

DS Enzyme Kit

Enzyme Retrieval Solution
for the ONCORE Pro Automated Slide Stainer
901-OPRI6060K-111620

Catalog Number: OPRI 6060K T60

Description: 60 tests

Intended Use:

For In Vitro Diagnostic Use

DS Enzyme is a ready-to-use solution intended for use as a pretreatment step on formalin-fixed, paraffin-embedded (FFPE) tissues in an immunohistochemistry (IHC) 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:

DS Enzyme is a ready-to-use solution of the proteolytic enzyme pepsin, which may be useful as a pretreatment step for epitope retrieval in FFPE tissue, as part of an IHC staining procedure on the ONCORE Pro Automated Slide Stainer. Pretreatment of FFPE tissues with DS Enzyme can significantly increase staining intensity. The solution is provided ready to-use and is intended to be applied as defined by the staining protocols on the ONCORE Pro Automated Slide Stainer.

Known Applications:

Immunohistochemistry (FFPE tissues)

Reagents Provided:

DS Enzyme is a low pH solution of pepsin enzyme, sufficient to perform a total of 60 tests: DS Enzyme (OPRI6049 T30) 60 tests (9.0 mL x 2)

Reconstitution, Dilution and Mixing:

DS Enzyme 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 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 expiration date.

Instructions for Use:

Note: DS Enzyme is referred as DSE-50 on ONCORE Pro Automated Slide Stainer. Use DS Enzyme when DSE-50 is required.

DS Enzyme is 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 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 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 antibodies 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 Pro; 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.

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 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. 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 CLSI document M29-A4 Wayne, PA 2014.