

## Pepsin

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### Intended Use

For In Vitro Diagnostic Use.

### Product Description

Pepsin is used for proteolytic digestion of formalin-fixed paraffin embedded (FFPE) tissue sections prior to application of antibodies. In immunohistochemistry (IHC), most commonly used fixatives such as formalin mask tissue antigens (cellular, membrane and nuclear) by their intrinsic crosslinking. This masking results in poor or no staining in IHC. Pepsin digestion of FFPE tissue sections improves accessibility of antibodies to tissue antigens.

### Summary and Explanation

Fixation is one of the most critical aspects of immunostaining. If the antigen is not properly fixed it will be washed out of the specimen. On the other hand, over fixation can cause severe problems such as masking or denaturing of the antigen. Formaldehyde is probably the best all-around fixative, due to its cross-linking characteristics. Length of fixation is very critical to prevent antigen masking. Immunoglobulins are especially susceptible to over fixation with formalin. In such cases, treatment with proteolytic enzyme is required to digest excess aldehyde linkages and to expose the antigen.

### Format

Clear, ready to use solution

### Volume/UOM

50 mL

### Storage and Handling

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

### Preparation of Working Solutions

1. Pepsin is ready to use and does not require any preparation.

### Protocol Recommendations

1. Deparaffinize tissue sections and wash slides with wash buffer.
2. Remove excess buffer from slide(s) without letting the tissues dry.
3. Depending on the size of the tissue section add 1-2 drops of pepsin solution.
4. Incubate the slide(s) for 5-10 minutes at 37°C.
5. Wash slide(s) with wash 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](http://www.clsi.org)). 2011

### Troubleshooting

Contact StatLab Medical Products Technical Support at (800) 442-3573, option 5 or [ihctech@statlab.com](mailto:ihctech@statlab.com) to report unusual staining.

### Warranty

There are no warranties, expressed or implied, which extend beyond this description. StatLab Medical Products 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 StatLab Medical 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

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 SDS is available upon request.
7. Consult OSHA, federal, state or local regulations for disposal of any toxic substances.