

CE IVD Rabbit anti-Ki-67 Cat. No.: BRB040 (16 ml Ready-to-use)

Instructions for use

Intended Use

This antibody is designed for the specific localization of Ki-67 antigen in formalin-fixed, paraffin-embedded tissue sections.

Anti-Ki-67 antibody is intended for in vitro diagnostic use.

Specifications	
Specificity:	Human Ki-67
Clone:	SP6
Isotype:	Rabbit IgG
Species reactivity:	Human +, others not tested

Summary and explanation

Ki-67 is a proliferation marker which is mainly detectable during the late G1-phase as well as during S-, M- and G2phases. Stationary cells (G0) are negative for Ki-67.

Ki-67 is more expressed in an uploid tumours than in diploid tumours and is associated with a high mitosis rate and high histological grading.

Reagent provided

Rabbit monoclonal antibody from tissue culture supernatant in TBS with carrier protein and preservative for stabilisation in the following format:

Ready-to-use: 16 ml (Cat. No. BRB040)

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 eye, skin or mucous membrane contact with the reagent. In case of the reagent coming into contact with a sensitive area, wash the area with large amounts of water.

Microbial contamination of the reagents must be avoided, since otherwise non-specific staining might appear. ProClin 300 and sodium azide (NaN₃) is 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 sheet (MSDS) for the pure substances 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.

<u>Parameters</u>	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
*Control tissue *Working dilution	Tonsil None

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 nuclei of proliferating 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

Zabaglo L et al. J Clin Pathol 63:800-804, 2010 Gerdes J et al. J Pathol 168:85-86, 1992 Nadji M and Morales AR. Ann NY Acad Sci 420:134-139, 1983 Gerdes J et al. Am J Pathol 138: 867-873, 1991 Catoretti G et al. J Pathol 168:357-363, 1992 Omata M et al. Am J Clin Pathol 73:626-632, 1989



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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 For Research Use Only