

Anti-Kappa Light Chain [HP6053+L1C1]

C (I N	D 1.41		
Catalog No.	Description		
	6 ml of Ready-to-Use Antibody for use with		
AM980-5M	BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	10 ml of Ready-to-Use Antibody in a		
AM980-10M	barcode labeled vial for use with BioGenex		
ANIJOU-IUNI	Super Sensitive TM Detection Systems and		
	i6000 TM Automated Staining Systems		
	1 ml of Concentrated Antibody for use with		
MU980-UC	BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	0.5 ml of Concentrated Antibody for use		
MU980-5UC	with BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	Ready-to-Use Antibody in Barcode labeled		
AX980-YCD	vial for use on the Xmatrx® Elite/Ultra		
	Staining System, 160 tests		
	Ready-to-Use Antibody in Barcode labeled		
AX980-50D	vial for use on the Xmatrx® Elite/Ultra		
	Staining System, 50 tests		

Clone	Species	Ig Class
HP6053+L1C1	Mouse	IgG1

Intended Use

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

Summary and Explanation

There are two types of light chain in humans (Kappa (K) Light Chain and Lambda (λ) Light Chain. Normally, the total Kappa to Lambda ratio is about 2:1 in serum, with a highly divergent ratio indicative of neoplasm. If one type of light chain level is significantly higher than that of the other type, it indicates a malignant condition, such as B-cell lymphoma. This antibody is designed specific for Kappa Light Chain of Immunoglobulin, as a B cell marker. Detection of gene rearrangements and abnormal expression of Kappa Light Chain in immunoglobulin, are important methods in the diagnosis of B-cell lymphoma, Plasma cell myeloma, and Reactive follicular hyperplasia. The most important role of the antibody would be in distinguishing atypical reactive follicular lymphoid hyperplasia from follicular lymphoma. In general, the neoplastic cells of follicle-like arrangement in extramedullary plasmacytoma and extracellular material are positive for Kappa Light Chain.

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 <u>primary antibody</u> 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 Kappa Light Chain 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	Tonsil tissue as available with Biogenex FB-980M* & FG-980M*		
Recommended Dilution for Concentrated Antibody	1:25-40 in HK941		
Recommended Pretreatment (Manual/i6000)**	EZ-AR1 (HK521-XAK)		
Recommended	EZ-AR1 Elegance (HX031-		
Pretreatment (Xmatrx)	YCD)		
Antibody Incubation (Manual/i6000)	30-60 Min at RT		
Antibody Incubation (Xmatrx)	45-60 Min at 25°C		
	Use BioGenex Two-Step OR		
Detection System for	One-Step Super Sensitive TM		
Manual, Xmatrx & i6000	Polymer-HRP IHC Detection		
systems***	System/DAB; see p. 2 for more information		

^{*}FB: positive control micro chamber slides, FG: positive control microscopic slides. Xmatrx requires barrier slides.

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

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 cytoplasm in positive cells in formalinfixed, 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 medicallyestablished 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. Matsuo FS, Barbosa de Paulo LF, Servato JP, de Faria PR, Cardoso SV, Loyola AM. Involvement of oral tissues by AL amyloidosis:a literature review and report of eight new cases. Clin Oral Investig. 2016 Nov;20(8):1913-1920
- 2. Lara-Torres CO, Ortiz-Hidalgo C. Well-differentiated (Marschalko-type) plasmacytoma resembling thyroid follicular structures. J Hematop. 2008 Sep;1(2):127-9
- 3. Lu C, He Q, Zhu W, Fu C, Zhou J, Tao Y, Liu S, Xiao D. The value of detecting immunoglobulin gene rearrangements in the diagnosis of B-celllymphoma. Oncotarget. 2017 Aug 18:8(44):77009-77019

2°C 8°C	Temperature Limitation	IVD	In Vitro Diagnostic Medical Device
\boxtimes	Use By Date	LOT	Batch Code
NON STERILE	Non-Sterile	[]i	Consult Instructions for Use
EC REP	Representative in the European Community		Manufacturer

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