# anti-MUC1 (H23) Mouse Monoclonal Primary Antibody

REF 790-4574

06316514001

IVD Σ 50

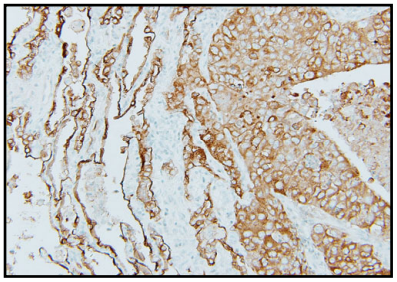

Figure 1. MUC1 expression on lung carcinoma.

## INTENDED USE

Anti-MUC1 (H23) Mouse Monoclonal Primary Antibody is directed against the membrane bound, glycosylated phosphoprotein MUC1. This antibody may be used to aid in the identification of normal and neoplastic MUC1 expressing cells. The antibody is intended for qualitative staining in sections of formalin-fixed, paraffin-embedded human tissue. MUC1 is overexpressed in breast carcinoma and non small cell lung carcinoma.

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) is a mouse monoclonal antibody produced against MUC1, a transmembrane glycoprotein in breast carcinomas and non-small cell lung carcinoma.

MUC1 is a glycoprotein expressed on the apical borders of secretory epithelial cells. In neoplastic tissues, MUC1 expression may be upregulated or the glycosylation may be altered so that MUC1 may be expressed on the entire cell surface (depolarized expression).[1,2] MUC1 is abundantly expressed on a number of epithelial cancers, where its aberrant distribution and glycosylation make it structurally and antigenically distinct from MUC1 expressed by non-malignant cells.[3,4] Glandular epithelia expresses MUC1 in a variety of normal tissue, such as the breast, eccrine and apocrine glands, and the pancreas.

## REAGENT PROVIDED

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

One 7.1 mL dispenser of anti-MUC1 (H23) contains approximately 51 µg of a mouse monoclonal antibody.

The antibody is diluted in phosphate buffered saline with ProClin 300 as a preservative.

Total protein concentration of the reagent is approximately 3 mg/mL. Specific antibody concentration is approximately 10.2 µg/mL. There is no known non-specific antibody reactivity observed in this product.

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

Refer to the appropriate Ventana detection kit package insert for detailed descriptions of: (1) Principles of the Procedure, (2) Materials and Reagents Needed but Not Provided, (3) Specimen Collection and Preparation for Analysis, (4) Quality Control Procedures, (5) Troubleshooting, (6) Interpretation of Results, and (7) General 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.

## STORAGE

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, formalin-fixed, paraffin-embedded tissues are suitable for use with this primary antibody when used with Ventana detection kits and a Ventana BenchMark Series automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.[5] 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. ProClin 300 is used as a preservative in this solution. 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.
3. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
4. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
5. Avoid microbial contamination of reagents as it may cause incorrect results.
6. Consult local and/or state authorities with regard to recommended method of disposal.
7. Refer to the product Safety Data Sheet for additional information.

## STAINING PROCEDURE

Ventana primary antibodies have been developed for use on a Ventana BenchMark Series automated slide stainer in combination with Ventana detection kits and accessories. Refer to Table 1 and 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's Operator's Manual. Refer to the appropriate Ventana detection kit package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocol for anti-MUC1 (H23) with *ultra*View DAB Universal Detection Kit on a BenchMark XT instrument and BenchMark ULTRA instrument.

| Procedure Type | Method |
|---|---|
| Deparaffinization | Selected |
| Cell Conditioning (Antigen Unmasking) | Cell Conditioning 1, Standard |
| Antibody (Primary) | BenchMark XT instrument 16 Minutes, 37°C<br>BenchMark ULTRA instrument 24 Minutes, 36°C |
| Counterstain | Hematoxylin II, 4 Minutes |
| Post Counterstain | Bluing, 4 Minutes |

Table 2. Recommended Staining Protocol for anti-MUC1 (H23) with *i*VIEW DAB Detection Kit on a BenchMark XT instrument.

| Procedure Type | Method |
|---|---|
| Deparaffinization | Selected |
| Cell Conditioning (Antigen Unmasking) | Cell Conditioning 1, Standard |
| Antibody (Primary) | BenchMark XT instrument 16 Minutes, 37°C |
| Counterstain | Hematoxylin II, 4 Minutes |
| Post Counterstain | Bluing, 4 Minutes |

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".[6]

## POSITIVE TISSUE CONTROL

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

## STAINING INTERPRETATION

The cellular staining pattern for anti-MUC1 (H23) is membranous on normal tissue and/or cytoplasmic on neoplastic tissue.

## SPECIFIC LIMITATIONS

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

## PERFORMANCE CHARACTERISTICS

Staining tests for specificity, sensitivity, and repeatability were conducted and the results are listed in Table 3 and Table 4 and in the Repeatability section.

