Diagnostic BioSystems

IHC Made Affordable

HistoZyme

Catalog Number: K046-xx

xx – This data sheet is applicable to all sizes (volume) of product. Actual volume indicated in vial or bottle.

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Effective Date: 12/18/2023

Intended Use
For In Vitro Diagnostic Use.

Product Description
HistoZyme is a proteolytic enzyme solution that results in superior staining over traditionally used enzyme pretreatments, such as pepsin and trypsin. Moreover, HistoZyme requires only a brief incubation at room temperature. Performing antigen recovery with HistoZyme, will allow you to dilute the primary antibody 5 to 10 fold further and achieve optimal staining.

Summary and Explanation
Formalin fixation of tissues induces protein cross links that helps in maintaining the cellular morphology by inactivating the digestive enzymes and preserving the cytoskeleton. Fixation stops tissue autolysis, preserves tissue structures, and immobilizes antigens. However, antigens undergo chemical alteration of their primary, secondary and tertiary structures during fixation. This may cause a loss of reactivity of a specific antibody to that antigen. High-energy treatment of such proteins in appropriate pH leads to restoration of the epitope structure and hence retrieves the reactivity of antibody to the target antigen. This process is defined as Antigen Retrieval. Shi et al 1991. It has been suggested that antigen retrieval loosens or breaks the cross linkages induced by formalin. This allows for the enhanced penetration of antibodies and accessibility of epitopes.

Format
Slightly viscous ready to use clear solution

Volume/UOM
See Vial / Bottle

Storage and Handling
Store at 2-8°C . Do not use after expiration date printed on label.

Preparation of Working Solutions
1. HistoZyme is ready to use and does not require any preparation.

Protocol Recommendations
1. Deparaffinize tissue sections and wash slides with buffer.
2. Remove excess buffer from slides without letting tissue dry.
3. Depending on tissue section size, add 1 or 2 drops of Histo/Zyme.
4. Incubate slides for 5 minutes at room temperature.
5. Wash slides with buffer and proceed with immunostaining.

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.

Troubleshooting
Contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2, techsupport@dbiosys.com or your local distributor to report unusual staining results.

Warranty
There are no warranties, expressed or implied, which extend beyond this description. Diagnostic BioSystems is not liable for property damage, personal injury, or economic loss caused by this product.

Performance Characteristics
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 Diagnostic BioSystems products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

Precautions
This product is a single-use, non-sterile, in vitro diagnostic device.

1. Wear disposable gloves when handling reagents.
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. 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 label.
6. The MSDS is available upon request.
7. Consult OSHA, federal, state or local regulations for disposal of any toxic substances.

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