



Cat. No.: AIB-30188 (1 ml Concentrate); AIB-30189 (0.5 ml Concentrate); AIB-30233 (6 ml Ready-to-use)

Instructions for use

Intended use

This antibody is designed for the specific localisation of terminal desoxynucleotidyltransferase (TdT) protein in formalin-fixed, paraffin-embedded tissue sections and in frozen sections.

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

Specifications

Specificity: TdT
Clone: Polyclonal
Isotype: Rabbit Ig

Species reactivity: Human +, others not tested

Summary and Description

This anti-TdT antibody labels cortical thymocytes and immature lymphocytes. The enzyme TdT (terminal deoxynucleotidyl transferase) is found in the nuclei of normal haematopoietic cells, in nuclei of cortical thymocytes and in the cytoplasm of bone marrow megakaryocytes.

A positive TdT expression is found in more than 90% of all acute lymphatic leukaemias with the exception of pre-Bcell leukaemia. It is not found in normal mature T- and B-cells.

Approximately 30% of all chronic-myeloid leukaemias are positive for TdT. If patient material shows a positive stain for TdT this is considered to be a good indicator for a better response to chemotherapy in these cases.

Reagent provided

Rabbit polyclonal antibody (purified immunoglobulin fraction) in PBS buffer pH 7.4 including carrier protein and preservative for stabilisation in the following formats:

Concentrate: 1 ml (Cat. No. AIB-30188)
Concentrate: 0.5 ml (Cat. No. AIB-30189)
Ready-to-use: 6 ml (Cat. No. AIB-30233)

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'.

Storage and handling

The antibody should be stored at 2-8°C without furt her dilution.

Dilutions of the concentrated antibody should be done in a suitable antibody dilution buffer (e.g. BCB-20005/BCB-20006 from Nordic Bioiste). The diluted antibody should be stored at 2-8°C after use. The 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 Bioste' 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	
ĵ	\bigcap_i	Consult Instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation	1	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. Sodium azide (NaN3), used for stabilisation, is not considered hazardous material in the concentration 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. A material safety data sheet (MSDS) for the pure substance 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.

<u>Parameters</u> <u>Nordic BioSites recommendations</u>

*Pre-treatment Heat Induced Epitope Retrieval (for example in EDTA Buffer pH 9.0 (BCB-

20019/-20020)

*Control tissue TdT-positive thymus

*Working dilution 1:100-1:500 (for concentrates)

*Incubation time 30-60 minutes

Quality control

The recommended positive control tissue for this antibody is TdT-positive thymus. 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 nuclei in formalin-fixed, paraffin-embedded tissue sections. Further details about the expression pattern of TdT can be found in the chapter 'Summary and Description'. 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. 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 Bioiste 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.

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Bibliography

Stauchen JA, Miller LK. Int J Surg Pathol 11:21-24, 2003 Ozdemirli M et al Mod Pathol 14:1175-1182, 2001 Lucas DR et al Am J Clin Pathol 115:933-934, 2001 Soslow RA et al Hum Pathol 28:1158-1165, 1997 Mathewson RC et al. Pediatr Pathol Lab Med 17:835-844, 1997 Suzumiya J et al. J Pathol 182:86-91, 1997 Arber DA et al. Am J Clin Pathol 106:462-468, 1996 Arber DA, Jenkins KA. Am J Clin Pathol 106:462-468, 1996 Orazi A et al. Mod Pathol 7:582-586, 1994 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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