



Cat. No.: MSK093-05 (0.5 ml Concentrate); MSG093 (6 ml Ready-to-use)

Instructions for use

Intended use

This antibody is designed for the specific localisation of CD11c in formalin-fixed, paraffin-embedded tissue sections and in frozen sections.

Anti-CD11c antibody is intended for in vitro diagnostic use.

Specifications

Specificity: CD11c Clone: 5D11

Isotype: Mouse IgG2a

Species reactivity: Human +, others not tested

Summary and Description

CD11c is especially suitable for detecting hairy cell leukaemia. Usually, it is expressed by monocytes and macrophages, neutrophiles, myeloic dendritic cells as well as a small subpopulation of lymphocytes. The CD11c antibody of clone 5D11 detects a formalin-resistant epitope of CD11c antigen. Johrens *et al.* recommend the antibody for diagnosis of hairy cell leukaemia because it is both sensitive and specific for this disease. They recommend adding the anti-CD11c to the panel of antibodies for IHC to differentiate hairy cell leukaemia from other small-cell lymphomas.

Reagent provided

Mouse monoclonal antibody in Tris buffer pH 7.3 to 7.7 with 1 % BSA carrier protein and <0.1 % sodium azide for stabilisation in the following formats:

Concentrate: 0.5 ml (Cat. No. MSK093-05) **Ready-to-use:** 6 ml (Cat. No. MSG093)

Dilution of primary antibody

Dilution of Zytomed Systems' 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 Zytomed Systems' 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 in a suitable antibody dilution buffer (e.g. ZUC025 from Zytomed Systems). 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 Zytomed Systems' 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. 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. Material safety data sheets (MSDS) are available upon request.

November 11, 2013 Rev: A1113 Doc: DBE MSK093-05 MSG093

Staining procedure for formalin-fixed paraffin sections

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>Zytomed Systems recommendations</u>

*Pre-treatment Heat Induced Epitope Retrieval (for example in EDTA buffer pH 9 (ZUC029) or citrate buffer

pH 6.0 (ZUC028))

*Control tissue Hairy cell leukaemia

*Working dilution 1:50-1:100 (for concentrates)

*Incubation time 30 - 60 minutes

Quality control

The recommended positive control tissue for this antibody is bone marrow with hairy cell leukaemia. 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 CD11c-positive cells in formalin-fixed, paraffin-embedded tissue sections. Further details about the expression pattern of CD11c 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.

Zytomed Systems 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 Zytomed System be liable for any damages arising out of the use of the reagent provided.

Performance characteristics

Zytomed Systems 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

Johrens K et al. Pathobiol 75:252-256, 2008 Jones G et al. Br J Hematol 156:186-195, 2012 Marotta G et al. Leuk Lymphoma 37:145-149, 2000 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

November 11, 2013 Rev: A1113 Doc: DBE_MSK093-05_MSG093

Explanations of the symbols on the product label Bestellnummer Verwendbar bis Gebrauchsanweisung beachten **REF** Catalog Number |i|Consult Instructions for use Use By Consulter les instructions d'utilisation Reference du catalogue Utiliser jusque Nur für Forschungszwecke Chargenbezeichnung Lagerungstemperatur LOT RUO Batch Code Temperature Limitation For Research Use Only Code du lot Limites de température Pour la recherche uniquement Hersteller / Manufacturer / Fabricant In vitro Diagnostikum Achtung Zytomed Systems GmbH • Anhaltinerstraße 16 IVD In Vitro Diagnostic Medical Device Warning 14163 Berlin, Germany • Tel: (+49) 30-804 984 990 Dispositif médical de diagnostic in vitro Attention www.zytomed-systems.com