Multiplex Detection 1

Alkaline Phosphatase and Horseradish Peroxidase Based Detection
for the ONCORE Pro Automated Slide Stainer
901-OPRI6061-101520

Catalog Number:	**OPRI 6061 T60**
Description:	60 tests

Intended Use:
For In Vitro Diagnostic Use
Multiplex Detection 1 is a cocktail of alkaline phosphatase (AP) anti-mouse antibody conjugate and horseradish peroxidase (HRP) anti-rabbit antibody conjugate intended for use in the detection of mouse IgG and IgM and rabbit IgG primary antibodies on formalin-fixed, paraffin embedded (FFPE) tissues in an immunohistochemistry (IHC) procedure performed on Biocare Medical's ONCORE Pro Automated Staining Instrument 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. Multiplex Detection 1 is a cocktail of AP anti-mouse antibody conjugate and HRP anti-rabbit antibody conjugate suitable for the detection of mouse and rabbit primary antibodies, respectively, as part of an IHC double-stain procedure on the ONCORE Pro Automated Staining Instrument. Multiplex Detection 1 is intended to be used in combination with ONCORE Pro Fast Red Chromogen (OPRI6042K) to produce a red stain at the site of mouse primary antibodies, and ONCORE Pro DAB Chromogen (OPRI6056K) to produce a brown stain at the site of rabbit primary antibodies. Multiplex Detection 1 is prepared using a proprietary micro-polymer technology that provides a highly sensitive detection system, with minimal background staining. Multiplex Detection 1 does not use biotin or streptavidin, thus avoiding non-specific staining associated with endogenous biotin. Multiplex Detection 1 is provided ready-to-use and is intended to be applied as defined by the staining protocols on the ONCORE Pro instrument.

Known Applications:
Immunohistochemistry (FFPE tissues)

Reagents Provided:
Multiplex Detection 1 is provided as a buffered aqueous solution, with proprietary stabilizer and preservative, sufficient to perform a total of 60 tests: Multiplex Detection 1 (OPRI6061 T60) 60 tests (10.5 mL)

Reconstitution, Dilution and Mixing:
Multiplex Detection 1 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 Pro Automated Slide Staining System User Manual for a complete list of materials and reagents required.

Storage and Stability:
Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date.

Instructions for Use:
Multiplex Detection 1 is provided in vials ready for use on the ONCORE Pro Automated Slide Stainer. Uncap the vial and place in the ONCORE Pro reagent tray. The ONCORE PRO 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 Pro 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 Pro 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 Pro; 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.

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. Refer to reagent Safety Data Sheet for precautions.
2. 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. (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.

IRRITANT

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.

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ONCORE™ PRO

BIOCARE MEDICAL

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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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