CE IVD

Mouse anti-Ki-67

Cat. No.: BMS009 (16 ml Ready-to-use)

Instructions for use

Intended Use
This antibody is designed for the specific localization of Ki-67 in formalin-fixed, paraffin-embedded tissue sections. Anti-Ki-67 antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	Ki-67
Clone:	K-2
Isotype:	Mouse IgG1
Species reactivity:	Human +, others not tested

Summary and explanation
Ki-67 is a nuclear protein which is expressed during all phases of the cell cycle except G0. With anti-Ki-67 antibody it is possible to identify proliferating cells and distinguish them from stationary cells. Thus, the test allows for the evaluation of the growth fraction or mitosis rate in a cell population. It is particularly useful in studying malignant tumors and other pathogenic states as a measure of the proportion of proliferating cells. Ki-67 shows a higher specificity then PCNA (*Proliferating Cell Nuclear Antigen*) for proliferating cells and a shorter halflife. Therefore detection of proliferating cells via Ki-67 is the state-of-the-art method in immunohistochemistry.
This Ki-67 antibody (clone K-2) stains lipoblasts and other fat containing cells and could therefore be useful in the detection of liposarcomas.

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. BMS009)

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 and sodium azide (NaN_3) 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. Discard the antibody solution in a large volume of running water to avoid formation of deposits. A material safety data sheet (MSDS) for the pure substances is 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	Tonsil
*Working dilution	None
*Incubation time	60 minutes

Quality control

The recommended positive control tissues for this antibody is tonsil. 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 nuclei 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

Gerdes J et al. Int J Cancer 31:13-20, 1982
Gerdes J et al. J Immunol 133:1710-1715, 1984
Lindboe CF und Torp SH. J Clin Pathol 55:467-471, 2002
Nadji M and Morales AR. Ann N.Y. Acad Sci 420:134-139, 1983
Omata M et al. Am J Clin Pathol 73:626-632, 1980

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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

RUO For Research Use Only