Denaturing Solution (Elution Step)

Ancillary Reagent
901-DNS001-053023

BIOCARE MEDICAL

Catalog Number: **DNS 001 L**

Description: 100 mL

Intended Use:
For In Vitro Diagnostic Use
Denaturing Solution (Elution Step) is intended to remove (elute) any potentially cross-reactive remnant antibodies in a 7-step double stain protocol. It is specifically designed to be used on formalin-fixed, paraffin-embedded (FFPE) tissues in an IHC procedure. It can be used manually or on an automated platform. 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:
Denaturing Solution is used as an elution step when using a double stain technique (Biocare's 7-step double stain procedure). This will ensure that the second staining protocol will not cross react with the first staining protocol.
Solution A (yellow) is a concentrate that must be diluted with Solution B (red, dilution buffer) for proper elution. It is recommended that the Denaturing Solution be used at different dilutions depending on tissue fixation and the type of antigen retrieval method used (for details see protocol recommendations below).

Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Materials and Methods:
Reagents Provided:

Kit Catalog No.	Component Catalog No.	Component Description	Quantity x Volume
DNS001L	DNSA025	Denaturing Solution A	1 x 25 mL
	DNSB075	Denaturing Solution B	1 x 75 mL

Reconstitution, Dilution and Mixing:
The Denaturing Solution (Elution Step) is optimized for use with Biocare antibodies and ancillary reagents and must be diluted just prior to use. Add appropriate amount of Denaturing Solution A to Denaturing Solution B per guidelines below. Mix well.
Solution A and B: Dilute 1 part A with 1 parts B
- No pretreatment on tissues (digestion or antigen retrieval)
Solution A and B: Dilute 1 part A with 2 parts B
- Digestion, citrate buffer or Reveal
Solution A and B: Dilute 1 part A with 3 parts B
- EDTA, high pH buffers and Borg Decloaker

Materials and Reagents Required but Not Provided:
Microscope slides, positively charged
Desert Chamber* (Drying oven)
Positive and negative tissue controls
Xylene (Could be substituted with xylene substitute*)
Ethanol or reagent alcohol
Decloaking Chamber* (Pressure cooker)
Deionized or distilled water
Wash buffer*(TBS/PBS)
Pretreatment reagents*
Enzyme digestion*
Avidin-Biotin Blocking Kit*(Labeled streptavidin kits only)
Peroxidase block*
Protein block*
Primary antibody*
Negative control reagents*
Detection kits*

Materials and Reagents Required but Not Provided Cont'd:
Detection components*
Chromogen*
Hematoxylin*
Bluing reagent*
Mounting medium*

* Refer to the Biocare Medical website located at http://biocare.net for information regarding catalog numbers and ordering.

Storage and Stability:
Store at room temperature. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at room temperature. The stability of user diluted reagent has not been established by Biocare.

Instructions for Use:
1. Deparaffinize tissues and hydrate to water. If necessary, perform a hydrogen peroxide block, wash in water, and rinse in PBS or TBS.
2. Apply first antibody with desired detection and chromogen. Wash in deionized water.
3. Apply the Denaturing Solution for 2-5 minutes. Wash in buffer.

Limitations:
The protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. 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.[1]
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.

This Denaturing Solution (Elution Step) contains components classified as indicated in the table below in accordance with the Regulation (EC) No. 1272/2008

Hazard	Code	Hazard Statement
	H317	May cause an allergic skin reaction

Biocare Medical
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IVD CE

Rev: 062117

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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. 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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