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

Anti-P16 [16p04]

Catalog No.	Description
AMA07-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AMA07-10M	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
MUA07-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
MUA07-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AXA07-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests
AXA07-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests

Clone	Species	Ig Class
16p04	Mouse	IgG1

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of P16 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

p16, also known as cyclin-dependent kinase inhibitor 2A, CDKN2A or multiple tumor suppressor 1, plays an essential role in controlling the cell cycle. It functions by inhibiting the cyclin dependent kinase that phosphorylates another tumor suppressor protein called retinoblastoma protein which regulates the cell cycle. Due to its role in the cell cycle, mutations or deletions in the p16 gene has been implicated in many cancers. p16 has the potential to be a powerful tool in diagnosing and prognosing many gynecologic cancers. In some human papilloma virus (HPV) infections, the phosphorylated retinoblastoma protein is inactivated which in turn leads to the over expression of p16. This makes p16 a useful marker in evaluating HPV-associated squamous and glandular neoplasia of the lower gynecologic tract. There are other HPV independent mechanisms which lead to over expression of p16 such as ovarian serous carcinoma.

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 P16is 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	Cervical cancer tissue as available with Biogenex FB-A07M* & FG-A07M*
Recommended Dilution for Concentrated Antibody	**1:20-50in 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)	45-60 Min at 25°C
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.
***For automation systems (Xmatrx-Elite, Xmatrx-Ultra & i6000 Diagnostics), refer to the factory protocols provided with the instrument.

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Detection System	Two-Step HRP Kit	One-Step HRP Kit	Link and Label Kit
Manual	QD440-XAKE (1000 Test)	QD630-XAKE (1000 Test)	QP300-XAKE (1000 Test)
	QD430-XAKE (1000 Test)		
	QD420-YIKE (500 Test)	QD620-XAKE (500 Test)	QP900-9LE (500 Test)
	QD400-60KE (60 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 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

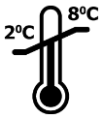
This antibody stains nucleus/cytoplasm in positive cells in formalin-fixed, paraffin embedded tissue sections. An example image of a tissue section stained with this antibody can be found on the product page on the BioGenex website. Interpretation of the staining result is solely the responsibility of 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

1. Qi-min Zhan, Lu-hua Wang, Yong-mei Song, Yun-weiOu, Jing Jiang, Jing Fan, Jing-bo Wang, Jie Shen. 18 - Esophageal Carcinoma. Editor(s): Xin-Yuan Liu, Sidney Pestka, Yu-Fang Shi. Recent Advances in Cancer Research and Therapy. Elsevier. 2012. Pages 493-534.
2. Joseph T. Rabban, Robert A. Soslow, Charles Z. Zaloudek. Chapter 18 - Immunohistology of the Female Genital Tract. Editor(s): David J. Dabbs. Diagnostic Immunohistochemistry (Third Edition). W.B. Saunders. 2010. Pages 690-762.
3. Liggett WH Jr, Sidransky D. Role of the p16 tumor suppressor gene in cancer. Journal of Clinical Oncology. 1998 Mar; 16(3):1197-206.
4. Rocco JW, Sidransky D. p16 (MTS-1/CDKN2/INK4a) in cancer progression. Exp Cell Res. 2001 Mar 10; 264(1):42-55.

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