

Probe Enhancer (RNA)

For *in situ* Hybridization Procedures on the ONCORE Automated Slide Stainer

Control Number: 901-6024-091117

Catalog Number: ORI6024 T120

Description: 8 ml (120 tests)

Intended Use:

For In Vitro Diagnostic Use

Probe Enhancer (RNA) is an ancillary hybridization reagent intended for use in *in situ* hybridization (ISH) procedures performed on Biocare Medical's ONCORE 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:

Probe Enhancer (RNA) is an ancillary hybridization reagent that promotes spreading and reduces drying of mRNA targeting ISH probes during hybridization reactions. Effective hybridization may facilitate enhanced staining and reduce artifacts.

Known Applications:

in situ hybridization (FFPE tissues)

Reagents Provided:

Probe Enhancer (RNA) is a buffered hybridization solution with preservative, sufficient to perform a total of 120 tests.

Probe Enhancer (RNA) (ORI6024 T120) 8 ml

Reconstitution, Dilution and Mixing:

Probe Enhancer (RNA) is provided ready-to-use.

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 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. Do not use after expiration date printed on vial.

Instructions for Use:

Heat Probe Enhancer (RNA) prior to each use by placing in a 60°C oven for 5-7 minutes to reduce solution viscosity. Be sure the reagent vial is tightly closed before placing in the oven. Invert the vial several times and shake the reagent down after preheating. Delayed start of the staining process is not recommended for ISH procedures.

Uncap the vial and place in the ONCORE reagent tray. The ONCORE will apply reagent as required in the selected protocol. Refer to the ONCORE 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 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; 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. 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 contains less than 0.1% sodium azide. Exposure to sodium azide may be harmful. 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. (3)
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. (4)
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 the data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

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. 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."
4. 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.