hour.
7.	Antibody & micro reagent Consumption per slide should not be more than 100pl.
8.	It should be open for third party primary antibody.
9.	It should able to do test as well as control on same slide without any extra consumption of reagents.
10.	Level sensors for the reagents on board the system.
11.	The system should have built in Antigen Retrieval System & not a separate module system.
12.	Should have a Slide Labelling System. (Bar code reader/ Printer).
13.	Should have facility of Individual programming for each slide with any protocol.
14.	Should have humidity and temperature regulation for operation between 35"C 100°C and 10-90% humidity.
15.	Should be compatible for use with standardized protocols or user-defined protocols.
16.	Should come with compatible computer and software.
17.	The software should be upgradable. Supplier must upgrade the software with latest version from time to time at no extra cost.
18.	The reagent carousal holds at least 25 ready to use reagent container.
19.	The equipment should be US-FDA / European CE and ISO certified.

28.6.2023

Dr. Rakhee Kar,
Professor & Head, Dept. of Pathology,
JIPMER- Puducherry

आचार्य एवं अध्यक्ष / Professor & Head
विकृतिविज्ञान विभाग / Department of Pathology
जिपमेर, पुदुच्चेरी / JIPMER, Puducherry - 605 006

Dr. Nighat Hussain,
Professor, Pathology/ Lab Medicine, AIIMS- Raipur

Dr. Nighat Hussain
Professor (Dept. of Pathology)
All India Institute of Medical Sciences, Raipur

Dr. Pritinanda Mishra,
Additional Professor, Dept. of Pathology & Lab Medicine,
AIIMS- Bhubaneswar

डॉ. प्रीतिनंदा मिश्र
Dr. PRITINANDA MISHRA
अतिरिक्त प्रोफेसर / Additional Professor
विकृति विज्ञान एवं प्रयोगशाला चिकित्सा विभाग
Dept. of Pathology & Lab Medicine
एम्स, भुवनेश्वर / AIIMS, Bhubaneswar

TECHNICAL SPECIFICATION OF THE FULLY AUTOMATED IMMUNOHISTOCHEMISTRY STAINING SYSTEM

Sl. No.	Specification
20.	All installation / service reports are to be attached along with satisfactory performance and servicing report from a government institute.
21.	Demonstration of equipment is required during technical evaluation
22.	Five years warranty and five years CMC should be provided.
23.	Instrument should be able to do FDA approved ALK (D5F3), Her-2/neu and PD-L1 assay for targeted drug therapy, MMR etc.
24.	Instrument should be able to perform FDA approved Dual ISH for Her-2/neu and Chromosome 17.
25.	Instrument should have the capability to run both DAB and red detection at the same time in a single run.
26.	Price of detection kits and reagent consumables should be sealed up to the contract period.
27.	Company should provide operators training, instrument qualifications, operation qualification, performance qualification, training certificate, free of cost.
28.	Should be modular, future attachment and upgradation of modules for higher workloads should be possible.

28-6-2023

Dr. Rakhee Kar,
Professor & Head, Dept. of Pathology,
JIPMER- Puducherry

आचार्य एवं अध्यक्ष / Professor & Head
विकृतिविज्ञान विभाग / Department of Pathology
जिपमेर, पुदुच्चेरी / JIPMER, Puducherry - 605 006

Dr. Nighat Hussain,
Professor, Pathology/ Lab Medicine, AIIMS- Raipur

Dr. Nighat Hussain
Professor (Dept. of Pathology)
All India Institute of Medical Sciences, Raipur

Dr. Pritinanda Mishra,
Additional Professor, Dept. of Pathology & Lab Medicine,
AIIMS- Bhubaneswar

डॉ. प्रीतिनंदा मिश्र
Dr. PRITINANDA MISHRA
अतिरिक्त प्रोफेसर/ Additional Professor
विकृति विज्ञान एवं प्रयोगशाला चिकित्सा विभाग
Dept. of Pathology & Lab Medicine
एम्स, भुवनेश्वर / AIIMS, Bhubaneswar