BioGenex
Accelerating the pace of precision medicine

Anti-Papillomavirus Type 16 (HPV-16) [Cam Vir-1]

Catalog No.	Description
AM362-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AM362-10M	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
MU362-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
MU362-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AX362-YCD	Ready-to-Use Antibody in Barcode labelled vial for use on the Xmatrx® Elite Staining System, 200 tests
AX362-50D	Ready-to-Use Antibody in Barcode labelled vial for use on the Xmatrx® Elite Staining System, 50 tests

Clone	Species	Ig Class
Cam Vir-1	Mouse	IgG2a

Intended Use

For Research Use. This antibody is designed for the specific localization of HPV16 antigen in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

Infection with certain types of HPV, the so-called "oncogenic HPVs" including 16, 18, 31, 33, and 35, has been associated as a major risk factor in the subsequent development of cervical cancer. The high-risk HPV 16 group is almost equally associated with cervical intraepithelial neoplasia (CIN) and cervical cancer. HPV 6 and 11 are found mainly in benign cervical lesions while HPV 16 and 18 have been associated with premalignant and malignant cervical lesions. The presence of HPV has been reported in malignant lesions of the skin, oral cavity, tongue, and lung. This antibody marks Papillomarvirus type 16 in the nucleus of infected cells or tissues stained by immunohistochemical techniques.

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 HPV16 protein antigen 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	HPV Infected Tissue as available with Biogenex FB-362M* & FG-362M*
Recommended Dilution for Concentrated Antibody	**1:50-100 in HK156**
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)	30-60 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 & 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-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)		
Xmatrx - Automation	QD490-YCDEN (200 Test)	QD610-YADEN (200 Test)	N/A
i6000 - Automation	QD410-YAXEN (200 Test)	QD610-YAXEN (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 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. Walboomers J, et al. In: Human Papillomaviruses and Cervical Cancer. Stern P and Stanley M, ed. Oxford Univ Press, 42-63, 1994.
2. Stanley M. In: Human Papillomaviruses and Cervical Cancer. Stern P and Stanley M, ed. Oxford Univ Press, 116, 1994.
3. Center for Disease Control. Decontamination of Laboratory Sink Drains to Remove Azide Salts. Center for Disease Control Manual Guide--Safety Management, No. CDC-22, Atlanta, Georgia. April 30, 1976.
4. Kiernan JA. Histological and Histochemical Methods: Theory and Practice. New York: Pergamon Press 1981.
5. Nadji M, Morales AR. Immunoperoxidase, part 1: the techniques and its pitfall. Lab Med 1983; 14:767-770.
6. Omata M, Liew CT, Ashcavai M, Peters Rl. 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.
7. U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
8. National Institute for Occupational Safety and Health, (NIOSH), Rockville, MD. Explosive azide hazard, Publication No. 78-127, 1976.

	Temperature Limitation		Manufacturer
	Use By Date		Batch Code
	Non-Sterile		Consult Instructions for Use

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