

Anti-HUMAN CD63 [EP211]

Catalog No.	Description		
AN720-5ME	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AN720-10ME	10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive TM Detection Systems and i6000 TM Automated Staining Systems		
NU720-UCE	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
NU720-5UCE	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AY720-YCDE	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 160 tests		
AY720-50DE	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 50 tests		

Clone	Species	Ig Class
EP211	Rabbit	IgG

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of Human CD63 in formalin-fixed, paraffinembedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

CD63 is a 53 kDa lysosomal membrane glycoprotein that has been identified as a platelet activation molecule that belongs to the tetraspanin family, which is characterized by the presence of four hydrophobic domains. The tetraspanin CD63 (also known as LAMP-3, It is also strongly expressed in early melanoma, breast carcinoma, merker cell carcinoma, astrocytoma and lung adenocarcinoma. Recent reports also indicate that CD63 is a good prognostic biomarker for human astrocytomas and earlier stages of lung carcinoma. Additionally, CD63 has been useful in differentiating renal oncocytomas (RO) from eosinophilic variants of chromophobe renal cell carcinoma (RCCs). CD63 deficiency is associated with Hermansky-Pudlak syndrome..

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 to CD63 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	PROSTATE/MELANOMAas available with Biogenex FB- 720NE* & FG-720NE*		
Recommended Dilution for Concentrated Antibody	1:30-50 in HK941		
Recommended Pretreatment (Manual/i6000)**	EZ-AR1 (HK521-XAK) (Twice)		
Recommended Pretreatment (Xmatrx)	EZ-AR1 Elegance (HX031- YCD) Twice		
Antibody Incubation (Manual/i6000)	30-60 mins at RT		
Antibody Incubation (Xmatrx)	30-60 mins at RT		
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.

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***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
Manual	QD440-XAKE (1000 Test) QD430-XAKE (1000 Test)	QD630-XAKE (1000 Test)	QP300-XAKE (1000 Test)
Mandai	QD420-YIKE (500 Test) QD400-60KE (60 Test)	QD620-XAKE (500 Test)	QP900-9LE (500 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 <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.

Ouality 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/membrane 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 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. Azorsa DO, et al.: Blood 1991, 78:280-284
- 2. Kishimoto T, et al. 1997. Leukocyte Typing V1. Oxford University Press New York.
- 3. Hildreth JE, et al. 1991. Blood 77:121.
- 4. Woegerbauer M, et al.: Mod Pathol 2010, 23:751-762
- 5. Huang CI, et al.: Am J Pathol 1998, 153:973-983
- 6. Rorive S, et al.: Mod Pathol 2010, 23:1418-1428
- 7. Kwon MS, et al.: Lung Cancer 2007, 57:46-53

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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