Name of Equipment	Qty.	Specifications	
Automatic I.H.C. Stainer	**01**	**1.**	The system must be a random access walk away fully Automated Slide Staining System to process slides for Immuno Histo Chemistry, In Situ Hybridization & Immuno Fluorescence.
		2.	It should able to do FDA approved ALK (D5F3) assay, MMR panel, PD-L1 (SP263), Her-2 (4B5) and Her-2 Dual In situ Hybridization.
		3.	1-30 slides with independent processing & functionality with temperature control for each of the position.
		4.	Automated IHC, ISH platform manages STAT requests with no impact to others in processing slides.
		5.	The system is fully automated to do the baking, deparaffinization, antigen retrieval, primary antibody and the counter staining within the same system.
		6.	The system should have an intuitive touchscreen interface, making system control, status checking, and workflow management easier and user-friendly
		7.	Up to 7 different bulk solutions can be changed "on the fly" without process interruption.
		8.	The System should be open for the third-party Primary antibodies also.
		9.	System should have throughput of 30 slides at a time.
		10.	System should have throughput 90 slides per 8-hour shift.
		11.	It should able to do test as well as control on same slide without any extra consumption of reagents.
		12.	The system must have individual Slide heaters for all the slide positions and the slide temperature is individually controlled.
		13.	The system should have liquid cover slip, which will be able to control evaporation and protect tissue integrity.
		14.	The reagents and the antibody should be mixed through air whirlpool and no mechanical part should be involved for mixing the reagents and antibodies.
		15.	Should have a Slide Labelling System Bar code reader Printer.
		16.	Should have facility of Individual programming for each slide with any protocol.
		17.	Only 100 micro litre of Primary antibody must be required to cover the whole slide, irrespective of the size and number of the tissue sections on the slide.
		18.	The system should be able to recognize Slide Specific Barcode label, which would provide automatic programming, patient and case identification.
		19.	There should not be any pre staining manual steps involved to cover the slides.
		20.	A single slide run should not consume more reagents per test compared to when run in batches with other slides.
		21.	The system should include a built-in waste treatment system that degrades hazardous DAB waste thus minimizing environmental impact and meeting stricter disposal regulations.

		22.	The system should offer extra space for reagent preparation and workflow without increasing the instrument footprint.
		23.	The system should be US FDA/CE IVD 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.
		26.	The reagent carousal holds 35 ready to use reagent container
		27.	The system or any variants of the system with the similar technology should be installed in minimum 70 Hospitals Labs across India in both Govt. and Private sectors.

Dr. Deepti Mishra
Chairperson
Asso. Prof. Pathology & Cancer Genetics, KSSCL

Dr. Shreshtha Ghosh
Member
Asso. Prof., Pathology & Cancer Genetics, KSSCL

Dr. Priyanka Sameer
Member
Assistant Prof. Pathology & Cancer Genetics, KSSCL

Mr. Ram Nawal
External Expert

Medical Superintendent

F&AO / Nominee

Prof. Akshay Anand
Director / Nominee

Kalyan Singh Super Specialty Cancer Institute

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

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

Email: procurement.ksssci@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(1) The indented goods are manufactured by **M/s Ventana Medical Systems (A unit of Roche Group)**

(2) No other make or model is acceptable for the following reasons:

a) For detection of PD-L1 (SP263) & PD-L1 (SP142) indicated as an aid to to identify patients eligible for targeted therapies for NSCLC, UC & TNBC patients

b) For detection of MMR IHC panel including BRAF V600 (VE1) assay that helps differentiate between sporadic colorectal cancer and probable lynch syndrome

c) Foe Detection of ALK (D5F3) CDx assay that is indicated as an aid in identifying NSCLC patients that are eligible for Alk-targeted therapy likely to get benefitted from Crizotinib, Certinib and Alectinib

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(Signature of Indentor)

Dr. Priyanka Sameer
Assistant Professor
Pathology & Cancer Genetics
Kalyan Singh Super Specialty
Cancer Institute, Lucknow

.....

