

## anti-MUC1 (H23) Mouse Monoclonal Primary Antibody

**REF** 790-4574  
06316514001

**IVD**  50

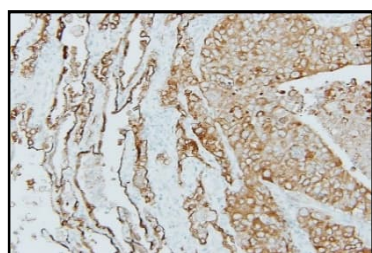


Figure 1. Anti-MUC1 (H23) antibody staining of lung carcinoma.

### INTENDED USE

Anti-MUC1 (H23) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of MUC1 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This antibody is intended for in vitro diagnostic (IVD) use.

### SUMMARY AND EXPLANATION

Anti-MUC1 (H23) Mouse Monoclonal Primary Antibody (anti-MUC1 (H23) antibody) is a mouse monoclonal antibody produced against the transmembrane glycoprotein mucin 1 (MUC1). MUC1 lines the apical surface of epithelial cells in several organs and tissues including the lungs, stomach, pancreas, kidney, colon, and breast.<sup>1-4</sup> MUC1 expression is characteristic of most epithelial tumors but is generally absent in lymphomas, leukemias, melanomas, and sarcomas.<sup>3-6</sup> Due to MUC1 expression in several epithelial tumors (carcinomas), an immunohistochemistry (IHC) assay for MUC1 may identify epithelial lineage but will not be a discriminatory assay to determine the tissue/organ of tumor origin.<sup>3-7</sup> The detection of MUC1 expression by IHC with anti-MUC1 (H23) antibody may be used to aid in the identification of tumors of epithelial origin. This antibody may be used as part of a panel of IHC studies.

### PRINCIPLE OF THE PROCEDURE

Anti-MUC1 (H23) antibody binds to the MUC1 protein in formalin-fixed, paraffin-embedded (FFPE) tissue sections. This antibody can be visualized using *ultraView* Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001). Refer to the respective method sheet for further information.

### MATERIAL PROVIDED

Anti-MUC1 (H23) antibody contains sufficient reagent for 50 tests

One 5 mL dispenser of anti-MUC1 (H23) antibody contains approximately 50 µg of a mouse monoclonal antibody.

The antibody is diluted in phosphate buffered saline with 0.10% ProClin 300, a preservative.

Specific antibody concentration is approximately 10 µg/mL. There is no known non-specific antibody reactivity observed in this product.

Anti-MUC1 (H23) antibody is a mouse monoclonal antibody produced as cell culture supernatant.

Refer to the appropriate VENTANA detection kit method sheet for detailed descriptions of: Principle of the Procedure, Material and Methods, Specimen Collection and Preparation for Analysis, Quality Control Procedures, Troubleshooting, Interpretation of Results, and Limitations.

### MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents, such as VENTANA detection kits and ancillary components, including negative and positive tissue control slides, are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. Recommended control tissue
2. Microscope slides, positively charged
3. Negative Control (Monoclonal) (Cat. No. 760-2014 / 05266670001)
4. *ultraView* Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001)
5. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
6. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
7. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
8. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
9. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
10. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
11. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
12. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
13. General purpose laboratory equipment
14. BenchMark IHC/ISH Instrument

### STORAGE AND STABILITY

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the antibody, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

Every antibody dispenser is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

### SPECIMEN PREPARATION


Routinely processed FFPE tissues are suitable for use with this primary antibody when used with VENTANA detection kits and BenchMark IHC/ISH instruments. The recommended tissue fixative is 10% neutral buffered formalin.<sup>8</sup> Sections should be cut at approximately 4 µm in thickness and mounted on positively charged slides. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time. It is recommended that positive and negative controls be run simultaneously with unknown specimens.

### WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. Do not use beyond the specified number of tests.
4. ProClin 300 solution is used as a preservative in this reagent. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
6. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.<sup>9,10</sup>
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components located at [navifyportal.roche.com](http://navifyportal.roche.com).
10. Consult local and/or state authorities with regard to recommended method of disposal.
11. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
12. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
	H317	May cause an allergic skin reaction.
	P261	Avoid breathing mist or vapours.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P280	Wear protective gloves.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 55965-84-9, reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

## STAINING PROCEDURE

VENTANA primary antibodies have been developed for use on BenchMark IHC/ISH instruments in combination with VENTANA detection kits and accessories. Refer to Table 2 for recommended staining protocols.

This antibody has been optimized for specific incubation times but the user must validate results obtained with this reagent.

The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument User Guide. Refer to the appropriate VENTANA detection kit method sheet for more details regarding immunohistochemistry staining procedures.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 790-4574.

Table 2. Recommended staining protocol for anti-MUC1 (H23) antibody with *ultraView* DAB Universal Detection Kit on BenchMark ICH/ISH instruments.

