



Instructions for use

Intended Use

This antibody is designed for the specific localization of p40 (or $\Delta Np63$), a truncated p63 protein, in formalin-fixed, paraffin-embedded tissue sections.

Anti-p40 antibody is intended for in vitro diagnostic use.

Specifications	
Specificity:	Human p40 (ΔNp63)
Immunogen:	Amino acid residues 5 – 17 of human p40
Clone:	BC28
Isotype:	Mouse IgG1
Species reactivity:	Human +, others not tested

Summary and explanation

Anti-p40 is a promising new antibody that may be a valuable marker in cases where anti-p63 traditionally has been used. In the moment p63 is the most commonly used antibody for detecting lung squamous cell carcinomas. It shows a high sensitivity but also detects lung adenocarcinomas from time to time; according to Au *et al.* up to 30% of all cases.

The p40 protein, an N-terminal truncated form of p63 protein (Δ Np63), seems to be more strictly bound to squamous cell carcinomas than p63. Recent studies (Bishop *et al.* und Nonaka) show that p40 staining is equivalent to p63 in sensitivity for squamous cell carcinoma but shows a considerably higher specificity. In the large study of Bishop *et al.* the sensitivity of p40 for lung squamous cell carcinomas is 100% and the specificity 98% whereas p63 only shows a specificity of 60% for this tumour entity.

Both authors conclude that p40 is superior to p63 when detecting squamous cell carcinomas of the lung, especially when it is important to differentiate them from adenocarcinomas of the lung.

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. BMS050)

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 (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. 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 Lung squamous cell carcinoma, normal prostate
*Working dilution None
*Incubation time 60 minutes

Quality control

The recommended positive control tissue for this antibody is lung squamous cell carcinoma or normal prostate. 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 of p40-positive 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

Nonaka D. Am J Surg Pathol 36:895-899, 2012 Pelosi G et al. J Thorac Oncol 7:281-290, 2012 Omata M et al. Am J Clin Pathol 73:626-632, 1980 Signoretti S, et al. Am J Pathol. 2000 Dec; 157(6):1769-75 Bishop JA et al. Mod Pathol 25:405-415, 2012 Au NH et al. Appl Immunohistochem Mol Morphol 12:240-247, 2004 Nadji M, Morales AR. Ann N Y Acad Sci 420:134-138, 1983 Sailer V, et al. Histopathology. 2013 Jul; 63(1):50-6



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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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