

Cytokeratin 19 (CK19)

Concentrated and Prediluted Monoclonal Antibody
901-242-021318

BIOCARE
M E D I C A L

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|------------------------|---------------------------|--------------------|----------------------|
| Catalog Number: | CM 242 A, C | PM 242 AA | OAI 242 T60 |
| Description: | 0.1, 1.0 ml, concentrated | 6.0 ml, prediluted | 60 tests, prediluted |
| Dilution: | 1:100 | Ready-to-use | Ready-to-use |
| Diluent: | Van Gogh Yellow | N/A | N/A |

Intended Use:

For In Vitro Diagnostic Use

Cytokeratin 19 (CK19) [Ks19.1] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of cytokeratin 19 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:

CK19 reacts with the rod domain of human keratin 19, a 40 kDa polypeptide. The antibody reacts with MCF-7 cells and has been shown to label trichoblastoma, thyroid tumors, oral cancer, and epithelial odontogenic tumors. CK19 is not expressed in most hepatocytes, therefore Cytokeratin 19 is useful in the identification of liver metastasis and can be used in a panel with Hepatocyte Specific Antigen (HepPar1).

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. A secondary antibody may be applied to bind the primary antibody, followed by an enzyme labeled polymer; or an enzyme labeled polymer may be applied directly to bind the primary antibody. The detection of the bound primary antibody is evidenced by an enzyme-mediated colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: Ks19.1

Isotype: IgG2a/kappa

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

Epitope/Antigen: CK19

Cellular Localization: Cytoplasmic

Positive Tissue Control: Colon cancer, skin

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 (intelliPATH and manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidized 1.

Pretreatment: Perform heat retrieval using Biocare's Borg Decloaker. Refer to the Borg Decloaker data sheet for specific instructions.

Alternative Digestion Method (recommended for skin tissues): Digest with Pepsin enzyme for 5 minutes at 37°C -or- for 15 minutes at RT.

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

Primary Antibody: Incubate for 30 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Protocol Recommendations (intelliPATH and manual use) Cont'd:

Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.

Chromogen: Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Biocare's Warp Red.

Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Protocol Recommendations (ONCORE Automated Slide Staining System):

OAI242 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Protocol Name: CK19

Protocol Template (Description): Ms HRP Template 1

Dewaxing (DS Option): DS2

Antigen Retrieval (AR Option): AR2, low pH; 90°C

Reagent Name, Time, Temp.: CK19, 30 min., 25°C

Technical Note:

This antibody, for intelliPATH and manual use, has been standardized with Biocare's MACH 4 detection system. Use TBS 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:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA, USA (www.clsi.org). 2011

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) (2)

2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and

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Precautions Cont'd:

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. (3)

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 SDS is available upon request and is located at <http://biocare.net>.

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:

1. Rorive S, *et al.* Changes in galectin-7 and cytokeratin 19 expression during the progression of malignancy in thyroid tumors: diagnostic and biological implications. *Mod Pathol.* 2002 Dec;15(12):1294-301.

2. 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."

3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.