Procedure Type	Method	
	XT	ULTRA or ULTRA PLUS <sup>a</sup>
Deparaffinization	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, Standard	ULTRA CC1, 64 minutes, 95°C
Antibody (Primary)	16 minutes, 37°C	24 minutes, 36°C
Counterstain	Hematoxylin II, 4 minutes	
Post Counterstain	Bluing, 4 minutes	

<sup>a</sup> Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

Due to variation in tissue fixation and processing, as well as general lab instrument and environmental conditions, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens, detection used, and reader preference. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances."<sup>11</sup>

## NEGATIVE REAGENT CONTROL

In addition to staining with the anti-MUC1 (H23) antibody, a second slide should be stained with the appropriate negative control reagent.

## POSITIVE TISSUE CONTROL

Optimal laboratory practice is to include a positive control section on the same slide as the test tissue. This helps identify any failures applying reagents to the slide. Tissue with weak positive staining is best suited for quality control. Control tissue may contain both positive and negative staining elements and serve as both the positive and negative control. Control tissue should be fresh autopsy, biopsy, or surgical specimen, prepared or fixed as soon as possible in a manner identical to test sections.

Known positive tissue controls should be utilized only for monitoring performance of reagents and instruments, not as an aid in determining specific diagnosis of test samples. If the positive tissue controls fail to demonstrate positive staining, results of the test specimen should be considered invalid.

Examples of positive control tissues for this antibody are lung and pancreas.

## STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for anti-MUC1 (H23) antibody is membranous and cytoplasmic.

## SPECIFIC LIMITATIONS

This antibody has shown slight reactivity to muscle in prostate samples.

All assays might not be registered on every instrument. Please contact your local Roche representative for more information.

## PERFORMANCE CHARACTERISTICS

### ANALYTICAL PERFORMANCE

Staining tests for sensitivity, specificity, and precision were conducted and the results are listed below.

### Sensitivity and Specificity

Table 3. Sensitivity/Specificity of anti-MUC1 (H23) antibody was determined by testing FFPE normal tissues.

Tissue	# positive / total cases	Tissue	# positive / total cases
Cerebrum	0/3	Heart	0/3
Cerebellum	0/3	Esophagus	2/3
Adrenal gland	0/2	Stomach	3/3
Ovary	0/3	Small intestine	1/3
Pancreas	3/3	Colon	3/3
Parathyroid gland	0/3	Liver	0/3
Pituitary gland	0/3	Salivary gland	3/3
Testis	0/3	Kidney	3/3
Thyroid	0/2	Prostate	0/3
Breast	2/5	Endometrium	3/3
Spleen	0/3	Cervix	0/1
Tonsil	3/3	Skeletal muscle	0/3
Thymus	0/3	Skin	1/3
Bone marrow	0/3	Nerve	0/3
Lung	14/15	Mesothelium	3/3

Table 4. Sensitivity/Specificity of anti-MUC1 (H23) antibody was determined by testing a variety of FFPE neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma (Brain)	0/1
Meningioma (Brain)	0/1
Ependymoma (Brain)	0/1
Oligodendroglioma (Brain)	0/1
Serous adenocarcinoma (Ovary)	1/1
Mucinous adenocarcinoma (Ovary)	1/1
Neuroendocrine neoplasm (Pancreas)	0/1
Adenocarcinoma (Pancreas)	1/1
Seminoma (Testis)	0/1
Embryonal carcinoma (Testis)	0/1
Medullary carcinoma (Thyroid)	0/1
Papillary carcinoma (Thyroid)	1/1
Medullary carcinoma (Breast)	11/11
Micropapillary carcinoma (Breast)	1/1
Mucinous adenocarcinoma (Breast)	2/3
Invasive cribriform carcinoma (Breast)	2/2
Metaplastic carcinoma (Breast)	1/1
Ductal carcinoma in situ (Breast)	6/6
Invasive ductal carcinoma (Breast)	95/102
Invasive lobular carcinoma (Breast)	8/9
Mixed ductal and lobular carcinoma (Breast)	3/4
Small cell carcinoma (Lung)	4/14
Squamous cell carcinoma (Lung)	33/45
Adenocarcinoma (Lung)	21/22
Large cell carcinoma (Lung)	7/10
Adenocarcinoma in situ (Lung)	11/11
Papillary adenocarcinoma (Lung)	17/17
Combined small cell carcinoma and squamous cell carcinoma (Lung)	3/6
Neuroendocrine carcinoma, atypical carcinoid (Lung)	1/2
Sarcomatoid carcinoma, giant cell carcinoma (Lung)	2/2
Squamous cell carcinoma (Esophagus)	1/1
Adenocarcinoma (Esophagus)	1/1
Mucinous adenocarcinoma (Stomach)	1/1
Gastrointestinal stromal tumor (GIST) (Small intestine)	0/1
Gastrointestinal stromal tumor (GIST) (Abdominal cavity)	0/1

