

Leica

BIOSYSTEMS

BOND™ Ready-to-Use Primary Antibody p63 (7JUL)

Catalog No: PA0103

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Instructions for Use

Please read before using this product.

Check the integrity of the packaging before use.

BOND™ Ready-To-Use Primary Antibody p63 (7JUL)

Catalog No: PA0103

Intended Use

This reagent is for *in vitro* diagnostic use.

p63 (7JUL) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human p63 protein in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining using the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

The clinical interpretation of any staining or its absence should be complemented by morphological studies and 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

Immunohistochemical techniques can be used to demonstrate the presence of antigens in tissue and cells (see "Using BOND Reagents" in your BOND user documentation). p63 (7JUL) primary antibody is a ready to use product that has been specifically optimized for use with BOND Polymer Refine Detection. The demonstration of human p63 protein is achieved by first allowing the binding of p63 (7JUL) to the section, and then visualizing this binding using the reagents provided in the detection system. The use of these products, in combination with the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system), reduces the possibility of human error and inherent variability resulting from individual reagent dilution, manual pipetting and reagent application.

Reagents Provided

p63 (7JUL) is a mouse anti-human monoclonal antibody produced as a tissue culture supernatant, and supplied in Tris buffered saline with animal serum and carrier protein, containing 0.35 % ProClin™ 950 as a preservative.

Total volume = 7 mL.

Clone

7JUL

Immunogen

Prokaryotic recombinant fusion protein corresponding to a region (amino acids 319-410) common to six isoforms of the p63 molecule.

Specificity

Human p63 protein.

Ig Class

IgG1, kappa.

Total Protein Concentration

Approx 10 mg/mL.

Antibody Concentration

Greater than or equal to 20 mg/L as determined by ELISA.

Dilution and Mixing

p63 (7JUL) primary antibody is optimally diluted for use on the BOND system (includes Leica BOND-MAX system and Leica BOND-III system). Reconstitution, mixing, dilution or titration of this reagent is not required.

Materials Required But Not Provided

Refer to "Using BOND Reagents" in your BOND user documentation for a complete list of materials required for specimen treatment and immunohistochemical staining using the BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

Storage and Stability

Store at 2–8 °C. Do not use after the expiration date indicated on the container label.

The signs indicating contamination and/or instability of p63 (7JUL) are: turbidity of the solution, odor development, and presence of precipitate.

Return to 2–8 °C immediately after use.

Storage conditions other than those specified above must be verified by the user¹.

Precautions

- This product is intended for *in vitro* diagnostic use.
- The concentration of ProClin™ 950 is 0.35 %. It contains the active ingredient 2-methyl-4-isothiazolin-3-one, and may cause irritation to the skin, eyes, mucous membranes and upper respiratory tract. Wear disposable gloves when handling reagents.
- To obtain a copy of the Material Safety Data Sheet contact your local distributor or regional office of Leica Biosystems, or alternatively, visit the Leica Biosystems' Web site, www.LeicaBiosystems.com

- 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 precautions². Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents or specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. Seek medical advice.
- Consult Federal, State or local regulations for disposal of any potentially toxic components.
- Minimize microbial contamination of reagents or an increase in non-specific staining may occur.
- Retrieval, incubation times or temperatures other than those specified may give erroneous results. Any such change must be validated by the user.

Instructions for Use

p63 (7JUL) primary antibody was developed for use on the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system) in combination with BOND Polymer Refine Detection. The recommended staining protocol for p63 (7JUL) primary antibody is IHC Protocol F. Heat induced epitope retrieval is recommended using BOND Epitope Retrieval Solution 2 for 20 minutes.

Results Expected

Normal Tissues

Clone 7JUL detected the p63 protein in the nucleus of basal cells in the epithelium of prostate, transitional epithelium of ureter, myoepithelial cells of the breast and salivary gland, squamous epithelium of tongue, esophagus, cervix, skin and tonsil, and mesothelial cells of the umbilical cord. (Total number of normal cases evaluated = 57).

Tumor Tissues

Clone 7JUL stained 1/31 breast tumors (including 1/28 ductal carcinomas, 0/1 atypical medullary carcinoma, 0/1 cystosarcoma phyllodes and 0/1 phyllodes tumor), 2/2 squamous cell carcinomas of the cervix, 2/2 squamous cell carcinomas of the tongue, 1/2 skin tumors (including 1/1 squamous cell carcinoma and 0/1 basal cell carcinoma), 1/2 metastatic tumors of unknown origin and 1/1 squamous cell carcinoma of the esophagus.

No staining was detected in prostate hyperplasia (0/1), prostate adenocarcinomas (0/9), ovarian tumors (0/4), liver tumors (0/4), thyroid tumors (0/4), renal tumors (0/2), gastric tumors (0/2), colon adenocarcinomas (0/2), soft tissue tumors (0/2), brain tumors (0/2), testicular seminomas (0/2), tumors of the rectum (0/2), a tumor of the thymus (0/1) and a squamous cell carcinoma of the larynx (0/1). (Total number of tumor cases evaluated = 74).

p63 (7JUL) is recommended for the assessment of p63 protein expression in normal and neoplastic tissues.

Product Specific Limitations

p63 (7JUL) has been optimized at Leica Biosystems for use with BOND Polymer Refine Detection and BOND ancillary reagents. Users who deviate from recommended test procedures must accept responsibility for interpretation of patient results under these circumstances. The protocol times may vary, due to variation in tissue fixation and the effectiveness of antigen enhancement, and must be determined empirically. Negative reagent controls should be used when optimizing retrieval conditions and protocol times.

Troubleshooting

Refer to reference 3 for remedial action.

Contact your local distributor or the regional office of Leica Biosystems to report unusual staining.

Further Information

Further information on immunostaining with BOND reagents, under the headings Principle of the Procedure, Materials Required, Specimen Preparation, Quality Control, Assay Verification, Interpretation of Staining, Key to Symbols on Labels, and General Limitations can be found in "Using BOND Reagents" in your BOND user documentation.

Bibliography

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