

ONCORE Pro ISH Dewax Kit

Deparaffinization Solutions for ISH Procedures on the ONCORE Pro Automated Slide Stainer
901-OPRI6020K-030421

Catalog Number: OPRI 6020K T60

Description: 60 tests

Intended Use:

For In Vitro Diagnostic Use

ONCORE Pro ISH Dewax Kit consists of ready-to-use solutions for the removal of paraffin wax from formalin-fixed, paraffin-embedded (FFPE) tissues, as part of an in situ hybridization (ISH) procedure 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:

Dewax Solution 3 (DS3) and Dewax Solution 4 (DS4) are water-based solutions for the removal of paraffin wax from FFPE tissue specimens, as part of an in situ hybridization staining procedure on the ONCORE Pro Automated Slide Stainer. Removal of paraffin wax must be performed prior to probe hybridization and the application of reagents necessary for target nucleic acid detection. The solutions are provided ready-to-use and are intended to be applied sequentially as defined by the staining protocols on the ONCORE Pro Automated Slide Stainer.

Known Applications:

In situ hybridization (FFPE tissues)

Reagents Provided:

ISH Dewax Kit is comprised of ready-to-use solutions. Sufficient reagents are provided to perform a total of 60 tests:

Dewax Solution 3, DS3 (OPRI6014 T30) 60 tests (9.0 mL x 10)

Dewax Solution 4, DS4 (OPRI6019 T30) 60 tests (9.0 mL x 2)

Reconstitution, Dilution and Mixing:

Dewax Solutions 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, 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. Do not use after expiration date printed on vial.

Instructions for Use:

Dewax Solutions 3 and 4 are 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 each dewax 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, 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 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.



Flammable Irritant Health Hazard

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. 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 CLSI document M29-A4 Wayne, PA 2014.