Mouse AP Detection

Alkaline Phosphatase Based Detection of Mouse Antibodies

for the ONCORE Automated Slide Stainer

Control Number: 901-6044-081517

Catalog Number: ORI6044 T60

Description: 60 tests

Intended Use:

For In Vitro Diagnostic Use

Mouse AP Detection is an alkaline phosphatase (AP)-antibody conjugate system intended for use in the detection of mouse IgG and mouse IgM primary antibodies on formalin-fixed, paraffin-embedded (FFPE) tissues in an immunohistochemistry (IHC) procedure performed on Biocare Medical's ONCORE Automated Slide Stainer and visualized by light microscopy. 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 & Explanation:

Immunohistochemistry (IHC) permits the visual identification of specific protein antigens in tissues for diagnostic purposes. Following application of the primary antibody, the presence of a target antigen is visualized by the sequential application of an enzyme-antibody conjugate that binds the primary antibody, and a chromogen reagent, to produce a colored reaction product that is visible by light microscopy.

Mouse AP Detection is an AP enzyme-antibody conjugate suitable for the detection of mouse IgG and mouse IgM primary antibodies as part of an IHC staining procedure on the ONCORE Automated Slide Stainer. Mouse AP Detection is prepared using a proprietary micropolymer technology that provides a highly sensitive detection system, with minimal background staining. Mouse AP Detection does not use biotin or streptavidin, thus avoiding non-specific staining associated with endogenous biotin.

Mouse AP Detection is provided ready-to-use and is intended to be applied as defined by the staining protocols on the ONCORE Automated Slide Stainer.

Known Applications:

Immunohistochemistry (FFPE tissues)

Reagents Provided:

Mouse AP Detection is provided as a buffered aqueous solution, with proprietary stabilizer and preservative, sufficient to perform a total of 60 tests:

Mouse AP Detection (ORI6044 T60) 60 tests (15.5 mL)

Reconstitution, Dilution and Mixing:

Mouse AP Detection is provided ready-to-use. No reconstitution, dilution or mixing is required.

Materials and Reagents Required But Not Provided:

Reagents and materials, such as primary antibodies, chromogens and ancillary reagents are not provided. Refer to the ONCORE Automated Slide Staining System User Manual for a complete list of materials and reagents required.

Storage and Stability:

Store at 2ºC to 8ºC. Do not use after expiration date printed on vial.

Instructions for Use:

Mouse AP Detection is provided in vials ready for use on the ONCORE Automated Slide Stainer. Uncap the vial and place in the ONCORE reagent tray. The ONCORE Automated Slide Stainer will apply reagent as required in the selected protocol.

Refer to the appropriate antibody data sheet for the recommended staining protocol. Refer to the ONCORE Automated Slide Staining System User Manual for detailed instructions on instrument operation and additional protocol options.

Limitations:

These reagents have been optimized for use with ONCORE antibodies and ancillary reagents. The protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, and tissue section thickness. Third party primary antibodies may be used on the ONCORE Automated Slide Stainer; however, appropriate antibody concentration may depend upon multiple factors and must be empirically determined by the user. 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 product is intended for *in vitro* diagnostic (IVD) use.
2. This product is classified as non-hazardous based on the concentrations and hazards of the components, in compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the US OSHA Hazard Communication Standard (HCS), and European Union Classification, Labeling, and Packaging (CLP) regulations.
3. 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. Avoid contacting the skin and mucous membranes with reagents and specimens, and follow standard laboratory precautions to prevent exposure to eyes and skin. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (3)
4. Microbial contamination of reagents may result in an increase in nonspecific staining.
5. The SDS is available upon request and is located at http://biocare.net/.

Troubleshooting:

Follow the reagent specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. Taylor CR, Cote RJ. Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist. 3rd Ed. Philadelphia: Saunders Elsevier, 2006.
2. Dabbs DJ. Diagnostic Immunohistochemistry: Theranostic and Genomic Applications. 3rd Ed. Philadelphia: Saunders Elsevier, 2010.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition (M29-A4) Wayne, PA 2014.

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