intelliPATH FLX™ Pepsin

Pretreatment Reagent

Control Number: 901-IPE5007-090617

Catalog Number:	Description:
IPE 5007 G20	20 ml, Ready-to-use

Intended Use:

For In Vitro Diagnostic Use

intelliPATH FLX™ Pepsin 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. 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:

Pepsin is a commonly used digestive enzyme. In formalin-fixed paraffin-embedded tissues, certain antibody protocols require enzyme pretreatment for proper immuno-histochemical staining. This product is provided as a single-component, ready- to-use solution.

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As:

Ready-to-use

Materials and Reagents Needed But Not Provided:

Microscope barrier 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*
Avidin-Biotin Blocking Kit*(Labeled streptavidin kits only)
Peroxidase block*
Primary antibody*
Negative control reagents*
Mounting medium*

* Biocare Medical Products: Refer to a Biocare Medical catalog for further information regarding catalog numbers and ordering information. Certain reagents listed above are based on specific application and detection system used.

Storage and Stability:

Store at 2ºC to 8ºC. 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.

Protocol Recommendations:

1. Deparaffinize tissues and hydrate to water.
2. If using a horseradish peroxidase (HRP) detection system, block for endogenous peroxidase. Use Biocare's intelliPATH FLX Peroxidase Blocking Reagent.
3. Wash in running tap water and rinse in deionized water (DI).
4. Apply the ready-to-use intelliPATH FLX Pepsin solution and cover tissue section.
5. Incubate tissue sections for 15-20 minutes at room temperature.
6. Wash with Biocare's TBS Wash Buffer.
7. Proceed with immunostaining procedure.

Protocol Notes:

Under-fixed and delicate tissues may require less digestion time. Pepsin can also be used at room temperature.

Staining Procedure:

Biocare protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the intelliPATH FLX automated stainer. Recommended staining protocols are specified in the data sheet of the antibody of interest. Pre-optimized intelliPATH FLX protocols with preset parameters can be displayed, printed and edited according to the procedure in the Operator's Manual. Refer to the Operator's Manual for additional instruction to navigate intelliPATH FLX software and stainer. Use TBS for washing steps unless otherwise specified.

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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

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. 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.
2. Microbial contamination of reagents may result in an increase in nonspecific staining.
3. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
4. The SDS is available upon request and is located at http://biocare.net/.
5. Do not use reagent after the expiration date printed on the vial.
6. Consult OSHA, federal, state or local regulations for disposal of any toxic substances.

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.

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