

## Rapid Histo-Sealer (10X)<sup>™</sup>

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### Intended Use

For In Vitro Diagnostic Use. This product is intended for qualitative immunohistochemistry with normal and neoplastic formalin-fixed, paraffin-embedded tissue sections, to be viewed by light microscopy. Clinical interpretation of staining results should be accompanied by histological studies with proper controls. Patients' clinical histories and other relevant diagnostic tests should be utilized by a qualified person(s) when evaluating and interpreting results.

### Product Description

Rapid Histo-Sealer<sup>™</sup> is a preservation solution that acts to rapidly dehydrate tissues mounted on microscope slides in preparation for permanent mounting. This quick-acting dehydrating solution is ideal for rapid immunohistochemistry procedures such as Mohs micrographic surgery. This solution seals the tissue to protect the tissues from drying artifacts to and improve tissue morphology. When applied to the stained section, specimens can be permanently mounted without chromogens fading. Additional benefits of the Rapid Histo-Sealer<sup>™</sup> include: saves hands on time when mounting slides, avoids the use of toxic chemicals such as xylene and eliminates accumulation of hazardous waste.

### Summary and Explanation

This product is designed for tissue specimens stained with peroxidase, alkaline phosphatase-based methods using a variety of chromogens.

### Format

Clear viscous, concentrated (10X) solution.

### Volume/UOM

10mL

### Storage and Handling

Store at room temperature. Do not use after expiration date printed on label.

### Preparation of Working Solutions

Rapid Histo-Sealer<sup>™</sup> is a concentrated solution and requires dilution in reagent alcohol. Compatible alcohols include ethanol, methanol, isopropyl alcohol, or combinations thereof. Do not use alcohol that contains water.

To prepare a working solution of Rapid Histo-Sealer add 1 part of the concentration Rapid Histo-Sealer to 9 parts of reagent alcohol.

### Protocol Recommendations for Single Slides

1. After counterstaining, rinse slide with water.
2. Wipe away excess water on both sides of the slide. Carefully wipe around tissue with an absorbent wipe.
3. While holding the slide in a vertical position, drip Rapid-Histo-Sealer down the face of the slide to remove all water. Allow excess solution to run off the slide.

Approximately 500 µL of Rapid Histo-Sealer is sufficient to remove all water from a single slide.

4. Carefully wipe excess Rapid Histo-Sealer from around the tissue with an absorbent wipe.
5. Lay slides flat and allow the sections to completely dry. Complete drying usually takes about 20 seconds
6. Mount and coverslip slide using any resin-based mounting medium.

### 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](http://www.clsi.org)). 2011.

### Troubleshooting

Contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2, [techsupport@dbiosys.com](mailto:techsupport@dbiosys.com) or your local distributor to report unusual 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. 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. Protective gloves should be worn and work should be performed in a ventilated area.
2. Rapid Histo-Sealer contains Reagent Alcohol which is flammable and must be stored in a flammable fire cabinet.
3. Do not use or store Rapid Histo-Sealer near any heat source, ignition source, or open flame.
4. 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.
5. Microbial contamination of reagents may result in an increase in nonspecific staining.
6. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
7. Do not use reagent after the expiration date printed on the label.
8. The MSDS is available upon request.
9. Consult OSHA, federal, state or local regulations for disposal of any toxic substances.