### Specificity

Table 3. Specificity of anti-MUC1 (H23) was determined by testing formalin-fixed, paraffin-embedded normal tissues.

| Tissue | # positive / total cases | Tissue | # positive / total cases |
|---|---|---|---|
| Cerebrum | 0/3 | Thymus | 0/3 |
| Cerebellum | 0/3 | Myeloid (bone marrow) | 0/3 |
| Adrenal gland | 0/2 | Lung | 2/3 |
| Ovary | 0/3 | Heart | 0/3 |
| Pancreas | 3/3 | Esophagus | 2/3 |
| Parathyroid gland | 0/2 | Stomach | 3/3 |
| Hypophysis | 0/3 | Small intestine | 1/3 |
| Testis | 0/3 | Colon | 3/3 |
| Thyroid | 0/3 | Liver | 0/3 |
| Breast | 1/3 | Salivary gland | 3/3 |
| Spleen | 0/3 | Kidney | 3/3 |
| Tonsil | 3/3 | Prostate | 0/3 |
| Endometrium | 3/3 | Cervix | 0/1 |
| Skeletal muscle | 0/3 | Skin | 1/3 |
| Nerve (sparse) | 0/3 | Mesothelium and lung | 3/3 |

### Sensitivity

Table 4. Sensitivity of anti-MUC1 (H23) was determined by testing a variety of formalin-fixed, paraffin-embedded neoplastic tissues.

| Pathology | # positive / total cases |
|---|---|
| Glioblastoma | 0/1 |
| Atypical meningioma | 0/1 |
| Malignant ependymoma | 0/1 |
| Malignant oligodendroglioma | 0/1 |
| Serous papillary adenocarcinoma | 1/1 |
| Mucinous papillary adenocarcinoma | 1/1 |
| Islet cell carcinoma | 0/1 |
| Pancreatic adenocarcinoma | 0/1 |
| Seminoma | 0/1 |
| Embryonal carcinoma | 0/1 |
| Medullary carcinoma | 0/1 |
| Papillary carcinoma | 1/1 |
| Breast medullary carcinoma | 11/11 |
| Breast micropapillary carcinoma | 1/1 |
| Breast mucinous adenocarcinoma | 2/3 |
| Breast infiltrating cribriform carcinoma | 1/1 |
| Breast metaplastic carcinoma | 1/1 |
| Breast intraductal carcinoma | 5/5 |
| Breast infiltrating ductal carcinoma | 51/54 |
| Breast lobular carcinoma | 0/1 |
| Breast invasive lobular carcinoma | 8/8 |
| Ductal-Lobular mixed carcinoma | 3/4 |
| Breast invasive ductal carcinoma | 54/58 |
| Diffuse B-cell lymphoma | 0/1 |
| Lung small cell undifferentiated carcinoma | 4/14 |
| Lung squamous cell carcinoma | 33/45 |
| Lung adenocarcinoma | 21/22 |
| Lung large cell undifferentiated carcinoma | 7/10 |
| Lung bronchioalveolar carcinoma | 11/11 |
| Lung papillary adenocarcinoma | 17/17 |
| Complexied small cell carcinoma | 3/6 |
| Atypical carcinoid | 1/2 |
| Giant cell carcinoma | 2/2 |
| Esophageal squamous cell carcinoma | 1/1 |
| Esophageal adenocarcinoma | 1/1 |

| Pathology | # positive / total cases |
|---|---|
| Gastric mucinous adenocarcinomas | 1/1 |
| Gastrointestinal adenocarcinoma | 1/1 |
| GIST | 0/1 |
| Hepatocellular carcinoma | 0/1 |
| Hepatoblastoma | 0/1 |
| Renal clear cell carcinoma | 1/1 |
| Prostatic adenocarcinoma | 0/1 |
| Prostatic transitional cell carcinoma | 0/1 |
| Leiomyoma | 0/1 |
| Endometrial adenocarcinoma | 1/1 |
| Endometrial clear cell carcinoma | 1/1 |
| Uterine squamous cell carcinoma | 1/1 |
| Embryonal rhabdomyosarcoma | 0/1 |
| Anal malignant melanoma | 0/1 |
| Basal cell carcinoma | 0/1 |
| Squamous cell carcinoma | 0/1 |
| Neurofibroma | 0/1 |
| Retroperitoneal neuroblastoma | 0/1 |
| Epithelial malignant mesothelioma | 0/1 |
| Diffuse malignant lymphoma | 0/1 |
| Hodgkin lymphoma | 0/1 |
| Diffuse malignant lymphoma | 0/1 |
| Bladder transitional cell carcinoma | 1/1 |
| Low grade leiomyosarcoma | 0/1 |
| Osteosarcoma | 0/1 |
| Spindle cell rhabdomyosarcoma | 0/1 |
| Intermediate grade leiomyosarcoma | 0/1 |
| Malignant melanoma | 0/1 |

### Repeatability

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

- Inter-lot reproducibility of the antibody.
- Intra-run and Inter-run reproducibility on a BenchMark XT instrument.
- Intra-platform reproducibility on the BenchMark XT instrument and the BenchMark ULTRA instrument.
- Inter-platform reproducibility between the BenchMark XT instrument and BenchMark ULTRA instrument.

All studies met their acceptance criteria.

## REFERENCES


1. Guddo F, et al. MUC1 (episialin) expression in non-small cell lung cancer is independent of EGFR and c-erbB-2 expression and correlates with poor survival in node positive patients. J Clin Pathol. 1998;51:667-71.
2. Guddo F, et al. Depolarized expression of episialin (EMA, MUC1) in lung adenocarcinoma is associated with tumor progression. Anticancer Res. 1998;18:1915-20.
3. Barratt-Boyes S. Making the most of mucin: a novel target for tumor immunotherapy, Cancer Immunol Immunother. 1996;43:142–151.
4. Taylor-Papadimitriou J, Epenetos A. Exploiting altered glycosylation patterns in cancer: progress and challenges in diagnosis and therapy. Trends Biotechnol. 1994;12:227–233.
5. Carson F, Hladik C. Histotechnology: A Self Instructional Text, 3rd edition. Hong Kong: American Society for Clinical Pathology Press; 2009.
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