Gross Cystic Disease Fluid Protein-15 (GCDFP-15)

Concentrated and Prediluted Monoclonal Antibody
901-113-121817

BIOCARE MEDICAL

Catalog Number:	**CM 113 A, B**	**PM 113 AA**	**IP 113 G10**
Description:	0.1, 0.5 ml, concentrated	6.0 ml, prediluted	10 ml, prediluted
Dilution:	1:50	Ready-to-use	Ready-to-use
Diluent:	Da Vinci Green	N/A	N/A

Intended Use:
For In Vitro Diagnostic Use
Gross Cystic Disease Fluid Protein-15 (GCDFP-15) [D6] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of GCDFP-15 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:
Gross cystic disease fluid is a pathologic secretion from breast composed of several glycoproteins, including GCDFP-15. It is considered to be a marker of apocrine differentiation. Numerous studies have shown GCDFP-15 (BRST-2) to be a specific marker for breast cancer in formalin-fixed paraffin-embedded tissues and in cytologic preparation (fine needle aspirates). Studies on breast cancer have shown, with respect to specificity and sensitivity, an overall rating of 95% and 74% respectively. Another study was conducted on fine needle aspirates and statistics showed that 56.5% of primary and recurrent or metastatic breast carcinomas were expressed with GCDFP-15. Other types of tissues that express GCDFP-15 are axillary sweat glands and submandibular salivary glands.

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, a secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: D6
Isotype: IgG2a
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Epitope/Antigen: Gross Cystic Disease Fluid Protein-15
Cellular Localization: Cytoplasmic
Positive Tissue Control: Breast cancer
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative
Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (intelliPATH and manual use):
Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Digestion Method: Digest with Pepsin enzyme for 5 minutes at 37°C -or- for 15 minutes at RT.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.

Protocol Recommendations (intelliPATH and manual use):
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.
Chromogen: Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Biocare's Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
intelliPATH™ Automated Slide Stainer:
IP113 is intended for use on the intelliPATH™ Automated Slide Stainer. Refer to the intelliPATH Automated Slide Stainer manual for specific instructions on its use. When using the intelliPATH, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.
Technical Note:
This antibody has been optimized for use with Biocare's MACH 4 Universal HRP-Polymer Detection and intelliPATH Universal HRP Detection Kit. 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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.
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) (6)
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 in contact with sensitive areas, wash with copious amounts of water. (7)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.

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Precautions Cont'd:

4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagents after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

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. Hall RE, *et al.* Prostate-specific antigen and gross cystic disease fluid protein-15 are co-expressed in androgen receptor-positive breast tumours. Br J Cancer. 1998 Aug;78(3):360-5.
2. Viacava P, Naccarato AG, Bevilacqua G. Spectrum of GCDFP-15 expression in human fetal and adult normal tissues. Virchows Arch. 1998 Mar;432(3):255-60.
3. Fiel MI, *et al.* Value of GCDFP-15 (BRST-2) as a specific immunocytochemical marker for breast carcinoma in cytologic specimens. Acta Cytol. 1996 Jul-Aug;40(4):637-41.
4. Wallace ML, Smoller BR. Differential sensitivity of estrogen/progesterone receptors and BRST-2 markers in metastatic ductal and lobular breast carcinoma to the skin. Am J Dermatopathol. 1996 Jun;18(3):241-7.
5. Wick MR, *et al.* Gross cystic disease fluid protein-15 as a marker for breast cancer: immunohistochemical analysis of 690 human neoplasms and comparison with alpha-lactalbumin. Hum Pathol. 1989 Mar;20(3):281-7.
6. 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."
7. 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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