Epithelial Membrane Antigen (EMA [Mc-5])

Concentrated and Prediluted Monoclonal Antibody
901-143-111318

BIOCARE MEDICAL

Catalog Number:	**CM 143 A, B, C**	**PM 143 AA**
Description:	0.1, 0.5, 1.0 mL, conc.	6.0 mL, RTU
Dilution:	1:200	Ready-to-use
Diluent:	Da Vinci Green	N/A

Intended Use:
For In Vitro Diagnostic Use
Epithelial Membrane Antigen (EMA [Mc-5]) is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of EMA 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:
Epithelial membrane antigen (EMA) belongs to a heterogeneous family of highly-glycosylated transmembrane proteins known as human milk fat globule (HMFG) membrane proteins. This family of antigens is not restricted to breast but may also be found in secretory epithelial cells, to a lesser degree, in nonsecretory epithelium (e.g., squamous epithelium) and rarely in nonepithelial cells. EMA is best considered a broad-spectrum antibody that is reactive against many types of adenocarcinoma. EMA can differentiate between the origins of glandular organs. Breast and skin adnexal tumors are strongly positive. A lesser degree of staining is seen in carcinomas of the endometrium, kidney, thyroid, stomach, pancreas, lung, colon, ovary, prostate and cervix. Embryonal carcinomas, medullary carcinomas of thyroid, squamous carcinomas, sarcomas, lymphomas, and melanomas all tend to be nonreactive or show rare positive cells. Transitional cell carcinomas may show weak reactivity. Note that the cells of anaplastic large cell lymphoma are positive for EMA in a minority of cases. EMA or Leu-M1 positivity, when coupled with CEA positivity, strongly favors metastasis to the liver.

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, a secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: Mc-5
Isotype: IgG1
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: EMA
Cellular Localization: Cytoplasmic and cell membrane
Positive Tissue Control: Breast carcinoma

Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Reveal Decloaker. Refer to the Reveal Decloaker product data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30-45 minutes at RT.
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.
Chromogen: Incubate for 5 minutes at RT with DAB – OR – Incubate for 5-7 minutes at RT with Warp Red.

Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

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.

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 (NaN_3) 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 reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

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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.

References:

1. Metze D, Luger TA. Ultrastructural localization of carcinoembryonic antigen (CEA) glycoproteins and epithelial membrane antigen (EMA) in normal and neoplastic sweat glands. J Cutan Pathol. 1996 Dec;23(6):518-29.
2. Taylor CR, *et al.* eds. Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist 2nd edition, Philadelphia:W.B. Saunders:1994.
3. Kuwashima Y, *et al.* Immunohisto-chemical characterization of undifferentiated carcinomas of the ovary. J Cancer Res Clin Oncol. 1994;120(11):672-7.
4. Russo J, Russo IH. lrrirnunocytochemical markers in breast cancer. In: DeLellis RA, ed, Advances in Immunohistochemisty. New York: Raven Press, 1988:431-75.
5. Wick MR. Swansson PF, Manivel JO. Immunohistochemical findings in tumors of the skin. In: DeLellis RA, ed. Advances In lmmunohistochemistry. New York: Raven Press. 1988:395-429.
6. Heyderman E, *et al.* A new monoclonal antibody to epithelial membrane antigen (EMA)-E29. A comparison of its immunocytochemical reactivity with polyclonal anti-EMA. Br J Cancer. 1985 Sep;52(3):355-61.
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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