

Anti-MESOTHELIN [5B2]

Catalog No.	Description		
AM433-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AM433-10M	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		
MU433-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
MU433-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AX433-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 160 tests		
AX433-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 50 tests		

Clone	Species	Ig Class
5B2	Mouse	IgG1

Intended Use

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

Summary and Explanation

Mesothelin, a 40kD glycosyl-phosphatidylinositol—linked cell surface glycoprotein, is present on the surface of the mesothelial cells and may be involved in cell adhesion. It is also seen on mesotheliomas, epithelial ovarian cancers, and some squamous cell carcinomas. Clone 5B2 reactivity has been seen in epitheloid mesotheliomas and adenocarcinomas of lung, ovary, peritoneum, endometrium, pancreas, stomach and colon to a varying degree. Mesothelin is abundant in normal mesothelial cells from which malignant mesotheliomas and ovarian cystadenocarcinomas are derived. This antibody can be used in conjunction with antibody to calretinin for evaluation of mesotheliomas.

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.

ECIREPI Emergo Europe, Prinsessegracht 20, 2514AP The Hague, The Netherlands

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 MESOTHELIN 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	OVARYADENOMA as available from BioGenex FB- 433M*&FG-433M*	
Recommended Dilution for Concentrated Antibody	1:10-25 in HK941-YAK	
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 Elegance (HK547- XAK)	
Recommended Pretreatment (Xmatrx)	EZ-AR2 Elegance (HX032- YCD)	
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 [™] 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.

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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)
	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 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.

Emergo Europe, Prinsessegracht 20, 2514AP The Hague, The Netherlands

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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 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.

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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