BIOCARE MEDICAL

ISO 9001&13485 CERTIFIED

p63, 3X (Breast)

Prediluted Monoclonal Antibody

Control Number: 901-3050-082014

Catalog Number: **API 3050 G3**

Description: 3.0 ml, prediluted

Dilution: Ready-to-use

Diluent: N/A

Intended Use:

For In Vitro Diagnostic Use

p63, 3X (Breast) [4A4] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of p63 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human breast 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:

p63, 3X (Breast) [4A4] is comprised of a mouse monoclonal anti-p63 antibody. p63 is a transcription factor present in the nuclei of myoepithelial cells of normal breast ducts (1,2). p63 has routinely been used in a panel of IHC markers to complement morphological evaluation in the assessment of breast lesions, due to the differential expression of the luminal vs. basal and myoepithelial markers (1-6). Cases of usual ductal hyperplasia (UDH) have been associated with expression of the basal cell markers, intermixed with cells expressing the keratins of luminal cells (1-3,7-11). Most cases of atypical ductal hyperplasia (ADH) and low grade ductal carcinoma *in situ* (LG DCIS) were negative for basal markers and exhibited an immunophenotype indicative of luminal cells (1,5-9). Additionally, the basal phenotype has been shown to be characterized by luminal expression of the basal and myoepithelial markers, using a cocktail of CK5, CK14 and p63 (12-14).

IHC, using CK5, CK14, p63, CK7 and CK18 antibodies, evaluated in combination with hematoxylin and eosin (H&E), has been shown to significantly increase interobserver agreement amongst pathologists, compared to H&E alone (15).

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. The detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human

Clone: 4A4

Isotype: IgG2a/kappa

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration

Epitope/Antigen: p63

Cellular Localization: Nuclear

Positive Tissue Control: Normal breast

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:

Peroxide Block:

Block for 5 minutes with Biocare's Peroxidazed 1.

Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.

Protocol Recommendations Cont'd:

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

Primary Antibody: Incubate for 10 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.

Counterstain:

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

Technical Notes:

This antibody has been standardized with Biocare's MACH 2 DS 2 detection system. Use TBS buffer 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) (16)
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. (17)
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 MSDS is available upon request and is located at http://biocare.net/support/msds/.

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.

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References:

1. Moriya T, *et. al.* New trends of immunohistochemistry for making differential diagnosis of breast lesions. Med Mol Morphol. 2006; 39:8-13.
2. Lerwill MF. Current Practical Applications of Diagnostic Immunohistochemistry in Breast Pathology. Am J Surg Pathol. 2004; 28:1076-91.
3. Hicks DG. Immunohistochemistry in the Diagnostic Evaluation of Breast Lesions. Appl Immunohistochem Mol Morph. 2011; 19:501-5.
4. Yeh IT, Mies C. Application of Immunohistochemistry to Breast Lesions. Arch Pathol Lab Med. 2008; 132:349-57.
5. Moriya T, *et. al.* Usefulness of immunohistochemistry for differential diagnosis between benign and malignant breast lesions. Breast Cancer. 2009; 16:173-8.
6. Tacha DE, *et. al.* A Rapid Double Immunostaining Technique with a Single Combination of CK5, CK14, p63, CK7 and CK18 Distinguishes Between Hyperplasia of the Usual Type, Atypical Hyperplasia, Microinvasive and Basal Phenotype Breast Cancers. Mod Pathol. 2009 Jan; 22(Supplement 1s):388A.
7. Otterbach F, *et. al.* Cytokeratin 5/6 immunohistochemistry assists in differential diagnosis of atypical proliferations of the breast. Histopathology. 2000; 37:232-40.
8. Lacroix-Triki M, *et. al.* Value of cytokeratin 5/6 immunostaining using D5/16 B4 antibody in the spectrum of proliferative intraepithelial lesions of the breast. A comparative study with 34betaE12 antibody. Virchows Arch. 2003; 442:548-54.
9. Boecker W, *et. al.* Usual ductal hyperplasia of the breast is a committed stem (progenitor) cell lesion distinct from atypical ductal hyperplasia and ductal carcinoma in situ. J Pathol. 2002; 198:458-67.
10. Koo JS, *et. al.* Comparison of Immunohistochemical Staining in Breast Papillary Neoplasm of Cytokeratin 5/6 and p63 in core Needle Biopsies and Surgical Excisions. Appl Immunohistochem Mol Morph. 2012; 20:108-15.
11. Ichihara S, *et. al.* Double immunostaining with p63 and high-molecular-weight cytokeratins distinguishes borderline papillary lesions of the breast. Path Int. 2007; 57:126-32.
12. Livasy CA, *et. al.* Phenotypic evaluation of the basal-like subtype of invasive breast carcinoma. Mod Pathol. 2006; 19:264-71.
13. Laakso M, *et. al.* Cytokeratin 5/14-positive breast cancer: true basal phenotype confined to BRCA1 tumors. Mod Pathol. 2005; 18:1321-8.
14. Bhargava R, *et. al.* CK5 is More Sensitive than CK5/6 in Identifying the "Basal-like" Phenotype of Breast Carcinoma. Am J Clin Pathol. 2008; 130:724-30.
15. Jain RK, *et. al.* Atypical ductal hyperplasia: interobserver and intraobserver variability. Mod Pathol. 2011; 24:917-23.
16. 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."
17. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory workers from occupationally Acquired Infections; Approved guideline-Third Edition CLSI document M29-A3 Wayne, PA 2005.

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