ONCORE Pro ISHzyme Kit

Enzyme Pretreatment Reagent for *in situ* Hybridization
Procedures on the ONCORE Pro Automated Slide Stainer
901-OPRI6039K-052623

Catalog Number: **OPRI 6039K T120**

Description: 120 tests

Intended Use:
For In Vitro Diagnostic Use
ONCORE Pro ISHzyme Kit contains a buffered digestive enzyme solution intended for use in pretreatment of formalin-fixed, paraffin-embedded (FFPE) tissues in an *in situ* hybridization (ISH) procedure performed on Biocare Medical's ONCORE Pro Automated Slide Stainer. 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:
ONCORE Pro ISHzyme Kit contains a digestive enzyme used in the pretreatment of formalin-fixed paraffin-embedded tissues (FFPE) to enhance probe accessibility to nucleic acid targets. In FFPE tissues, certain *in situ* hybridization protocols require enzymatic pretreatment for proper ISH staining. ISHzyme is an aggressive enzyme and can be used at room temperature. Certain tissues require this type of aggressive enzyme digestion prior to heat retrieval for optimal results. When used in combination with ISH Retrieval for ONCORE Pro, a synergistic effect on probe accessibility to nucleic acid targets may be achieved. This product is provided as a two-component system and may be prepared at various concentrations, as desired by the user.

Known Applications:
in situ hybridization (FFPE tissues)

Supplied As:
ONCORE Pro ISHzyme Kit is supplied as two solutions; concentrated enzyme and buffer with preservative, intended to be mixed prior to use:
ISHzyme (OPRI6022 G3) 3 mL
ISHzyme Buffer (OPRI6023 T30) 120 tests (7.8 mL x 4)

Reconstitution, Dilution and Mixing:
ONCORE Pro ISHzyme Kit is provided as an enzyme concentrate with buffer for dilution. Add 8 drops or 320 µl of ISHzyme to 1 buffer vial for an approximate 1:25 dilution. Add 4 drops or 160 µl of ISHzyme to 1 buffer vial for an approximate 1:50 dilution.

ISHzyme Buffer incorporates a color-coded pH indicator. The end-user can visually inspect the solution and see that the mixture or buffer is at the proper pH. If the mixed solution is purple, the pH is too high for optimal digestion. If the buffer or ISHzyme solution turns orange or yellow, the pH is too low for optimal digestion.

Materials and Reagents Required But Not Provided:
Reagents and materials, such as ISH probes, detection kits, 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

Storage and Stability Cont'd:
expiration date. The working solution is stable for 14 days after addition of ISHzyme to ISHzyme Buffer, when stored at 2°C to 8°C.

Instructions for Use:
Mix ISHzyme in ISHzyme Buffer as desired (see Reconstitution, Dilution and Mixing). Cap the vial and invert several times to thoroughly mix contents. Uncap the vial and place in the ONCORE Pro reagent tray.

The ONCORE Pro 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:
This reagent has been optimized for use with ONCORE Pro ISH probes, detections 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.

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.

HEALTH HAZARD

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.

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References:

1. Wilkinson DG. In Situ Hybridization: A Practical Approach (Practical Approach Series). 2nd Ed. Oxford: Oxford University Press, 1999.
2. Nuovo GJ. In Situ Molecular Pathology and Co-Expression Analyses. 1st Ed. San Diego: Academic Press, 2013.
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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