MUC-1

Concentrated and Prediluted Monoclonal Antibody
901-319-111318

BIOCARE MEDICAL

Catalog Number:	**CM 319 B**	**PM 319 AA**
Description:	0.5 mL, conc.	6.0 mL, RTU
Dilution:	1:100	Ready-to-use
Diluent:	Renoir Red	N/A

Intended Use:
For In Vitro Diagnostic Use
MUC-1 [695] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of MUC-1 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:
MUC-1 is a large cell surface mucin glycoprotein expressed by most glandular and ductal epithelial cells and some hematopoietic cell lineages. The MUC-1 mucin (Cancer Antigen 15-3) is secreted from tumor cells. The apoprotein of the MUC-1 mucin contains a transmembrane domain, a cytoplasmic domain, and an extracellular carbohydrate rich domain. Abnormal overexpression of MUC-1 in cancer cells is thought to contribute to their aggressive growth, but molecular mechanisms associated with this effect are still unclear. MUC-1 stains cell membranes, but also the cytoplasm of most epithelial cell types. It is expressed on most secretory epithelium, including mammary gland and some hematopoietic cells. It is expressed abundantly in lactating mammary glands and over-expressed abundantly in >90% breast carcinomas and metastases. As an exception, mucinous carcinomas are significantly less MUC-1 reactive. Aberrant cytoplasmic and membranous localization of MUC-1 expression has been associated with poor patient outcome. Adenocarcinomas are generally positive and squamous carcinomas and nonepithelial malignancies negative. High grade prostate carcinomas were negative, in contrast to low grade ones. Bladder and kidney cancers were either strongly positive or negative. Hepatocellular carcinomas are negative, but cholangiogenic carcinomas are positive.

Principle of Procedure:
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. This detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: 695
Isotype: IgG1
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: MUC-1
Cellular Localization: Cytoplasmic/cell membrane
Positive Tissue Control: Lung

Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30-60 minutes at RT.
Probe: N/A
Polymer: Incubate for 30 minutes at RT with a secondary-conjugated polymer.
Chromogen: Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 2 detection system. Use TBS for washing steps.

Limitations:
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

Quality Control:
Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN_3) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (7)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (8)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. Rakha EA, *et al*. Expression of mucins (MUC1, MUC2, MUC3, MUC4, MUC5AC and MUC6) and their prognostic significance in human breast cancer. Mod Pathol. 2005 Oct; 18(10):1295-304.
2. Chauhan SC, *et al*. Aberrant expression of MUC4 in ovarian carcinoma: diagnostic significance alone and in combination with MUC1 and MUC16 (CA125). Mod Pathol. 2006 Oct; 19(10):1386-94.
3. Nassar H, *et al.* Pathogenesis of invasive micropapillary carcinoma: role of MUC1 glycoprotein. Mod Pathol. 2004 Sep;17(9):1045-50.
4. Langner C, *et al*. Expression of MUC1 (EMA) and E-cadherin in renal cell carcinoma: a systematic immunohistochemical analysis of 188 cases. Mod Pathol. 2004 Feb;17(2):180-8.
5. Khoury T, *et al*. Inclusion of MUC1 (Ma695) in a panel of immunohistochemical markers is useful for distinguishing between endocervical and endometrial mucinous adenocarcinoma. BMC Clin Pathol. 2006 Jan 12;6(1):1.
6. Ohno T, *et al*. Prognostic significance of combined expression of MUC1 and adhesion molecules in advanced gastric cancer. Eur J Cancer. 2006 Jan;42(2):256-63.
7. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
8. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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