.....

(Signature of HOD)

Dr. Deepti Mishra
Associate Professor
Department of Pathology & Cancer Genetics
Kalyan Singh Super Specialty
Cancer Institute, Lucknow

Date: 19 May 2025

PROPRIETARY ARTICLE CERTIFICATE

(AUTOMATED IMMUNOHISTOCHEMISTRY SLIDE STAINER- VENTANA Benchmark Ultra Plus)

1. It is certified that we, M/s Ventana Medical Systems, Inc. is the sole legal manufacturer of the items listed in **Annexure-1** for Automated IHC Stainer-VENTANA Benchmark Ultra Plus, located at, and having factory at 1910 E, Innovation Park Drive, Tuscon, AZ 85755, USA.
2. This is a proprietary product of M/s Ventana Medical Systems, It is confirmed that no other firm is manufacturing Automated IHC Stainer-VENTANA Benchmark Ultra Plus. The reagents (as per attached list) are exclusive to the equipment.
3. The above product is presently being solely imported by M/s Roche Diagnostic India Private Limited, B501, Silver Utopia, Chakala, Andheri East, Mumbai- 400069 in India.
4. The product is marketed in India under the brand name of VENTANA Benchmark Ultra Plus and VENTANA Benchmark Ultra Plus consumables & Reagents as per Annexure-1.

Ventana Medical Systems, Inc.

1910 East Innovation Park Drive
Tucson, AZ 85755
USA

Roche

Annexure-1

List of VENTANA Benchmark Ultra Plus consumables & Reagents

Basic Reagents				
Sr. No.	**GMMI No.**	**Description**	**Pack size/No. of Tests Per Pack**	**Aid in Drug Analysis**
1	5269806001	UltraView DAB	25ml	
2	5266769001	Bluing Reagent	25ml	
3	5266726001	Hematoxylin	25ml	
4	5353955001	Reaction Buffer	2L	
5	5424534001	BENCHMARK ULTRA LCS	2L	
6	5279771001	EZ Prep	2L	
7	5424569001	BENCHMARK ULTRA CC1	2L	
8	5353947001	SSC	2L	
Breast Panel Antibodies				
10	5278414001	ANTI-ER (SP1)	25ml	
11	5278392001	ANTI-PR (1E2)	25ml	
12	5278368001	ANTI-HER-2/NEU (4B5)	5ml	Herceptin ® (trastuzumab) or KADCYLA® (ado-trastuzumab emtansine)
13	5278406001	CONFIRM ANTI-ER (SP1)	5ml	
14	5277990001	CONFIRM ANTI-PR (1E2)	5ml	
ALK(D5F3), ROS-1, PD-L1(SP263), PD-L1(SP142), MMR Panel, CLDN 18				
15	7494190001	VENTANA PD-L1 (SP263)	50	**NSCLC:** KEYTRUDA® (pembrolizumab) OPDIVO® (nivolumab). **Urothelial Carcinoma:** IMFINZI™ (durvalumab)
16	6718663001	OptiView Amplification Kit (250)	250	
17	6683380001	Rabbit Mono Neg Ctl Ig	250	
18	6396500001	OptiView DAB Detection Kit	250	
P16 Antibody				
19	6695248001	P16	5ml	
ISH Reagents and ISH Probes				
20	5278511001	ISH IVIEW BLUE DETECTION KIT	200	
21	5272017001	RED COUNTERSTAIN II	100	
Her2-neu-DISH Reagents				
22	5277965001	Hematoxylin II	250	
23	8318832001	VENTANA RED ISH DIG DETECTION KIT	60	
24	5640300001	HER2 Dual ISH 3-in-1 Xenograft Slides	10	
25	5917557001	HybReady Solution	50	
26	8318883001	VENTANA SILVER ISH DNP DETECTION KIT	60	
27	5273331001	ISH Protease 3	200	

Ventana Medical Systems, Inc.

