

GCDFP-15 + Mammaglobin

Prediluted Multiplex Cocktail (4-Step)

Control Number: 902-317DS-082417

Catalog Number: APR 317 DS AA

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

Diluent: N/A

Intended Use:

For Research Use Only. Not for use in diagnostic procedures.

Summary and Explanation:

Gross cystic disease fluid protein (mouse monoclonal) is a 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). Other types of tissues that express GCDFP-15 are axillary sweat glands and submandibular salivary glands.

Mammaglobin (rabbit monoclonal), a mammary-specific member of the uteroglobin family, is known to be overexpressed in human breast cancer. Studies suggest that mammaglobin is one of the first relatively mammary-specific and mammary-sensitive markers. In normal breast tissue, mammaglobin labels breast ductal and lobular epithelial cells. However, mammaglobin is expressed in a higher percentage of lobular carcinoma versus ductal cell carcinoma. Studies have also shown that mammaglobin was not altered at the metastatic lymph node site. Mammaglobin has been shown to be expressed in non-breast cancer sites such as endometrioid carcinomas (39%), endocervical adenocarcinoma in situ (45%), sweat gland carcinomas (40%), salivary gland carcinoma (20%), melanoma (6%) and is also found in a small percentage of ovarian carcinomas and pancreatic adenocarcinomas.

Mammaglobin is expressed in 50-60% of metastatic breast cancers while GCDFP-15 is expressed in approximately 20-25%. Mammaglobin is a more sensitive marker than GCDFP-15 for breast carcinoma; however, it lacks the specificity of GCDFP-15. The combination of GCDFP-15 and Mammaglobin and other markers may help to establish the correct interpretation of metastatic breast carcinoma.

Principle of Procedure:

This product is a primary antibody cocktail of mouse and rabbit antibodies, which may be used in a Multiplex IHC staining procedure to produce a two-color stain. Following application of the primary antibody cocktail to the tissue sample, detection is performed by separate secondary antibodies specific for each species (i.e. mouse or rabbit) of the primary antibody cocktail, which are conjugated to horseradish peroxidase (HRP) or alkaline phosphatase (AP) enzymes. Visualization is accomplished by the application of chromogenic substrates (DAB and Warp Red), which are enzymatically activated (by HRP or AP, respectively) to produce a colored reaction product at the antigen site. The specimen may be counterstained and coverslipped. Results are interpreted using a light microscope.

Source: Mouse monoclonal and Rabbit monoclonal

Species Reactivity: Human; others not tested

Clone: D6 (GCDFP-15) and 31A5 (Mammaglobin)

Isotype: IgG2a (GCDFP-15) and IgG (Mammaglobin)

Epitope/Antigen: GCDFP-15 and Mammaglobin

Cellular Localization:

GCDFP-15 (Cytoplasmic): Brown

Mammaglobin (Cytoplasmic): Red

Positive Control: Breast

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.

Staining Protocol Recommendations:

Peroxide Block: Block for 5 minutes with Biocare's Peroxidized 1

Pretreatment Solution (recommended): Diva

Pretreatment Protocol:

Heat Retrieval Method:

Preheat the retrieval solution to 95°C for 30 minutes in Biocare's Decloaking Chamber. Then, place slides into the preheated solution and retrieve under pressure at 95°C for 40 minutes; alternatively, steam tissue sections for 45-60 minutes or use a water bath at 95°C for 40 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 30 minutes at RT.

Double Stain Detection:

Incubate for 30 minutes at RT using Biocare's MACH 2 Double Stain 2.

Chromogen (1): Incubate for 5 minutes at RT with Biocare's Betazoid DAB.

Chromogen (2): Incubate for 5-7 minutes at RT with Biocare's Warp Red. Rinse in deionized water.

Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:

This antibody has been standardized with Biocare's MACH 2 Double Stain 2. It can also be used on an automated staining system. Use TBS buffer for washing steps.

* For optimum results, breast tissues should be fixed for 8-24 hours.

Limitations:

This product is provided for Research Use Only (RUO) and is not for use in diagnostic procedures. Suitability for specific applications may vary and it is the responsibility of the end user to determine the appropriate application for its use.

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 (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) (4)

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. (5)

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>.

Technical Support:

Contact Biocare's Technical Support at 1-800-542-2002 for questions regarding this product.

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References:

1. Bhargava R, Beriwal S, Dabbs DJ. Mammaglobin vs GCDFP-15: An Immunohistologic Validation Survey for Sensitivity and Specificity. *Am J Clin Pathol.* 2007 Jan;127(1):1-11.
2. 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.
3. Han JH, *et al.* Mammaglobin expression in lymph nodes is an important marker of metastatic breast carcinoma. *Arch Pathol Lab Med.* 2003 Oct; 127(10):1330-4.
4. 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."
5. 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.