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

Anti-CYTOKERATIN 16 [KRT16/2043R]

Catalog No.	Description
AN933-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AN933-10M	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
NU933-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
NU933-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AY933-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx®Elite/Ultra Staining System, 160tests
AY933-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx®Elite/Ultra Staining System, 50 tests

Clone	Species	Ig Class
KRT16/2043R	Rabbit	IgG

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of CYTOKERATIN 16 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

The KRT16 protein is a member of the keratin (type I) family. The keratins are intermediate filament proteins responsible for the structural integrity of epithelial cells and are subdivided into cytokeratins and hairkeratins. Epidermis-specific type I keratin that plays a key role in skin,acts as a regulator of innate immunity in response to skin barrier breachThis keratin has been coexpressed with keratin 14 in a number of epithelial tissues, including esophagus, tongue, and hair follicles. Cytokeratin 16 is expressed in benign stratified squamous epithelium and squamous cell carcinoma of the head and neck, as well as luminal cells of mammary gland and sweat ducts. It is absent in non-invasive breast carcinomas and normal breast tissue.

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

Rabbit Monoclonal Antibody CYTOKERATIN 16 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	Skin, tonsil and esophageal cancer tissue as available with Biogenex FB-933N* & FG-933N*
Recommended Dilution for Concentrated Antibody	**1:50-100 in HK941**
Recommended Pretreatment (Manual/i6000)**	EZ-AR1 (HK521-XAK)/EZ-AR1 Elegance (HK546-XAK)
Recommended Pretreatment (Xmatrx)	EZ-AR1 Elegance (HX031-YCD)
Antibody Incubation (Manual/i6000)	30 Min at RT
Antibody Incubation (Xmatrx)	30 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.

48810 Kato Road, Suite 100E & 200E, Fremont, CA 94538, Tel: +1 (800) 421-4149, Fax: +1 (510) 824-1490, support@biogenex.com, www.biogenex.com

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 1-800-421-4149orsupport@biogenex.com or your local distributor to report unusual staining.

Expected Results

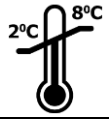
This antibody stains cell membrane in positive cells in formalin-fixed, paraffin embedded tissue sections. An example image of a tissue section stained with this antibody can be found on the product page on the BioGenex website. Interpretation of the staining result is solely the responsibility of the 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 pseudoperoxidase 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. Markey et al. Keratin expression in basal cell carcinomas. 1992. Br J Dermatol. 126(2):154-60.
2. Rosenberg M1, et al. A group of type I keratin genes on human chromosome 17: characterization and expression. Mol Cell Biol. 1988 Feb;8(2):722-36.
3. Lessard JC1, et al. Keratin 16 regulates innate immunity in response to epidermal barrier breach. Proc Natl Acad Sci U S A. 2013 Nov 26;110(48):19537-42.
4. Adegboyega PA1, Qiu S. Immunohistochemical profiling of cytokeratin expression by endometrial stroma sarcoma. Hum Pathol. 2008 Oct;39(10):1459-64

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