CE IVD

Mouse anti-p40 (ΔNp63

Cat. No.: AIB-40004 (16 ml Ready-to-use)

Instructions for use

Intended use
This antibody is designed for the specific localization of p40 (or ΔNp63), a truncated p63 protein, in formalin-fixed, paraffin-embedded tissue sections. Anti-p40 receptor antibody is intended for in vitro diagnostic use.

Specifications

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

Summary and Description
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 (ΔNp63), 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
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. AIB-40004)

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. BCB-20005/BCB-20006 from Nordic Biosite). 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 Nordic Biosite' technical support or your local distributor.

Explanations of the symbols on the product label:

REF	Catalog Number Bestellnummer Reference du catalogue	LOT	Batch Code Chargenbezeichnung Code du lot	Manufacturer Nordic BioSite AB Propellervägen 4A S-183 62 Täby Sweden Tel: +46 (0)8 5444 33 40 Fax: +46 (0)8 756 94 90 info@nordicbiosite.com www.nordicbiosite.com
	Use By Verwendbar bis Utiliser jusque	IVD	In Vitro Diagnostic Medical Device In vitro Diagnostikum Dispositif médical de diagnostic in vitro	
	Consult Instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation		Temperature Limitation Lagerungstemperatur Limites de température	

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	Nordic BioSites recommendations
*Pre-treatment	Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0 (BCB-20015/-20016)
*Control tissue	Lugn squamous cell carcinoma
*Working dilution	None
*Incubation time	30-60 minutes

Quality control
The recommended positive control tissue for this antibody is lung squamous cell 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
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, 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.
Nordic Biosite 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 Nordic Biosite be liable for any damages arising out of the use of the reagent provided.

Performance characteristics
Nordic Biosite 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 crossreactivity.

Bibliography

Nonaka D. Am J Surg Pathol 36:895-899, 2012
Bishop JA et al. Mod Pathol 25:405-415, 2012
Pelosi G et al. J Thorac Oncol 7:281-290, 2012
Au NH et al. Appl Immunohistochem Mol Morphol 12:240-247, 2004
Nadji M and Morales AR Ann N.Y. Acad Sci 420:134-9, 1983
Omata M et al. Am J Clin Pathol 73(5): 626-32, 1980

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