

Dewax Solution Kit

Deparaffinization Solutions for the ONCORE
Automated Slide Stainer
901-6004K-080717

ONCORE

BIOCARE

M E D I C A L

Catalog Number: ORI6004K T60

Description: 60 tests

Intended Use:

For In Vitro Diagnostic Use

Dewax Solution Kit consists of ready-to-use solutions for the removal of paraffin wax from formalin-fixed, paraffin-embedded (FFPE) tissues, as part of an immunohistochemistry (IHC) procedure 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:

Dewax Solutions 1a, 1b and 2 (DS1a, DS1b, DS2) are water-based solutions for the removal of paraffin wax from FFPE tissue specimens, as part of an IHC staining procedure on the ONCORE Automated Slide Stainer. Removal of paraffin wax must be performed prior to antigen retrieval and the application of reagents for immunostaining. The solutions are provided ready-to-use and are intended to be applied sequentially as defined by the staining protocols on the ONCORE Automated Slide Stainer.

Known Applications:

Immunohistochemistry (FFPE tissues)

Reagents Provided:

Dewax Solution Kit is comprised of ready-to-use solutions. Sufficient reagent is provided to perform a total of 60 tests:

Dewax Solution 1a, DS1a (ORI6001 T60) 60 tests (15.5 mL)

Dewax Solution 1b, DS1b (ORI6002 T60) 60 tests (15.5 mL)

Dewax Solution 2, DS2 (ORI6003 T60) 60 tests (15.5 mL)

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 primary antibodies, 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:

Dewax Solutions 1a, 1b and 2 are provided in vials ready for use on the ONCORE Automated Slide Stainer. Uncap the vial and place in the ONCORE reagent tray. The ONCORE Automated Slide Stainer will apply each dewax reagent as required in the selected protocol.

Refer to the appropriate antibody data sheet for the recommended staining protocol. Some antibodies may require use of DS Buffer in place of DS2. Therefore, it is expected to observe significant quantities of DS2 remaining in the reagent vials after 60 tests as only one of these two reagents is consumed in each test. Note that in software version 2.5 or above, DS Buffer is applied directly from the Buffer Carboy. Refer to the ONCORE 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 antibodies, detections 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 Automated Slide Stainer; 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. 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. Dewax Solutions may be harmful and irritating to the eyes, respiratory system and skin. They may cause lung or gastrointestinal damage if inhaled or ingested. Avoid contact with reagents and wear disposable gloves when handling reagents.
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. (3)
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. 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.