



p63 (PulmoPanel™)
Prediluted Monoclonal Antibody
Control Number: 901-163AAK-022511

ISO
9001:2000
CERTIFIED

Catalog Number: PM 163 AAK
Description: 6.0 ml, prediluted
Dilution: Ready-to-use
Diluent: N/A

Intended Use:

For In Vitro Diagnostic Use. Optimized for lung cancer only. Not recommended for prostate cancer.

Summary and Explanation:

Tumor protein p63, also known as transformation-related protein 63 is a protein that in humans is encoded by the TP63 gene. Many studies have shown that p63 is a sensitive (90%) and fairly specific marker for squamous cell carcinoma and may be used in distinguishing poorly differentiated lung squamous cell carcinomas (SqCC) from adenocarcinomas. p63 has been shown to mark approximately 5 to 10% of lung adenocarcinomas.

p63 is a nuclear stain and has been specially titrated for lung SqCC. This optimized p63 antibody is part of the PulmoPanel™ set used for discriminating between lung adenocarcinoma vs. lung SqCC.

A cocktail of p63 and TRIM29 can also be utilized for lung SqCC and studies have shown that when p63 and/or TRIM29 is expressed in lung SqCC, a 95.4% sensitivity and 100% specificity was achieved, if Napsin A and TTF-1 were both negative in the same case.

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; others not tested

Clone: BC4A4

Isotype: IgG2a/kappa

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

Epitope/Antigen: p63

Cellular Localization: Nuclear

Positive Control: Lung squamous cell carcinoma

Normal Tissue: Prostate, bladder

Abnormal Tissue: Lung squamous cell carcinoma

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 Peroxidized 1.

Pretreatment Solution: Diva or Reveal

Protocol Recommendations Cont'd:

Pretreatment Protocol:

Heat Retrieval Method:

Retrieve sections using Biocare's Decloaking Chamber at 125°C for 30 seconds. Allow solution to cool for 10 minutes then wash in distilled water.

Protein Block:

Incubate for 10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 20-30 minutes at RT.

Probe: Incubate for 10 minutes at RT with MACH 4 Probe.

Polymer: Incubate for 10 minutes at RT with a MACH 4 Polymer.

Chromogen:

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

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 4 detection system. It can also be used on an automated staining system. Use TBS buffer for washing steps.

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.

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.

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References:

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2. Tacha D, Yu C, Haas T. TTF-1, Napsin A, p63, TRIM29, Desmoglein-3 and CK5: An Evaluation of Sensitivity and Specificity and Correlation of Tumor Grade for Lung Squamous Cell Carcinoma vs. Lung Adenocarcinoma. Modern Pathology; USCAP, 2011 (Abstract Accepted)
3. Mukhopadhyay S, Katzenstein AL. Subclassification of non-small cell lung carcinomas lacking morphologic differentiation on biopsy specimens: Utility of an immunohistochemical panel containing TTF-1, napsin A, p63, and CK5/6. Am J Surg Pathol. 2011 Jan; 35(1):15-25.
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5. Conde E, et al. The use of P63 immunohistochemistry for the identification of squamous cell carcinoma of the lung. PLoS One. 2010 Aug 17; 5(8):e12209.
6. Uke M, et al. The use of p63 as an effective immunomarker in the diagnosis of pulmonary squamous cell carcinomas on de-stained bronchial lavage cytological smears. Cytopathology. 2010 Feb; 21(1):56-63. Epub 2009 Sep 9.
7. 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."
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