



GCDFP-15 + Mammaglobin
Prediluted Double Stain Antibody (4-Step)
Control Number: 901-317DS-061509

ISO
9001:2000
CERTIFIED

Catalog Number: PM 317 DS AA
Description: 6.0 ml, prediluted
Dilution: Ready-to-use
Diluent: N/A

Intended Use:
For In Vitro Diagnostic Use

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 endometroid 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:

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 universal, affinity-purified, 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 and Rabbit Monoclonal

Species Reactivity: Human; others not tested

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

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

Epitope/Antigen: GCDFP-15 and Mammaglobin

Cellular Localization:

GCDFP-15: Cytoplasmic – Brown

Mammaglobin: Cytoplasmic - Red

Positive Control: Breast

Normal Tissue: Breast

Abnormal Tissue: Breast cancers (Lobular breast cancer)

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

Peroxide Block:

Block for 5 minutes with BIOCARE's PEROXIDAZED 1.

Pretreatment Solution (recommended): Diva

Pretreatment Protocol:

Heat Retrieval Method:

Retrieve sections under pressure using BIOCARE's Decloaking Chamber, followed by a wash in distilled water. Alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Protein Block:

Incubate for 10-15 minutes at RT with BIOCARE's Background Sniper.

Primary Antibody: Incubate for 30 minutes at RT.

Double Stain Detection:

Incubate for 30 minutes at RT using BIOCARE's Double Stain Kit #2.

Chromogen (1): Incubate for 5 minutes at RT when using BIOCARE's Betazoid DAB.

Chromogen (2):

Incubate for 10 minutes at RT with BIOCARE's Vulcan Fast Red. Rinse in deionized water.

Counterstain:

Rinse with deionized water. Incubate for 30-60 seconds with Tacha's Automated Hematoxylin. Rinse with deionized water. Apply Tacha's Bluing solution for 1 minute.

Technical Note:

This antibody has been standardized with BIOCARE's Double Stain Kit #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.

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.

Precautions:

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.





GCDFP-15 + Mammaglobin

Prediluted Double Stain Antibody (4-Step)
Control Number: 901-317DS-061509

ISO
9001:2000
CERTIFIED

Troubleshooting:

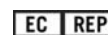
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact BIOCARE's Technical Support at 1-800-542-2002.

Limitations and Warranty:

There are no warranties, expressed or implied, which extend beyond this description. BIOCARE is not liable for property damage, personal injury, or economic loss caused by this product.

References:

1. Bhargava R, Beriwal S, Dabbs DJ. Mammaglobin vs GCDFP-15: An Immunohistologic Validation Survey for Sensitivity and Specificity. 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, Lillemoe TJ, Copland GT, Swanson PE, Manivel JC, Kiang DT. 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, Kang Y, Shin HC, Kim HS, Kang YM, Kim YB, Oh SY. Mammaglobin expression in lymph nodes is an important marker of metastatic breast carcinoma. (Polyclonal) 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. 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.



GCDFP-15 + Mammaglobin

Prediluted Mouse Monoclonal and Rabbit Monoclonal Double Stain Antibody (4-Step)

Control Number: 901-317DSIP-061509

Catalog Number: IP 317DS G10
Description: 10 ml, predilute

Intended Use:

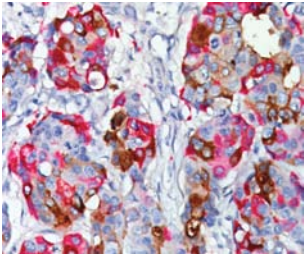
For In Vitro Diagnostic Use

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 endometroid 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.



Breast cancer stained with GCDFP-15 + Mammaglobin.

Source: Mouse Monoclonal and Rabbit Monoclonal

Species Reactivity: Human; others not tested

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

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

Antibody Category: Double Stain, breast cancer

Epitope/Antigen: GCDFP-15 and Mammaglobin

Cellular Localization:

GCDFP-15: Cytoplasmic – Brown, Mammaglobin: Cytoplasmic - Red

Positive Control: Breast

Normal Tissue: Breast

Abnormal Tissue: Breast cancers (Lobular breast cancer)

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): Diva

Pretreatment Protocol:

Heat Retrieval Method:

Retrieve sections under pressure using BIOCARE's Decloaking Chamber at 95°C for 40 minutes, followed by a wash in distilled water. Alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Peroxide Block:

Block for 5 minutes at RT.

Primary Antibody:

Incubate for 30 minutes at RT.

Double Stain Detection:

Incubate for 30 minutes at RT using BIOCARE's Multiplex Kit 2.

Chromogen (1):

Incubate for 5 minutes at RT when using BIOCARE's DAB.

Chromogen (2):

Incubate for 15-20 minutes at RT with BIOCARE's Fast Red. Rinse in deionized water.

Counterstain:

1. Rinse with deionized water. 2. Incubate for 5 minutes with Tacha's 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. Pre-optimized *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

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.

Precautions:

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.



GCDFP-15 + Mammaglobin

Prediluted Mouse Monoclonal and Rabbit Monoclonal Double Stain Antibody (4-Step)

Control Number: 901-317DSIP-061509

Precautions cont'd:

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.

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.

Limitations and Warranty:

There are no warranties, expressed or implied, which extend beyond this description. BIOCARE is not liable for property damage, personal injury, or economic loss caused by this product.

References:

1. Bhargava R, Beriwal S, Dabbs DJ. Mammaglobin vs GCDFP-15: An Immunohistologic Validation Survey for Sensitivity and Specificity. 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, Lillemoe TJ, Copland GT, Swanson PE, Manivel JC, Kiang DT. 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, Kang Y, Shin HC, Kim HS, Kang YM, Kim YB, Oh SY. Mammaglobin expression in lymph nodes is an important marker of metastatic breast carcinoma. (Polyclonal) 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. 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.

Pour visualiser ou imprimer cette fiche technique en français, veuillez vous rendre sur www.biocare.net

Auf der Website www.biocare.net können Sie dieses Datenblatt in deutsch aufrufen und ausdrucken

Per visualizzare o stampare questo foglio dati in italiano, visitare la pagina www.biocare.net

Para ver o imprimir esta ficha de datos en español, vaya a www.biocare.net

