

Anti-Melanoma Marker (MART1+Tyrosinase+gp100) [A103+T311+HMB45]

Catalog No.	Description	
AMA69-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
AMA69-10M 10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive TM Detection Systems and i6000 M Automated Staining Systems		
MUA69-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
MUA69-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
AXA69-YCD Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests		
AXA69-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 50 tests	

Clone	Species	Ig Class
A103+T311+HMB45	Mouse	IgG1+IgG2a+IgG1

Intended Use

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

Summary and Explanation

Melanoma marker is a cocktail antibody that has three melanoma-specific proteins, which include MART1, Tyrosinase and gp100. This cocktail antibody labels melanomas and tumors melanocytic differentiation. Melanoma-associated antigen recognized by T cells-1 (MART-1) (also known as Melan-A) is a melanocyte differentiation antigen recognized by autologous cytotoxic T lymphocytes. It is a transmembrane protein which is hydrophobic in nature. Tyrosinase is a coppercontaining metalloglycoprotein that catalyzes several steps in the melanin pigment biosynthetic pathway; the hydroxylation of tyrosine to L-3,4-dihydroxy-phenylalanine (dopa), and the subsequent oxidation of dopa to dopaquinone. This Antibody is a useful marker for melanocytes and melanomas.gp100, also designated ME20-M, ME20-S and PMEL 17, is classified as a melanocyte differentiation antigen and is expressed at low levels

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in normal cell lines and tissues, but is upregulated in melanocytes.

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 Melanoma marker 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	Melanoma tissue as available with Biogenex FB-A69M* & FG-A69M*
Recommended Dilution for Concentrated Antibody	1:50-100 in HK941
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 (HK522-XAK)
Recommended	EZ-AR2 Elegance
Pretreatment (Xmatrx)	(HX032-YCD)
Antibody Incubation (Manual/i6000)	30-60 Min at RT
Antibody Incubation (Xmatrx)	30-60 Min at RT

Category	Antibodies	Revision No.	С
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X	BioGenex
	Accelerating the pace of precision medicine

	Use BioGenex Two-Step OR
Detection System for	One-Step Super Sensitive™
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 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.

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 www.biogenex.com .			

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. Jungbluth AA et al. A103: An anti-melan-a monoclonal antibody for the detection of malignant melanoma in paraffin-embedded tissues. Am J Surg Pathol 1998 May;22 (5):595-602.
- 2. Blessing K, Sanders DS, Grant JJ. Comparison of immunohistochemical staining of the novel antibody Melan-A with S100protein and HMB-45 in malignant melanoma and melanoma variants. Histopathology 1998 Feb; 32 (2):139-146.
- 3. Jungbluth AA et al. A103: An anti-melan-a monoclonal antibody for the detection of malignant melanoma in paraffin-embedded tissues. Am J Surg Pathol 1998 May;22 (5):595-602.
- 4. Beaty MW et al. Effusion cytology of malignant melanoma: A morphologic and immunocytochemical analysis including application of the MART-1 antibody. Cancer 1997 Feb 25;81(1):57-63.
- 5. Bonetti F, et al. False-positive immunostaining of normal epithelia and carcinomas with ascites fluid preparations of antimelanoma monoclonal antibody HMB45. J. clin Pathol 1991:95:454

2°€ 8°€	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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