Pathology	# positive / total cases
Adenocarcinoma (Colon)	2/2
Adenocarcinoma (Rectum)	1/1
Gastrointestinal stromal tumor (GIST) (Rectum)	0/1
Melanoma (Rectum)	0/1
Hepatocellular carcinoma (Liver)	0/1
Hepatoblastoma (Liver)	0/1
Clear cell carcinoma (Kidney)	1/1
Adenocarcinoma (Prostate)	0/2
Leiomyoma (Uterus)	0/1
Adenocarcinoma (Uterus)	1/1
Clear cell carcinoma (Uterus)	1/1
Squamous cell carcinoma (Cervix)	1/2
Embryonal rhabdomyosarcoma (Striated muscle)	0/1
Basal cell carcinoma (Skin)	0/1
Squamous cell carcinoma (Skin)	0/1
Neurofibroma (Soft tissue)	0/1
Ganglioneuroblastoma (Retroperitoneum)	0/1
Mesothelioma (Abdominal cavity)	0/1
Spindle cell rhabdomyosarcoma (Retroperitoneum)	0/1
Lymphoma; NOS	0/1
Hodgkin lymphoma	0/1
B-cell lymphoma, NOS	0/1
Diffuse large B-cell lymphoma	0/2
Urothelial carcinoma (Bladder)	1/1
Osteosarcoma (Bone)	0/1
Leiomyosarcoma	0/2

### Precision

Precision studies for anti-MUC1 (H23) antibody were completed to demonstrate:

- Between lot precision of the antibody.
- Within run and between day precision on a BenchMark XT instrument.
- Between instrument precision on the BenchMark XT and BenchMark ULTRA instrument.
- Between platform precision between the BenchMark XT and BenchMark ULTRA instrument.

All studies met their acceptance criteria.

Precision on the BenchMark ULTRA PLUS instrument was demonstrated using representative assays. Studies included Within-run Repeatability, Between-day and Between-run Intermediate Precision. All studies met their acceptance criteria.

## CLINICAL PERFORMANCE

Clinical performance data relevant to the intended purpose of anti-MUC1 (H23) antibody were assessed by systematic review of the literature. The data gathered support the use of the device in accordance with its intended purpose.

## REFERENCES

1. Lau SK, Weiss LM, Chu PG. Differential Expression of MUC1, MUC2, and MUC5ac in Carcinomas of Various Sites: An Immunohistochemical Study. *Am J Clin Pathol*. 2004;122(1):61-69.
2. Lopez-Ferrer A, Curull V, Barranco C, et al. Mucins as Differentiation Markers in Bronchial Epithelium. Squamous Cell Carcinoma and Adenocarcinoma Display Similar Expression Patterns. *Am J Respir Cell Mol Biol*. 2001;24(1):22-29.
3. Pinkus GS, Kurtin PJ. Epithelial Membrane Antigen--a Diagnostic Discriminant in Surgical Pathology: Immunohistochemical Profile in Epithelial, Mesenchymal, and Hematopoietic Neoplasms Using Paraffin Sections and Monoclonal Antibodies. *Hum Pathol*. 1985;16(9):929-940.
4. Sloane JP, Ormerod MG. Distribution of Epithelial Membrane Antigen in Normal and Neoplastic Tissues and Its Value in Diagnostic Tumor Pathology. *Cancer*. 1981;47(7):1786-1795.
5. Collado Martin R, Garcia Palomo A, de la Cruz Merino L, et al. Clinical Guideline SEOM: Cancer of Unknown Primary Site. *Clin Transl Oncol*. 2014;16(12):1091-1097.
6. Massard C, Lortet Y, Fizazi K. Carcinomas of an Unknown Primary Origin--Diagnosis and Treatment. *Nat Rev Clin Oncol*. 2011;8(12):701-710.
7. Lin F, Liu H. Immunohistochemistry in Undifferentiated Neoplasm/Tumor of Uncertain Origin. *Arch Pathol Lab Med*. 2014;138(12):1583-1610.
8. Carson FL, Cappellano C. *Histotechnology: A Self-Instructional Text*, 5th edition. American Society for Clinical Pathology Press; 2020, 2022.
9. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
10. Directive 2000/54/EC of the European Parliament and Council of 24 June 2020 on the protection of workers from risks related to exposure to biological agents at work.
11. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology, 6th edition. In: NR Rose, ed. ASM Press; 2002.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

The summary of safety and performance can be found here:

<https://ec.europa.eu/tools/eudamed>

## Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see [elabdoc.roche.com/symbols](http://elabdoc.roche.com/symbols) for more information).



Global Trade Item Number

Rx only

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

## REVISION HISTORY

Rev	Updates
E	Updates to Warnings and Precautions section. Updated to current template.

## INTELLECTUAL PROPERTY

VENTANA, BENCHMARK, and ULTRAVIEW are trademarks of Roche. All other product names and trademarks are the property of their respective owners.

© 2025 Ventana Medical Systems, Inc.

For USA: Rx only

## CONTACT INFORMATION



Ventana Medical Systems, Inc.  
1910 E. Innovation Park Drive  
Tucson, AZ 85755

USA

+1 520 887 2155

+1 800 227 2155 (USA)

[www.roche.com](http://www.roche.com)



Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany  
+800 5505 6606



0123