

Anti-Human CD21 [EP64]

Catalog No.	Description	
6 ml of Ready-to-Use Antibody for use witAN825-5MBioGenex Super SensitiveSystems OR equivalent detection system		
AN825-10M10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGene Super Sensitive TM Detection Systems and i6000 TM Automated Staining Systems		
NU825-UC 1 ml of Concentrated Antibody for use wi BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
NU825-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
AY825-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 160 tests	
AY825-50DReady-to-Use Antibody in Barcode labele vial for use on the Xmatrx [®] Elite/Ultra Staining System, 50 tests		

Clone	Species	Ig Class
EP64	Rabbit	IgG

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of CD21 in formalin-fixed, paraffinembedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

CD21 is a single-pass type 2 transmembrane protein that serves as the complement receptor for C3d and the Epstein-Barr virus. Anti-CD21 is valuable in differentiating follicular lymphoma with marginal zone differentiation from marginal zone lymphoma with follicular involvement. It also plays a role in separating among nodular lymphocyte predominant Hodgkin lymphoma, lymphocyte-rich classic Hodgkin lymphoma, and Tcell/histiocyte-rich B-cell lymphoma in combination with other B-cell and T-cell markers. The antigen is absent on Tlymphocytes, monocytes, and granulocytes.

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 (<u>IHC</u>) 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</u> <u>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

Rabbit Monoclonal Antibody CD21 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 as available with Biogenex FB-825N* & FG-825N*	
Recommended Dilution for Concentrated Antibody	1:20-50 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 TM Polymer-HRP IHC Detection System/DAB; see p. 2 for more information	

*FB: positive control barrier slides, FG: positive control nonbarrier slides. Xmatrx requires barrier 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.

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CE	Emergo Europe, Prinsessegracht 20, 2514AP The Hague, The Netherlands
EC RE	P

Detection	Two-Step	One-Step	Link and
System	HRP Kit	HRP Kit	Label Kit
Manual	QD440-XAKE (1000 Test) QD430-XAKE (1000 Test)	QD630-XAKE (1000 Test)	QP300-XAKE (1000 Test)
	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 <u>support@biogenex.com</u> or your local distributor to report unusual staining.

Expected Results

This antibody stains membrane 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

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- 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.
- 8. U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
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2°C	Temperature Limitation	IVD	In Vitro Diagnostic Medical Device
	Use By Date	LOT	Batch Code
NON STERILE	Non-Sterile	ii	Consult Instructions for Use
ECREP	Representative in the European Community		Manufacturer

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