



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

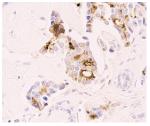
Prediluted Mouse Monoclonal Antibody Control Number: 901-113IP-073115

**Description:** Catalog Number: IP 113 G10 10 ml, predilute

#### Intended Use:

For In Vitro Diagnostic Use **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 conducted on fine needle aspirates showed that 56.5% of primary and recurrent or metastatic breast carcinomas expressed GCDFP-15. Other types of tissues that express GCDFP-15 are axillary sweat glands and submandibular salivary glands.



Breast cancer stained with GCDFP antibody.

## **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

Antibody Category: Carcinoma, breast cancer

Epitope/Antigen: Gross Cystic Disease Fluid Protein-15

Total Protein Concentration: Call for lot specific Ig Concentration.

Cellular Localization: Cytoplasmic Positive Control: Breast Cancer

Normal Tissue: Breast

Abnormal Tissue: Ductal cell carcinoma

**Known Applications:** 

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative.

## Storage and Stability:

Store at 2°C to 8°C. 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 2°C to 8°C.

#### **Protocol Recommendations:**

Pretreatment Solution (recommended): N/A Peroxide Block: Block for 5 minutes at RT.

**Digestion Method:** 

Digest with Pepsin enzyme for 15 minutes at RT.

**Protein Block:** 

Optional: Incubate for 10-15 minutes at RT. **Primary Antibody:** Incubate for 30 minutes at RT. Secondary: Incubate for 10 minutes at RT.

Tertiary: Incubate for 10 minutes at RT. Chromogen: Incubate for 5 minutes with DAB at RT.

#### Counterstain:

- 1. Rinse with deionized water.
- 2. Incubate for 5 minutes with automated Hematoxylin.
- 3. Rinse with TBS Buffer for 1 minute followed by a rinse with deionized water.

### **Quality Statement:**

Biocare protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the intelliPATH FLX automated stainer. Recommended staining protocols are specified in the datasheet of the antibody of interest. Preoptimized intelliPATH FLX protocols with preset parameters can be displayed, printed and edited according to the procedure in the operator's manual. Refer to the operator's manual for additional instruction to navigate intelliPATH FLX software and stainer. Use TBS for washing steps unless otherwise specified.

### **Performance Characteristics:**

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. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

#### **Quality Control:**

Refer to NCCLS Quality Assurance for Immunocytochemistry approved guidelines, December 1999 MM4-A Vol.19 No.26 for more information about tissue controls.

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 (NaN3) 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)

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.

Microbial contamination of reagents may result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request.

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EC REP EMERGO EUROPE Molenstraat 15





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### **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, Clements JA, Birrell SN, Tilley WD. 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. 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."
- 4. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. Villanova, PA 1991;7(9). Order code M29-P.

USA

The Netherlands