**p63, 3X (Breast)**

**Prediluted Monoclonal Antibody**

**Control Number:** 901-3050-082014

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**Catalog Number:** API 3050 G3

**Description:** 3.0 ml, prediluted

**Dilution:** Ready-to-use

**Diluent:** N/A

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**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) 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:**

**Primary Antibody:** Incubate for 10 minutes at RT.

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

**Probe:** N/A

**Chromogen:**

Incubate for 30 minutes at RT with a secondary-conjugated polymer.

**Counterstain:**

Incubate for 5 minutes at RT with Biocare’s DAB.

**Counterstain:**

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:**


**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) (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.
References: