



Wash Buffer

Buffered solution for washing specimens for the **ONCORE Automated Slide Stainer**

Control Number: 901-6012-090717

ORI6012 MM Catalog Number:

1 liter **Description:**

Intended Use:

For In Vitro Diagnostic Use

Wash Buffer is a ready-to-use Tris-buffered solution intended for use in washing formalin-fixed, paraffin-embedded (FFPE) tissue sections between steps of an immunohistochemistry (IHC) procedure 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:

Immunohistochemistry (IHC) permits the visual identification of specific protein antigens in tissues for diagnostic purposes. Following application of the primary antibody, the presence of a target antigen is visualized by the sequential application of an enzyme-antibody conjugate that binds the primary antibody, and a chromogen reagent, to produce a colored reaction product that is visible by light microscopy.

Wash Buffer is used to rinse tissue sections after each incubation step, effectively removing the previous reagent and preparing the tissue for application of the following reagent. Wash Buffer is a Tris-buffered solution (pH 7.6-7.8) with added surfactant to improve spreading and a preservative to inhibit microbial growth. Wash Buffer is provided ready-to-use and is intended to be applied as defined by the staining protocols on the ONCORE Automated Slide Stainer.

Known Applications:

Immunohistochemistry (FFPE tissues)

Reagents Provided:

Wash Buffer is a Tris-buffered aqueous solution with surfactant and preservative, provided as a ready-to-use solution to be added to the buffer carboy of the ONCORE Automated Slide Stainer:

Wash Buffer (ORI6012 MM) 1 liter

Reconstitution, Dilution and Mixing:

Wash Buffer is 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 20-25°C. Do not use after expiration date printed on bottle.

Instructions for Use:

Wash Buffer is provided in vials ready for use on the ONCORE Automated Slide Stainer. Add Wash Buffer to the buffer carboy of the ONCORE Automated Slide Stainer. The ONCORE Automated Slide Stainer will apply reagent as required in the selected protocol.

Refer to the appropriate antibody data sheet for the recommended staining protocol. 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. This product is classified as non-hazardous based on the concentrations and hazards of the components, in compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the US OSHA Hazard Communication Standard (HCS), and European Union Classification, Labeling, and Packaging (CLP) regulations.
- 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
- 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.

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