

## Anti-Ki67

Catalog No.	Description
AMA01-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AMA01-10M	10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive™ Detection Systems and i6000™ Automated Staining Systems
MUA01-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
MUA01-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AXA01-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite Staining System, 160 tests
AXA01-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite Staining System, 50 tests
AXA01-4M	Ready-to-Use Antibody in Barcode labeled vial for use on the NanoVIP® Staining System, 50 tests
VMA01-5M	6 ml of Ready-to-Use Antibody for use with BioGenex / equivalent Detection systems on third party automation.
AXA01-10M	Ready-to-Use Antibody in Barcode labeled vial for use on the NanoVip™ 300 Staining System, 100 tests

Clone	Species	Ig Class
MKI67/2462	Mouse	IgG2b, kappa

### Intended Use

**For In Vitro Diagnostic Use.** This antibody is designed for the specific localization of human Ki67 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

### Summary and Explanation

Ki-67 is a nuclear protein that is only present in proliferating cells. This makes Ki-67 a useful marker for distinguishing proliferating cells. Ki-67 is present in the cells during all times of the cell cycle except for G0 phase. Due to this characteristic, Ki-67 can be used to reliably calculate the growth fractions of cell populations. This can make Ki-67 useful in providing efficacy of cancer.

### 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

Mouse Monoclonal Antibody to human Ki67 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-A01M* & FG-A01M*
Recommended Dilution for Concentrated Antibody	<b>1:20-50 in HK941</b>
Recommended Pretreatment (Manual/i6000)**	EZ-AR1 (HK521-XAK)
Recommended Pretreatment (Xmatrx & NanoVIP)	EZ-AR1 Elegance (HX031-YCD & HX045-08XN)
Antibody Incubation (Manual/i6000)	30-60 Min at RT
Antibody Incubation (Xmatrx & NanoVIP)	45-60 Min at 25°C
Detection System for Manual, Xmatrx, NanoVIP & i6000 systems***	Use BioGenex Two-Step <b>OR</b> 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 & NanoVIP requires micro chamber slides.

\*\*Pretreatment times will vary based on individual microwave power.

\*\*\*For automation systems (Xmatrx-Elite, NanoVIP & i6000 Diagnostics), refer to the factory protocols provided with the instrument.

Category	Antibodies	Revision No.	G
Document No.	932-A01M-EN	Release Date	05-May-2025

Detection System	Two-Step HRP Kit	One-Step HRP Kit	Link and Label Kit
Manual	QD440-XAKEN (1000 Test)	QD630-XAKEN (1000 Test)	QP300-XAKE (1000 Test)
	QD430-XAKEN (1000 Test)		
	QD420-YIKEN (500 Test)	QD620-XAKEN (500 Test)	QP900-9LE (500 Test)
	QD400-60KEN (60 Test)		
Xmatrix - Automation	QD550-YCDEN (200 Test)	QD610-YADEN (200 Test)	N/A
NanoVIP-Automation	QD551-YCDEN (100 Test)	QD611-YADEN (100 Test)	N/A
i6000 - Automation	QD410-YAXEN (200 Test)	QD610-YAXEN (200 Test)	N/A
For more information, visit <a href="http://www.biogenex.com">www.biogenex.com</a> .			

### 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](mailto:support@biogenex.com) or your local distributor to report unusual staining.

### Expected Results

This antibody stains nucleus 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 medically-established 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

- Scholzen T, Gerdes J. The Ki-67 protein: from the known and the unknown. *J Cell Physiol.* 2000 Mar; 182(3):311-22.
- Gerdes J, Lemke H, Baisch H, Wacker HH, Schwab U, Stein H. Cell cycle analysis of a cell proliferation-associated human nuclear antigen defined by the monoclonal antibody Ki-67. *J Immunol.* 1984 Oct; 133(4):1710-5.
- Brown DC, Gatter KC. Monoclonal antibody Ki-67: its use in histopathology. *Histopathology.* 1990 Dec; 17(6):489-503.
- Urruticoechea A1, Smith IE, Dowsett M. Proliferation marker Ki-67 in early breast cancer. *J ClinOncol.* 2005 Oct 1; 23(28):7212-20.

	Temperature Limitation	<b>IVD</b>	In Vitro Diagnostic Medical Device
	Use By Date	<b>LOT</b>	Batch Code
	Non-Sterile		Consult Instructions for Use
	Representative in the European Community		Manufacturer

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Document No.	932-A01M-EN	Release Date	05-May-2025