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USA

28	527332300	ISH Protease 2	200	
29	544672400	ultraView Silver Wash II	60	
Other Consumables				
30	526981400	Ultraview universal AP Red detection kit	25ml	
31	542454200	BENCHMARK ULTRA CC2	1L	
32	525093500	Prep Kits - 250T	1Pk	

Yours Sincerely,
Ventana Medical Systems, Inc

DocuSigned by:
Mariana Roldan
CA259B3D9AFD470...

Mariana Roldan
Regulatory Specialist Diagnostics
International Regulatory Affairs

Ventana Medical Systems, Inc.

1910 East Innovation Park Drive
Tucson, AZ 85755
USA

Date: 19 May 2025

PROPRIETARY ARTICLE CERTIFICATE

(AUTOMATED IMMUNOHISTOCHEMISTRY SLIDE STAINER- VENTANA Benchmark Ultra Plus)

1. It is certified that we, **M/s Roche Diagnostics GmbH** is the sole legal manufacturer of the items listed in **Annexure-1** for Automated IHC Stainer-VENTANA Benchmark Ultra Plus, located at, and having factory at *Sandhofer Strasse 116, 68305 Mannheim, Germany*.
2. This is a proprietary product of M/s Ventana Medical Systems, It is confirmed that no other firm is manufacturing Automated IHC Stainer-VENTANA Benchmark Ultra plus, the reagents (as per attached list) are exclusive to the equipment,
3. The above product is presently being solely imported by M/s Roche Diagnostic India Private Limited, B501, Silver Utopia, Chakala, Andheri East, Mumbai- 400069 in India,
4. The product is marketed in India under the brand name of VENTANA Benchmark Ultra Plus and VENTANA Benchmark Ultra Plus consumables & Reagents as per Annexure-1.

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890
Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Annexure-1

List of VENTANA Benchmark Ultra plus consumables & Reagents

Basic Reagents				
Sr No	**GMMI No**	**Description**	**Pack size/No of Tests Per Pack**	**Aid in Drug Analysis**
ALK(D5F3), ROS-1, PD-L1(SP263), PD-L1(SP142), MMR Panel, CLDN 18				
01	7419821001	VENTANA PD-L1 (SP263)	50	**NSCLC:** KEYTRUDA® (pembrolizumab) OPDIVO® (nivolumab). **Urothelial Carcinoma:**
02	9588604001	anti-ALK (D5F3)	50	XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib)
03	8008540001	VENTANA PD-L1 (SP142) Assay	50	TECENTRIQ
04	8033668001	MLH1 (M1) MM PAB-US Export	50	
05	8033684001	MSH2 (G219-1129) MM PAB-US Export	50	
06	8033676001	MSH6 (SP93) RM PAB-US Export	50	
07	8033692001	PMS2 (A16-4) MM PAB-US Export	50	
08	8033706001	BRAF V600E (VE1) MM PAB-US Export	50	
09	8404160001	Ventana ROS-1 (SP384) Rabbit Monoclonal Primary Antibody	50	
10	8504148001	VENTANA CLDN18 (43-14A) Assay	50	
ISH Reagents and ISH Probes				
11	5278660001	EBER ISH Probe	50	
12	5278678001	KAPPA ISH Probe	50	
13	5278686001	LAMBDA ISH Probe	50	
Her2-neu-DISH Reagents				
14	8314373001	VENTANA HER2 DISH DNA PRB CKT- US Export	30	Herceptin (trastuzumab)

Sincerely,
Roche Diagnostics GmbH

ppa. / on behalf of the company

Signed by:
Andrea Weber
ECA5294AC4E94AF...

Andrea Weber
Sub Chapter Lead International Regulatory NPC

i.V. / on behalf of the company

DocuSigned by:
Anja von Au
713481226825460...

Anja von Au
Regulatory Affairs Manager

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Aufsichtsratsvorsitzender: Dr. Thomas Schinecker