Prediluted Monoclonal Antibody

Control Number: 901-357VP-112415

VP Echelon[™] Series

Catalog Number:	VP 357 G
Description:	6.0 ml, prediluted
Dilution:	Ready-to-use

Intended Use:

For In Vitro Diagnostic Use

Factor XIIIa [E980.1] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of Factor XIIIa protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:

This is a monoclonal antibody to the A-subunit of human coagulation Factor XIII. Studies have shown it recognizes human Factor XIII A-chain in both reduced and nonreduced forms. It does not react with human Factor XIII B-chain or human Factor XII. Factor XIII is a beta-globulin found in plasma and is composed of two subunits. Factor XIII-A is the catalytic subunit and is a dimer of M.W. 160,000. According to studies, Factor XIII is present in plasma as an alpha2beta2 heterodimer (M.W. 320,000); whereas in platelets, only the alpha2 unit exists. Factor XIIIa is a dermal dendrocyte marker and shows variable reaction with these types of tumors (3,4). It can be used for histiocytic phenotyping and has been reported to mark capillary hemangiomas and tumors of the central nervous system (1-6). Factor XIIIa has also been used with CD34 to differentiate between dermatofibroma and dermatofibrosarcoma protuberans (3).

Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested.

Clone: E980.1

Isotype: IgG1

Total Protein Concentration: ~10 mg/ml. Call for lot specific IgG concentration.

Epitope/Antigen: Factor XIIIa C-terminus

Cellular Localization: Cytoplasmic

Positive Control: Dermatofibroma, placenta or skin

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2°C to 8°C. 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:

Using ultraVIEW Detection Kit

Pretreatment Solution (recommended): CC1

Pretreatment Protocol: Standard

Primary Antibody: Incubate for 40 minutes at 37°C.

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Technical Note:

Biocare's VP Echelon Series of predilutes have been developed for use with Ventana® Medical Systems, BenchMark® XT Immunohistochemistry Staining System in combination with Ventana® Detection Kits and Ventana® Prep Kit Dispensers.

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Limitations:

The optimum antibody dilution and 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. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (7)

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. (8)

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 reagents after the expiration date printed on the vial.
- 6. The SDS is available upon request and is located at http://biocare.net.

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.

Factor XIIIa

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References:

1. Probst-Cousin S, Rickert CH, Gullotta F. Factor XIIIa-immunoreactivity in tumors of the central nervous system. Clin Neuropathol. 1998 Mar;17(2):79-84.

2. Silverman JS, Tamsen A. High grade malignant fibrous histiocytomas have bimodal cycling populations of factor XIIIa + dendrophages and dedifferentiated mesenchymal cells possibly derived from CD34+ fibroblasts. Cell Vis. 1998 Jan;5(1):73-6.

3. Goldblum JR, Tuthill RJ. CD34 and factor-XIIIa immunoreactivity in dermatofibrosarcoma protuberans and dermatofibroma. Am J Dermatopathol. 1997 Apr;19 (2):147-53.

4. Zelger BG, et al. Granular cell dermatofibroma. Histopathology. 1997 Sep;31 (3):258-62.

5. Silverman JS, Lomvardias S. An unusual soft tissue tumor with features of angiomatoid malignant fibrous histiocytoma composed of bimodal CD34 and factor XIIIa positive dendritic cell subsets. CD34 and factor XIIIa in angiomatoid MFH. Pathol Res Pract. 1997;193(1):51-8.

6. Sangueza OP, *et al.* Juvenile xanthogranuloma: a clinical, histopathologic and immunohistochemical study. J Cutan Pathol. 1995 Aug;22(4):327-35.

7. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."

8. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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