CE IVD

Mouse anti-Cytokeratin Broad Spectrum (AE1 & AE3)

Cat. No.: AIB-30067 (1 ml Concentrate); AIB-30068 (0.5 ml Concentrate); AIB-30066 (6 ml Ready-to-use)

Instructions for use

Intended use

This antibody is designed for the specific localisation of cytokeratins in formalin-fixed, paraffin-embedded tissue sections. Anti-Cytokeratin Broad Spectrum antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	Cytokeratin pan
Immunogen:	Epidermal human keratins
Clone:	Cocktail composed of AE1 and AE3
Isotype:	Mouse IgG1a / Mouse IgG1a
Species reactivity:	Human +, mouse +, rat +, dog +, others not tested

Summary and Description

Cytokeratins (CK) are intermediate filaments that constitute the cytoskeletal structure of virtually all epithelial but also of 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.

The antibody of clone AE1 detects the acidic (Type I) cytokeratins 10, 15, 16 and 19. The antibody derived from clone AE3 detects all basic (Type II) cytokeratins, i.e. CK1 to 8. That means the antibody cocktail AE1/AE3 detects all cells containing cytokeratins and is therefore called “pan-Cytokeratin“ antibody.

Detection of cytokeratins with a broad spectrum (“pan“-) antibody allows for the staining of epithelial cells in normal and abnormal tissues. It is especially useful in characterisation of metastases with unknown origin. Lerwill (2004) has shown that cocktail AE1/AE3 detects carcinomic metastases in lymph nodes more specific than other pan-CK antibodies.

Reagent provided

Cocktail of mouse monoclonal antibodies from ascites in buffer with carrier protein and preservative for stabilisation in the following formats:

Concentrate:	1 ml	(Cat. No. AIB-30067)
Concentrate:	0.5 ml	(Cat. No. AIB-30068)
Ready-to-use:	6 ml	(Cat. No. AIB-30066)

Dilution of primary antibody

Dilution of Nordic Biosite’ concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The elaboration of staining protocol should be done by an experienced specialist. For Nordic Biosite’ recommendations see chapter ‘Staining procedure’.

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	

Storage and handling
The antibody should be stored at 2-8°C without furt her dilution.
Dilutions of the concentrated 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 suitable for use 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.

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	Skin, adeno- or squamous cell carcinoma
*Working dilution	1:100-1:200 (for concentrates)
*Incubation time	30-60 minutes

Quality control
The recommended positive control tissues for this antibody are skin, adeno- or squamous cell carcinomas. 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
This antibody stains positive in the cytoplasm of epithelial cells in formalin-fixed, paraffin-embedded tissue sections. Interpretation of the staining 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.

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	

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 for use with 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

Moll R et al. Cell 31:11-24, 1982
Southgate J et al. Histopathol 14:657-664, 1999
Chu PG und Weiss LM. Histopathol 40:403-439, 2002
Lerwill MF. Am J Surg Pathol 28:1076-1091, 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

October 15, 2013 Rev: A1013 Doc: DBE_AIB-30067/-30068/-30066

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	