

## Anti-Human ALK/p80

Catalog No.	Description
AN770-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AN770-10M	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
NU770-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
NU770-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AY770-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests
AY770-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests

Clone	Species	Ig Class
SP8	Rabbit	IgG

### Intended Use

**For In Vitro Diagnostic Use.** This antibody is designed for the specific localization of ALK/p80 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

### Summary and Explanation

This antibody recognizes a human p80 protein, identified as a hybrid of the anaplastic lymphoma kinase (ALK) gene and the nucleophosmin (NPM) gene resulting from the t(2;5)(p23;q35) translocation found in a third of large cell lymphomas. This antibody can be used to detect p80 in these lymphomas and may also be used to detect a recently described subtype of large B cell lymphoma, which expresses the full-length ALK protein.

### 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

Rabbit Monoclonal Antibody ALK/p80 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	Adenocarcinoma as available with Biogenex FB-770N* & FG-770N*
Recommended Dilution for Concentrated Antibody	<b>1:10-25 in HK941</b>
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 (HK522-XAK)
Recommended Pretreatment (Xmatrx)	EZ-AR2 Elegance (HX032-YCD)
Antibody Incubation (Manual/i6000)	120 min at RT
Antibody Incubation (Xmatrx)	120 min at 25°C
Detection System for Manual, Xmatrx & i6000 systems***	Use BioGenex Two-Step <b>OR</b> One-Step Super Sensitive™ Polymer-HRP IHC Detection System/DAB; see p. 2 for more information

\*FB: positive control micro chamber slides, 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.

Category	Antibodies	Revision No.	J
Document No.	932-770N-EN	Release Date	24-May-2024

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)		
Xmatrix - 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 <a href="http://www.biogenex.com">www.biogenex.com</a> .			

### 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](mailto:support@biogenex.com) or your local distributor to report unusual staining.

### Expected Results

This antibody stains nucleus/cytoplasm 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

- Kutok JL et al.: “ Molecular biology of anaplastic lymphoma kinase-positive anaplastic large-cell lymphoma”. J ClinOncol V20:17 3691-3702 Sep 2002.
- Onciu M, et al.:” ALK-positive plasmablastic B-cell lymphoma with expression of the NPM-ALK fusion transcript: report of 2 cases”.Blood 2003 Oct 1; 102(7):2642-4.
- Center for Disease Control. Decontamination of Laboratory Sink Drains to Remove Azide Salts. Center for Disease Control Manual Guide--Safety Management, No. CDC-22, Atlanta, Georgia. April 30, 1976.
- Nadji M, Morales AR. Immunoperoxidase, part 1: the techniques and its pitfall. Lab Med 1983; 14:767-770.
- Omata M, Liew CT, Ashcavai M, Peters RI. Nonimmunologic binding of horseradish peroxidase to hepatitis B surface antigen. A possible source of error in immunohistochemistry. Am J Clin Pathol. May, 1980; 73(5):626-632.
- U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
- National Institute for Occupational Safety and Health, (NIOSH), Rockville, MD. Explosive azide hazard, Publication No. 78-127, 1976.

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

© 2020, BioGenex Laboratories. All rights reserved.

<b>Category</b>	Antibodies	<b>Revision No.</b>	J
<b>Document No.</b>	932-770N-EN	<b>Release Date</b>	24-May-2024