CE IVD

Mouse anti-Epithelial Specific Antigen (Ep-CAM, ESA)

Cat. No.: MSK109 (1 ml Concentrate); MSK109-05 (0.5 ml Concentrate)

Instructions for use

Intended use
This antibody is designed for the specific localisation of Epithelial Specific Antigen in formalin-fixed, paraffin-embedded tissue sections. Anti-Ep-CAM antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	Epithelial Specific Antigen (Ep-CAM, ESA)
Immunogen	MCF-7 cells (human breast carcinoma cell line)
Clone:	Ber-EP4
Isotype:	Mouse IgG1 κ
Species reactivity:	Human +, others not tested

Summary and Description
Ep-CAM/Epithelial Specific Antigen, also known as epithelial antigen and epithelial glycoprotein, is expressed in the cytoplasmic membrane and the cytoplasm of nearly all epithelial cells. However, there are some exceptions like most squamous epithelia, hepatocytes, renal proximal tubular cells, gastric parietal cells, and myoepithelial cells. Occasionally focal positivity is observed in basal cells of endodermal squamous epithelia (e.g. in tonsil) and basosquamous epithelial cells (e.g. cervix).

Ep-Cam is found in the majority of adenocarcinomas (50 – 100 % according to diverse studies) and in neuroendocrine tumours, including small cell carcinomas. 30% of all renal and liver cell carcinomas are positive for Ep-Cam. Endodermal and mesodermal squamous cell carcinoma are anti-Ber-EP4 positive in almost all cases whereas the majority of ectodermal squamous cell carcinomas are negative for Ep-Cam. Basal cell carcinomas and basosquamous carcinomas are mostly positive for anti-Ber-EP4. Plexus papilloma and plexus carcinoma are typically negative.

Reagent provided
Mouse monoclonal antibody in buffer with carrier protein and preservative for stabilisation in the following formats:

Concentrate:	1 ml	(Cat. No. MSK109)
	0.5 ml	(Cat. No. MSK109-05)

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 elaboration 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 with 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.
ProClin300 and sodium azide (NaN3) are used for stabilisation. 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 ZUC028) or proteolytic pre-treatment with Fast Enzyme (ZUC059)
*Control tissue	Colon carcinoma
*Working dilution	1:100-1:200 (for concentrates)
*Incubation time	30 - 60 minutes

Quality control
The recommended positive control tissue for this antibody is colon carcinoma. 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 cytoplasmic membrane and the cytoplasm of epithelial 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, alkaline phosphatase 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

Ordóñez NG. Adv Anat Pathol13:16-25, 2006
Carella R et al. Am J Surg Pathol 25:43-50, 2001
Latza U et al. J Clin Pathol 43:213-219, 1990
Omata M et al. Am J Clin Pathol 73:626-632, 1980
Ordóñez NG. Mod Pathol 19:417-428, 2006
Ordóñez NG. Am J Clin Pathol 109:85-89, 1998
Nadji M and Morales AR. Ann N.Y. Acad Sci 420:134-139, 1983

Explanations of the symbols on the product label:

REF	Bestellnummer Catalog Number Reference du catalogue		Verwendbar bis Use By Utiliser jusque		Gebrauchsanweisung beachten Consult Instructions for use Consulter les instructions d'utilisation
LOT	Chargenbezeichnung Batch Code Code du lot		Lagerungstemperatur Temperature Limitation Limites de température	RUO	Nur für Forschungszwecke For Research Use Only Pour la recherche uniquement
IVD	In vitro Diagnostikum In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro		Achtung Warning Attention		Hersteller / Manufacturer / Fabricant Zytomed Systems GmbH • Anhaltinerstraße 16 14163 Berlin, Germany • Tel: (+49) 30-804 984 990 www.zytomed-systems.com

Explanations of the symbols on the product label:

REF	Bestellnummer Catalog Number Reference du catalogue		Verwendbar bis Use By Utiliser jusque		Gebrauchsanweisung beachten Consult Instructions for use Consulter les instructions d'utilisation
LOT	Chargenbezeichnung Batch Code Code du lot		Lagerungstemperatur Temperature Limitation Limites de température	RUO	Nur für Forschungszwecke For Research Use Only Pour la recherche uniquement
IVD	In vitro Diagnostikum In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro		Achtung Warning Attention	Hersteller / Manufacturer / Fabricant Zytomed Systems GmbH • Anhaltinerstraße 16 14163 Berlin, Germany • Tel: (+49) 30-804 984 990 www.zytomed-systems.com	