

Anti-Cytokeratin 14 ILI.0021

[EE002]				
Catalog No.	Description			
AM146-5M 6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system				
AM146-10M 10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGe Super Sensitive TM Detection Systems ar i6000 TM Automated Staining Systems				
MU146-UC 1 ml of Concentrated Antibody for use v BioGenex Super Sensitive™ Detection Systems OR equivalent detection system				
MU146-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system			
AX146-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite Staining System, 160 tests			
AX146-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite Staining System, 50 tests			
AX146-4M Ready-to-Use Antibody in Barcode labe vial for use on the NanoVIP® Staining System, 50 tests				

Clone	Species	Ig Class
LL002	Mouse	IgG1, Kappa

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of Cytokeratin 14 in formalin-fixed, paraffinembedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

Cytokeratin 14 (molecular weight 50 kD), an acidic (Type I) cytokeratin protein, is one of the cytokeratin pair (50/58 kD) that distinguish stratified epithelial cell types from simple epithelial types. Cytokeratin 14 is homogeneously expressed in all cells of the keratinizing squamous epithelium and is confined to the basal and parabasal cells in the nonkeratinizing squamous epithelium of the normal adult urinary tract. According to some studies cytokeratin 14 is a minor component of the human mammary gland. Monoclonal antibody to cytokeratin 14 may be helpful in distinguishing cells types of human mammary gland, thus it may also be used to study histogenesis of breast 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 Cytokeratin 14 is affinity purified and diluted in PBS, pH 7.2, containing 1% BSA and 0.09% sodium

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	Squamous cell Carcinoma tissue as available with Biogenex FB- 146M* & FG-146M*	
Recommended Dilution for Concentrated Antibody	1:30-60 in HK156	
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 (HK522-XAK)	
Recommended Pretreatment (Xmatrx & NanoVIP)	EZ-AR2 Elegance (HX032-YCD & HX046-08XN)	
Antibody Incubation (Manual/i6000)	30-60 Min at RT	
Antibody Incubation(Xmatrx & NanoVIP)	30-60 Min at 25°C	
	Use BioGenex Two-Step OR	
Detection System for	One-Step Super Sensitive TM	
Manual, Xmatrx, NanoVIP	Polymer-HRP IHC Detection	
& i6000systems***	System/DAB; see p. 2 for more information	

^{*}FB: positive control micro chamber slides, FG: positive control microscopic slides. Xmatrx & NanoVIP require micro chamber

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.

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EC	REF	•						

Detection Two-Step		One-Step	Link and	
System	HRP Kit	HRP Kit	Label Kit	
Manual	QD440-XAKEN (1000 Test) QD430-XAKEN (1000 Test)	QD630-XAKEN (1000 Test)	QP300-XAKE (1000 Test)	
wanuar	QD420-YIKEN (500 Test) QD400-60KEN (60 Test)	QD620-XAKEN (500 Test)	QP900-9LE (500 Test)	
Xmatrx - Automation	QD550-YCDEN (200 Test)	QD610-YADEN (200 Test)	N/A	
NanoVIP- Automation	QD551-YCDEN (100 Test)	QD611-YADEN (100 Test)	N/A	
i6000 - QD410-YAXEN Automation (200 Test)		QD610-YAXEN (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.

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. Corson, J.M., Pathol Annu 21(Part2):47-81, 1986.
- 2. Moll, R., et al. Cell 31:11-24, 1982.

2°C 8°C	Temperature Limitation		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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