ONCORE Pro ISH HRP Detection

Horseradish Peroxidase Detection of Digoxigenin Labeled Probes
on the ONCORE Pro Automated Slide Stainer
901-OPRI6047K-021721

Catalog Number: **OPRI 6047K T60**

Description: 60 tests

Intended Use:
For In Vitro Diagnostic Use
ONCORE Pro ISH HRP Detection is intended for use in the detection of digoxigenin labeled probes on formalin-fixed, paraffin-embedded (FFPE) tissues in an *in situ* hybridization (ISH) procedure performed on Biocare Medical's ONCORE Pro 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:
Chromogenic *in situ* hybridization (ISH) permits the visual identification of specific mRNA or DNA nucleic acid sequences in tissues. Following application of the probe, the presence of a target nucleic acid is visualized by the sequential application of a secondary reagent that binds the digoxigenin labeled probe, followed by a tertiary enzyme-antibody conjugate, and a chromogen reagent, to produce a colored reaction product that is visible by light microscopy.
ISH HRP Detection is comprised of a mouse anti-digoxigenin antibody as a secondary reagent and an HRP enzyme-antibody conjugate as a tertiary reagent, suitable for the detection of digoxigenin labeled probes as part of an ISH staining procedure on the ONCORE Pro Automated Slide Stainer. ISH HRP Detection is provided ready-to-use and is intended to be applied as defined by the staining protocols on the ONCORE Pro Automated Slide Stainer.

Known Applications:
in situ hybridization (FFPE tissues)

Reagents Provided:
ONCORE Pro ISH HRP Detection is comprised of two buffered solutions with preservative, sufficient to perform a total of 60 tests:
ISH Secondary Reagent (OPRI6025 T60) 10.5 ml
ISH HRP Tertiary Reagent (OPRI6026 T60) 10.5 ml

Reconstitution, Dilution and Mixing:
ISH Secondary Reagent and ISH HRP Tertiary Reagent are provided ready-to-use. No reconstitution, dilution or mixing is required.

Materials and Reagents Required but Not Provided:
Reagents and materials, such as ISH probes, dewax solutions, 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 2ºC to 8ºC. 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:
ISH Secondary Reagent and ISH HRP Tertiary Reagent are provided in vials ready for use on the ONCORE Pro Automated Slide Stainer. Uncap the vials 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 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 ISH probes and ancillary reagents. The protocols for a specific application can vary. These include, but are not limited to fixation, enzymatic digestion, heat-retrieval method, incubation times, and tissue section thickness. Third party ISH probes may be used on the ONCORE Pro; however, appropriate probe concentration and protocol parameters 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.

Technical Note:
Bone Marrow Biopsies: For optimal results, bone marrow biopsies should be fixed for 24 hours in 10% neutral buffered formalin (NBF) or zinc formalin prior to decalcification. Biocare recommends for preservation of RNA integrity that bone marrows are decalcified in a formic acid or 10% EDTA based solution (1,2). However, there are many methods of fixation and decalcification used in the clinical laboratory. All decalcification methods, including those mentioned, should be empirically determined for optimal pretreatment parameters.

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. (5)
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

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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. Beck RC, *et al*. Automated colorimetric in situ hybridization (CISH) detection of immunoglobulin (Ig) light chain mRNA expression in plasma cell (PC) dyscrasias and non-Hodgkin lymphoma. Diagn Mol Pathol. 2003 Mar; 12(1):14-20.
2. Shibata Y, *et al*. Assessment of decalcifying protocols for the detection of specific RNA by non-radioactive in situ hybridization in calcified tissues. Histochem Cell Biol. 2000 Mar; 113(3):153-9.
3. Wilkinson DG. In Situ Hybridization: A Practical Approach (Practical Approach Series). 2nd Ed. Oxford: Oxford University Press, 1999.
4. Nuovo GJ. In Situ Molecular Pathology and Co-Expression Analyses. 1st Ed. San Diego: Academic Press, 2013.
5. 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.

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