BOND™ Ready-to-Use Primary Antibody MLH1 (Mismatch Repair Protein) (ES05)

Catalog No: PA0610

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle Upon Tyne NE12 8EW
United Kingdom
+44 191 215 4242

EN

Instructions for Use

Please read before using this product.

Check the integrity of the packaging before use.

BOND™ Ready-To-Use Primary Antibody
MLH1 (Mismatch Repair Protein) (ES05)
Catalog No: PA0610

Intended Use
This reagent is for *in vitro* diagnostic use.

MLH1 (Mismatch Repair Protein) (ES05) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human mismatch repair protein (MLH1) 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). MLH1 (Mismatch Repair Protein) (ES05) primary antibody is a ready to use product that has been specifically optimized for use with BOND Polymer Refine Detection. The demonstration of human mismatch repair protein (MLH1) is achieved by first allowing the binding of MLH1 (Mismatch Repair Protein) (ES05) 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
MLH1 (Mismatch Repair Protein) (ES05) is a mouse anti-human monoclonal antibody produced as a tissue culture supernatant, and supplied in Tris buffered saline with carrier protein, containing 0.35 % ProClin™ 950 as a preservative.

Total volume = 7 mL.

Clone
ES05

Immunogen
Prokaryotic recombinant protein corresponding to 210 amino acids of human MLH1.

Specificity
Human mismatch repair protein (MLH1) molecule.

Ig Class
IgG1

Total Protein Concentration
Approx 10 mg/mL.

Antibody Concentration
Greater than or equal to 11 mg/L as determined by ELISA.

Dilution and Mixing
MLH1 (Mismatch Repair Protein) (ES05) 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 MLH1 (Mismatch Repair Protein) (ES05) 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 user[1].

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 precautions[2]. 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

MLH1 (Mismatch Repair Protein) (ES05) 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 MLH1 (Mismatch Repair Protein) (ES05) primary antibody is IHC Protocol F. Heat induced epitope retrieval is recommended using BOND Epitope Retrieval Solution 1 for 30 minutes.

Results Expected

Normal Tissues

Clone ES05 detected the MLH1 protein in the nuclei of cells in a variety of tissues. Staining was observed in cerebrum, cerebellum, ovary, parathyroid, pituitary, testis, thyroid, breast, spleen, tonsil, thymus, esophagus, stomach, small intestine, colon, salivary gland, kidney, endometrium, cervix, skin, peripheral nerve, mesothelium, eye, larynx, appendix and bladder. (Total number of normal cases evaluated = 135).

Tumor Tissues

Clone ES05 stained 55/102 bowel tumors (including 43/76 adenocarcinomas, 5/14 mucinous adenocarcinomas, 4/5 papillary adenocarcinomas, 2/2 adenomas and 1/5 signet-ring adenocarcinomas), 6/8 breast tumors, 6/6 tumors of the esophagus, 5/7 brain tumors, 5/7 thyroid tumors, 5/7 lung tumors, 5/6 stomach tumors, 4/5 tumors of the cervix, 4/5 bladder tumors, 4/5 metastatic tumors, 3/4 liver tumors, 3/4 pancreatic tumors, 3/4 tumors of the gallbladder, 3/4 prostatic tumors, 3/3 lymphomas, 3/3 ovarian tumors, 2/5 kidney tumors, 2/3 tumors of the adrenal gland, 2/2 bone tumors, 2/2 tumors of the head and neck, 2/2 endometrial tumors, 2/2 testicular tumors, 1/2 tumors of the salivary gland, 1/2 melanomas, 1/1 skin tumor, 1/1 prostatic hyperplasia and 1/1 tongue tumor. (Total number of abnormal cases evaluated = 203).

MLH1 (Mismatch Repair Protein) (ES05) is recommended for the detection of the MLH1 protein in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Product Specific Limitations

MLH1 (Mismatch Repair Protein) (ES05) 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

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
3. Bancroft JD and Stevens A. Theory and Practice of Histological Techniques. 4th Edition. Churchill Livingstone, New York. 1996.
4. Eberhard J, Gaber A, Wangefjord S, et al. A cohort study of the prognostic and treatment predictive value of SATB2 expression in colorectal cancer. British Journal of Cancer. 2012; 106: 931-938.
5. Matsukuma S, Okada K, Takeo H, et al. Histopathological study of colo-ileal carcinoma. Oncology Letters. 2012; 3: 689-693.

Date of Issue

22 September 2020

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle Upon Tyne NE12 8EW
United Kingdom
✆ +44 191 215 4242

Leica Biosystems Canada
71 Four Valley Drive
Concord, Ontario L4K 4V8
Canada
✆ +1 800 248 0123

Leica Biosystems Inc
1700 Leider Lane
Buffalo Grove IL 60089
USA
✆ +1 800 248 0123

Leica Biosystems Melbourne
Pty Ltd
495 Blackburn Road
Mt Waverley VIC 3149
Australia
✆ +61 2 8870 3500