BioGenex
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CE Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
EC REP

Anti-ALK/CD246

Catalog No.	Description
AMB41-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AMB41-10M	10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive™ Detection Systems and i6000™ Automated Staining Systems
MUB41-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
MUB41-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AXB41-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests
AXB41-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests

Clone	Species	Ig Class
ALK/1031	Mouse	IgG2b

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of ALK/CD246 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

ALK Antibody also designated CD246 antibody, ALK RTK antibody, or type 1 receptor tyrosine kinase ALK antibody. This antibody recognizes a formalin-resistant epitope in both the 80 kDa NPM-ALK chimeric and the 200 kDa normal human ALK proteins. The wild-type anaplastic lymphoma kinase (ALK) protein expression is restricted to a few scattered cells in the nervous system (some glial cells and neurons, and a few endothelial cells and pericytes). The hybrid gene, *NPM-ALK*, formed by the chromosomal translocation encodes part of the nucleolar phosphoprotein, nucleophosmin (NPM), adhered to the cytoplasmic portion of the anaplastic lymphoma kinase (ALK) receptor tyrosine kinase. ALK plays a major in development of brain and can effect specific neurons in nervous system. Recent study shows that the NPM-ALK fusion gene is oncogenic. A truncated form containing the catalytic domain of ALK is expressed as the result of a translocation occurring in many non-Hodgkin′s lymphomas. ALK Antibody stains cytoplasm and nuclear in t(2;5)-positive cells. This antibody helps in the identifying anaplastic large cell lymphoma (ALCL) and also used in a panel with CD15, CD30, TIA-1 and EMA

Storage and Handling

Store at 2-8°C. Fresh dilutions, if required, should be prepared prior to use and are stable and steady for up to one day at room temperature (20-26°C). Diluted antibody preparations can be refrigerated or frozen for extended shelf life.

Principles of the Procedure

Antigen detection by immunohistochemistry (IHC) is a two-step process wherein the primary antibody binds to the antigen of interest and that binding is detected by a chromogen. The primary antibody may be used in IHC using manual techniques or BioGenex Automated Staining System. Positive and negative controls should always be run simultaneously with all patient specimens.

Reagents Provided

Mouse Monoclonal Antibody ALK/CD246 is affinity purified and diluted in PBS, pH 7.2, containing 1% BSA and 0.09% sodium azide.

Dilution of Primary Antibody

BioGenex Ready-to-Use antibodies have been optimized for use with the recommended BioGenex Detection System and should not require further dilution.

BioGenex concentrated antibodies must be diluted in accordance with the recommended protocol when used with the recommended BioGenex Detection System.

Recommended Protocol

Refer to the following table for conditions specifically recommended for this antibody. Refer to the BioGenex website for guidance on specific staining protocols or other requirements.

Parameter	BioGenex Recommendations
Control Tissue	Lymphoma tissue as available with Biogenex FB-B41M* & FG-B41M*
Recommended Dilution for Concentrated Antibody	**1:10-25 in HK941**
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 (HK522-XAK)
Recommended Pretreatment (Xmatrx)	EZ-AR2 Elegance (HX032-YCD)
Antibody Incubation (Manual/i6000)	30-60 Min at RT
Antibody Incubation (Xmatrx)	30-60 Min at 25°C
Detection System for Manual, Xmatrx & i6000 systems***	Use BioGenex Two-Step **OR** One-Step Super Sensitive™ Polymer-HRP IHC Detection System/DAB; see p. 2 for more information

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*FB: positive control micro chamberslides, FG: positive control microscopic slides. Xmatrx requires micro chamber slides.
**Pretreatment times will vary based on individual microwave power.
***For automation systems (Xmatrx-Elite, Xmatrx-Ultra & i6000 Diagnostics), refer to the factory protocols provided with the instrument.

Detection System	Two-Step HRP Kit	One-Step HRP Kit	Link and Label Kit
Manual	QD440-XAKE (1000 Test)	QD630-XAKE (1000 Test)	QP300-XAKE (1000 Test)
	QD430-XAKE (1000 Test)		
	QD420-YIKE (500 Test)	QD620-XAKE (500 Test)	QP900-9LE (500 Test)
	QD400-60KE (60 Test)		
Xmatrx - Automation	QD550-YCDE (200 Test)	QD610-YADE (200 Test)	N/A
i6000 - Automation	QD410-YAXE (200 Test)	QD610-YAXE (200 Test)	N/A
For more information, visit www.biogenex.com.			

Precautions

This product contains sodium azide at concentrations of less than 0.1%. Sodium azide is not classified as a hazardous chemical at the product concentrations, but proper handling protocols should be observed. For more information, a Safety Data Sheet (SDS) for sodium azide is available upon request. Dispose of unused reagents according to Local, State and Federal Regulations. Wear suitable Personal Protective Equipment, do not pipette reagents by mouth, and avoid contact of reagents and specimens with skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with copious amounts of water.

Quality Control

Refer to BioGenex detection system documents for guidance on general quality control procedures.

Troubleshooting

Refer to the troubleshooting section in the documentation for BioGenex Detection Systems (or equivalent detection systems) for remedial actions on detection system related issues, or contact BioGenex Technical Support Department at 1-800-421-4149 or support@biogenex.com or your local distributor to report unusual staining.

Expected Results

This antibody stains cytoplasmic and nuclear in positive cells in formalin-fixed, paraffin embedded tissue sections. An example image of a tissue section stained with this antibody can be found on the product page on the BioGenex website. Interpretation of the staining result is solely the responsibility of the user. Experimental results should be confirmed by a medically-established diagnostic product or procedure.

Limitations of the Procedure

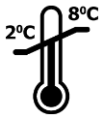
Improper tissue handling and processing prior to immunostaining can lead to inconsistent results. Variations in embedding and fixation or the nature of the tissue may lead to variations in results. Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and tissue biotin may result in non-specific staining based on the detection system employed. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive with horseradish peroxidase systems. Improper counterstaining and mounting may compromise the interpretation of results.

Bibliography

1. Pulford K, Lamant L, Morris SW, Butler LH, Wood KM, Stroud D, et al. Detection of anaplastic lymphoma kinase (ALK) and nucleolar protein nucleophosmin (NPM)-ALK proteins in normal and neoplastic cells with the monoclonal antibody ALK1. Blood 1997;89:1394-404.

2. Haase, V.H., et al. 1991. Alternatively spliced LTK mRNA in neurons predicts a receptor with a larger putative extracellular domain. Oncogene 6: 2319-2325.

3. Morris, S.W., et al. 1994. Fusion of a kinase gene, ALK, to a nucleolar protein gene, NPM, in non-Hodgkin's lymphoma. Science 263: 1281-1284.

	Temperature Limitation		In Vitro Diagnostic Medical Device
	Use By Date		Batch Code
	Non-Sterile		Consult Instructions for Use
	Representative in the European Community		Manufacturer