p63
Prediluted Mouse Monoclonal Antibody
Control Number: 901-163IP-081913

Catalog Number: Description:
IP 163 G10 10 ml, predilute

Intended Use:
For In Vitro Diagnostic Use
p63 [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 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, a homolog of the tumor suppressor p53, has been identified in basal cells in the epithelial layers of a variety of tissues, including epidermis, cervix, urothelium, breast and prostate (1). p63 was detected in nuclei of the basal epithelium in normal prostate glands; however, it was not expressed in malignant tumors of the prostate (2). As a result, p63 has been reported as a useful marker for differentiating benign from malignant lesions in the prostate, particularly when used in combination with markers of high molecular weight cytokeratins and the prostate-specific marker AMACR (P504S) (3-4).

p63 has also been shown to be a sensitive marker for lung squamous cell carcinomas (SqCC), with reported sensitivities of 80-100% (5-8). Specificity for lung SqCC, vs. lung adenocarcinoma (LADC), has been reported to be approximately 70-90%, as positive staining with p63 has been typically observed in 10-30% of LADC cases (5-8).

In breast tissue, p63 has been identified in myoepithelial cells of normal ducts (9). Reports have described the utility of p63 in a panel of IHC markers for the assessment of breast lesions, due to the differential expression of the luminal vs. basal and myoepithelial markers (9-11).

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, mouse and rat
Clone: 4A4
Isotype: IgG2a/kappa
Antibody Category: Carcinoma
Epitope/Antigen: p63
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Cellular Localization: Nuclear
Positive Control: Normal prostate
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.

Protocol Recommendations:
Pretreatment Solution (recommended): Reveiw
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 10 minutes then wash in distilled water.
Peroxide Block: Block for 5 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.

Staining Procedure:
Biocare protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the intelliPATH automated stainer. Recommended staining protocols are specified in the data sheet of the antibody of interest. Pre-optimized intelliPATH 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 software and stainer. Use TBS for washing steps unless otherwise specified.

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) (12)
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. (13)
Precautions Cont’d:
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:

References: