

C€ IVD Mouse anti-Cytokeratin HMW (34βE12) Cat. No.: BMS015 (16 ml Ready-to-use)

Instructions for use

Intended Use

This antibody is designed for the specific localization of high molecular cytokeratins antigen in formalin-fixed, paraffin-embedded tissue sections.

Anti-Cytokeratin HMW antibody is intended for in vitro diagnostic use.

Specifications	
Specificity:	Human Cytokeratin HMW (High Molecular Weight cytokeratins 1, 5, 10 and 14)
Clone:	34βE12
lsotype:	Mouse IgG1
Species reactivity:	Human +, others not tested

Summary and explanation

Cytokeratins (CK) are intermediate filaments which exist in nearly all epithelial but also in some non-epithelial cells. According to R. Moll they are divided into Type I (acidic cytokeratins, CK9 to 20) and Type II (basic cytokeratins, CK1 to 8) cytokeratins. Each Type I cytokeratin is co-expressed with a Type II cytokeratin inside a single cell. Hence, it follows that all epithelial cells contain at least two different cytokeratins. Only CK19 is expressed unpaired. Cytokeratins can also be characterised by their molecular weight as low molecular (CK7 and 8 and CK17 to 20) or high molecular weight cytokeratins (CK1 to 6 and CK9 to 16). The antibody of clone 34βE12 detects the high molecular weight cytokeratins 1, 5, 10 and 14.

Usually, high molecular weight cytokeratins are detectable in squamous cell epithelia. Staining of cytokeratins with this antibody is useful for detection of the basal cell layer of several tissue types. In this context it is frequently used for staining of benign glands of the prostate.

Reagent provided

Mouse monoclonal antibody in TBS with carrier protein and preservative for stabilisation in the following format: **Ready-to-use:** 16 ml (Cat. No. BMS015)

Dilution of primary antibody

None

Storage and handling

The antibody should be stored at 2-8°C without further dilution.

If necessary, dilutions of the 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 stable 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 is used for stabilisation. 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	Skin
*Working dilution	None
*Incubation time	60 minutes

Quality control

The recommended positive control tissues for this antibody is 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

The antibody stains positive in the cytoplasm of epithelial cells in formalin-fixed, paraffin-embedded tissue. The interpretation of the 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 utilising 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 Sturm N et al. Histopathol 42:156-166, 2003 O'Malley, FP et al. Virch Arch A 1990; 417:191 Wojno, KJ et al. Am J Surg Pathol 1995; 19:251-60

Moll R et al. Cell 31:11-24, 1982 Yang XJ et al. Am J Surg Pathol 26:921-925, 2002 Gown, AM et al. Am J Pathol 1984; 114:309 Amin, MB. Arch Pathol Lab Med March 1994; 118:260-264 Moinfar, F et al. Am J Surg Pathol 1999; 23:1048-58



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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

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