CE IVD

Mouse anti-CD15

Cat. No.: AIB-30021 (1 ml Concentrate); AIB-30022 (0.5 ml Concentrate); AIB-30020 (6 ml Ready-to-use)

Instructions for use

Intended use
This antibody is designed for the specific localisation of CD15 in formalin-fixed, paraffin-embedded tissue sections. Anti-CD15 antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	CD 15 (Granulocytes / Reed-Sternberg cells)
Immunogen:	Myelomonocytic leukaemia cells
Clone:	Carb-3
Isotype:	Mouse IgM
Species reactivity:	Human +, others not tested

Summary and description
The antibody clone Carb-3 recognises the 3-fucosyl-N-acetyl-lactosamine epitope of the CD15 antigen. It is present on the cell surface of myeloid cells, mainly on granulocytes, but not on B- or T-cells, monocytes, erythrocytes, or platelets. Additionally, the antibody reacts with Hodgkin cells and Reed-Sternberg cells.
Most adenocarcinomas are positive for CD15.

Reagent provided
Mouse monoclonal antibody in buffer with carrier protein and preservative for stabilisation in the following formats:

Concentrate:	1 ml	(Cat. No. AIB-30021)
Concentrate:	0.5 ml	(Cat. No. AIB-30022)
Ready-to-use:	6 ml	(Cat. No. AIB-30020)

Dilution of primary antibody
Dilution of Nordic BioSites' 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 BioSites' recommendations see chapter 'Staining procedure'.

Storage and handling
The antibody should be stored at 2-8℃ 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℃ 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℃. 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.

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 (NaN_3), 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) 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	Nordic BioSite recommendations
*Pre-treatment:	Heat Induced Epitope Retrieval (for example in citrate buffer pH 6.0 BCB-20015/20016
*Control tissue:	Hodgkin's lymphoma (Reed-Sternberg cells)
*Working dilution:	1:50 – 1:200 (for concentrated antibodies only)
*Incubation time:	30 - 60 minutes

Quality control
The recommended positive control tissue for this antibody is Hodgkin's lymphoma. 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 cytoplasmic membrane of CD15-positive cells in formalin-fixed, paraffin-embedded tissue sections. Further details about the expression pattern of CD15 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 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

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Omata M et al. Am J Clin Pathol 73(5): 626-32, 1980

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Explanations of the symbols on the product label:

REF	Bestellnummer Catalog Number Reference du catalogue		Verwendbar bis Use By Utiliser jusque		Gebrauchsanweisung beachten Consult Instructions for use Consulter les instructions d'utilisation
LOT	Chargenbezeichnung Batch Code Code du lot		Lagerungstemperatur Temperature Limitation Limites de température	RUO	Nur für Forschungszwecke For Research Use Only Pour la recherche uniquement
IVD	In vitro Diagnostikum In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro		Achtung Warning Attention		Hersteller / Manufacturer / Fabricant Nordic BioSite AB • Propellervägen 4A 183 62 Täby, Sweden • Tel: (+46) 5444 3340 www.nordicbiosite.com