CE IVD

Mouse anti-EMA (Epithelial Membrane Antigen)

Cat. No.: MSK059 (1 ml Concentrate); MSK059-05 (0.5 ml Concentrate); MSG059 (6 ml Ready-to-use)

Instructions for use

Intended use
This antibody is designed for the specific localisation of epithelial membrane antigen (EMA) in formalin-fixed, paraffin-embedded tissue sections.
Anti-EMA antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	EMA
Clone:	E29
Isotype:	Mouse IgG2a kappa
Species reactivity:	Human +, others not tested

Summary and Description
The epithelial membrane antigen (EMA) belongs to the human milk fat globulins (HMFG) and is, beside milk, present in various epithelial cells of normal and neoplastic tissue.
EMA is a useful marker for staining of many carcinomas. The antibody reacts with normal and neoplastic cells from various tissues including epithelia of the breast, the sweat gland and squamous epithelium. Meningiomas are frequently positive for EMA.
Hepatocellular carcinomas, adrenal carcinomas, and embryonic carcinomas are consistently EMA negative.
Negative EMA staining is also characteristic for seminomas, paragangliomas, and hepatomas.
It was observed, that this antibody also detects plasma cells. EMA seems to be present in plasma cell neoplasias, but is rarely also observed in other types of lymphomas.

Reagent provided
Mouse monoclonal antibody from cell culture supernatant in PBS buffer with carrier protein and preservative for stabilisation in the following formats:

Concentrate:	1 ml	(Cat. No. MSK059)
Concentrate:	0.5 ml	(Cat. No. MSK059-05)
Ready-to-use:	6 ml	(Cat. No. MSG059)

Dilution of primary antibody
Dilution of Zytomed Systems' concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The validation of staining protocol should be done by an experienced specialist. For Zytomed Systems' recommendations see chapter 'Staining procedure'.

Storage and handling
The antibody should be stored at 2-8°C without further dilution.
Dilutions of the concentrated antibody should be done in a suitable antibody dilution buffer (e.g. ZUC025 from Zytomed Systems). The diluted antibody should be stored at 2-8°C after use. Stability of this working solution depends on various parameters and has to be confirmed by appropriate controls. The antibody provided is suitable for use until the expiry date indicated on the label, if stored at 2-8°C. Do not use product after the expiry date.
Positive and negative controls should be run simultaneously with all specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Zytomed Systems' technical support or your local distributor.

Precautions
Use through qualified personnel only.
Wear protective clothing to avoid contact of reagents and specimens with eye, skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with large amounts of water.
Microbial contamination of the reagent must be avoided, since otherwise non-specific staining may occur.
Sodium azide (NaN_3), used for stabilisation, is not considered hazardous material in the concentration used.
Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides.Sodium azide should be discarded in a large volume of running water to avoid formation of deposits.
Material safety data sheets (MSDS) are available upon request.

Staining procedure

Refer to the following table for conditions specifically recommended for this antibody. Also refer to detection system data sheets for guidance on specific staining protocols or other requirements.

Parameters	Zytomed Systems recommendations
*Pre-treatment	Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0)
*Control tissue	Breast tissue, skin
*Working dilution	1:200-1:400 (for concentrates)
*Incubation time	60 minutes

Quality control

The recommended positive control tissues for this antibody are breast tissues or skin. We recommend carrying out a positive and a negative control with every staining run. Please refer to the instructions of the detection system for guidance on general quality control procedures.

Troubleshooting

If you observe unusual staining or other deviations from the expected results please read these instructions carefully, refer to the instructions of the detection system for relevant information or contact your local distributor.

Expected results

This antibody stains positive in the cytoplasm and the cytoplasmic membrane of EMA expressing cells in formalin-fixed, paraffin-embedded tissue sections. Interpretation of the staining results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

Limitations of the Procedure

Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining, for example variations in fixation and embedding or the inherent nature of the tissue can cause inconsistent results (Nadji and Morales, 1983). Endogenous peroxidase, pseudoperoxidase activity in erythrocytes or biotin may cause non-specific staining depending on the detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive results with HRP (horse radish peroxidase) detection systems (Omata *et al*, 1980). Inadequate counterstaining and mounting can influence the interpretation of the results.
Zytomed Systems warrants that the product will meet all requirements described from its shipping date until the expiry date is reached, if the product is stored and utilised as recommended. No additional guarantees can be given. Under no circumstances shall Zytomed System be liable for any damages arising out of the use of the reagent provided.

Performance characteristics

Zytomed Systems has conducted studies to evaluate the performance of the antibody for use with a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no cross-reactivity.

Bibliography

Omata M et al. Am J Clin Pathol 73: 626-32, 1980
Nadji M and Morales AR. Ann N.Y. Acad Sci 420:134-9, 1983
Heydemann E et al. Brit J Cancer 52:355-361, 1985
Pinkus GS, et al. Am J Clin Pathol. 1986; 77:269-77
Redding WH, et al. Lancet 1983; 1271-4
Beer TW, et al. Histopathology. 2000; 37:218- 23
Fraga M, et al. Am J Clin Pathol. 1995; 103:82-9
Sloane JP and Ormerod MG. Cancer 47:1786-1795, 1981
Cordell J et al. Brit J Cancer 52:347-354, 1985
Pinkus GS, et al. Hum Pathol. 1985; 16:929- 40
Dearnaly DP, et al. Br J Cancer. 1981; 44:85-90
Attanoos RL, et al. Histopathology. 2003; 43:231-8
Lee JS, et al. Acta Cytol. 1996; 40:631-6

www.zytomed-systems.de
Zytomed Systems GmbH • Anhaltinerstraße 16 • 14163 Berlin, Germany • Tel: (+49) 30-804 984 990

Explanations of the symbols on the product label

Symbols are used in accordance with ISO 15223-1. Further symbols on the product label might be:

GSH07: Warning / Attention

RUO For Research Use Only