



Cat. No.: AIB-30037 (1 ml Concentrate); AIB-30038 (0.5 ml Concentrate); AIB-30036 (6 ml Ready-to-use)

Instructions for use

Intended use

This antibody is designed for the specific localization of CD43 (leukosialin) in formalin-fixed, paraffin-embedded tissue sections. Anti-CD43 antibody is intended for in vitro diagnostic use.

Specifications

Specificity: CD43 (leukosialin, sialophorion) **Immunogen:** Pluripotent human cell line K562

Clone: DF-T1

Isotype: Mouse IgG1 kappa

Species reactivity: Human +, rat +, others not tested

Summary and Description

The CD43 antigen (synonyms: leukosialin, gp95, sialophorin, leucocyte sialoglycoprotein) is an integral typ-1 membrane protein with molecular weight of about 95-110 kDa. It belongs to the family of cell surface mucins and functions in T-cell immunity and cell-cell interactions.

CD43 is expressed on most T-cells, on activated B-cells, NK-cells, granulocytes, macrophages, and megakaryocytes. Resting B-cells are CD43 negative.

In immunohistochemistry CD43 is used to identify and classify T-cell neoplasias. 80 – 90 % of all T-cell lymphomas, mantel cell lymphomas, Burkitt lymphomas and B-cell SLL are CD43 positive. ALL and the majority of AML are also positive too. Antibodies of the clone DF-T1 detect an extra cellular epitop of the CD43 antigen.

Reagent provided

Mouse monoclonal antibody in TBS with carrier protein and preservative for stabilisation in the following formats:

 Concentrate:
 1 ml
 (Cat. No. AIB-30037)

 Concentrate:
 0.5 ml
 (Cat. No. AIB-30038)

 Ready-to-use:
 6 ml
 (Cat. No. AIB-30036)

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
	Use By Verwendbar bis Utiliser jusque	IVD	In Vitro Diagnostic Medical Device In vitro Diagnostikum Dispositif médical de diagnostic in vitro	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
	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 stable until the expiry date indicated on the label, if stored at 2-8°C. Do n ot 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 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), used for stabilisation, are not considered hazardous material in the concentrations used. 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 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 or EDTA Buffer pH 8.0 BCB-20017/BCB-20018)

*Control tissue Tonsil

*Working dilution 1:100-1:200 (for concentrated antibodies)

*Incubation time 30-60 minutes

Quality control

The recommended positive control tissue 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 cytoplasmic membrane of T-cells, macrophages, monocytes, activated B-cells, and epidermal Langerhans cells in formalin-fixed, paraffin-embedded tissue. Further details about the expression pattern of CD43 can be found in the chapter 'Summary and Description'. The interpretation of the results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

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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

Lai R, et al., Am J Clin Pathol 111, 488 ff. 1999 Schlossman, S.F. et al. Eds., Leucocyte Typing V, Oxfort University Press, 1995. McMichael, A.J. et al. Eds., Leucocyte Typing III, Oxfort University Press, 1987. 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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