

Anti-Human Cytokeratin 5 & Cytokeratin 14 [EP24/EP61]

Catalog No.	Description		
AN730-5ME	6 ml of Ready-to-Use Antibody for use with		
	BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	10 ml of Ready-to-Use Antibody in a		
AN730-10ME	barcode labeled vial for use with BioGenex		
ALL VIOLET TOTAL	Super Sensitive TM Detection Systems and		
	i6000 TM Automated Staining Systems		
NU730-UCE	1 ml of Concentrated Antibody for use with		
	BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	0.5 ml of Concentrated Antibody for use		
NU730-5UCE	with BioGenex Super Sensitive TM Detection		
	Systems OR equivalent detection system		
	Ready-to-Use Antibody in Barcode labeled		
AY730-YCDE	vial for use on the Xmatrx® Elite/Ultra		
	Staining System, 160 tests		
	Ready-to-Use Antibody in Barcode labeled		
AY730-50DE	vial for use on the Xmatrx® Elite/Ultra		
	Staining System, 50 tests		

Clone	Species	Ig Class
CK5: EP24;	Rabbit	IaC
CK14: EP61	Kabbit	IgG

Intended Use

For In Vitro Diagnostic Use. This antibody is designed for the specific localization of Cytokeratin 5 and Cytokeratin 14 in formalin-fixed, paraffin-embedded tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

Keratins are cytoplasmic intermediate filament proteins expressed by epithelial cells. The two keratins specifically expressed in these cells are the type II keratin CK5 and its corresponding partner, type I keratin CK14, both of which are essential for the formation of 8-nm filaments. CK5 labels myoepithelial cells of breast and prostate basal cells. It has been reported that cytokeratin 5/14-positive breast cancers are true basal phenotype confined to BRCA1 tumors. It is considered a prognostic marker in breast carcinomas.

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 to Cytokeratin 5 & Cytokeratin 14 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	PROSTATEas available with Biogenex FB-730NE* & FG-730NE*		
Recommended Dilution for Concentrated Antibody	1: 30-50 in HK941		
Recommended Pretreatment	EZ-AR1 Elegance (HK546-XAK)/		
(Manual/i6000)**	EZ-AR2 Elegance (HK547-XAK)		
Recommended Pretreatment (Xmatrx)	EZ-AR1 Elegance (HX031-YCD)		
Antibody Incubation (Manual/i6000)	30-60 mins at RT		
Antibody Incubation (Xmatrx)	30-60 mins at 25°C		
	Use BioGenex Two-Step OR		
Detection System for	One-Step Super Sensitive TM		
Manual, Xmatrx & i6000	Polymer-HRP IHC Detection		
systems***	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.

Category	Antibodies	Revision No.	I
Document No.	932-730N-EN	Release Date	11-Jan-2022

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

Detection System	Two-Step HRP Kit	One-Step HRP Kit	Link and Label Kit
Manual	QD440-XAKE (1000 Test) QD430-XAKE (1000 Test)	QD630-XAKE (1000 Test)	QP300-XAKE (1000 Test)
Manuai	QD420-YIKE (500 Test) QD400-60KE (60 Test)	QD620-XAKE (500 Test)	QP900-9LE (500 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 <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. Lersch R, et al.: Mol Cell Biol 1989, 9:3685-3697
- 2. Tokar EJ, et al. Stem/progenitor and intermediate cell types and the origin of human prostate cancer. Differentiation. 2005 Dec;73(9-10):463-73.
- 3. Cid Mouteira P, et al.: Actas Urol Esp 2006, 30:367-371
- 4. Collins AT, et al. Identification and isolation of human prostate epithelial stem cells based on alpha(2) beta(1)integrin expression. J Cell Sci. 2001 Nov;114(Pt21):3865-72.
- 5. Betz RC, et al.: Am J Hum Genet 2006, 78:510-519
- 6. Zhou M, et al.: Am J Surg Pathol 2003, 27:365-371

2°C 8°C	Temperature Limitation	IVD	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

© 2020, BioGenex Laboratories. All rights reserved.

Category	Antibodies	Revision No.	I
Document No.	932-730N-EN	Release Date	11-Jan-2022