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

Anti-Human Cytokeratin 14 [EP61]

Catalog No.	Description
AN831-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AN831-10M	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
NU831-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
NU831-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system
AY831-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests
AY831-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests

Clone	Species	Ig Class
EP61	Rabbit	IgG

Intended Use

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

Summary and Explanation

Keratins are cytoplasmic intermediate filament proteins expressed by epithelial cells. The mitotically active basal layers of most stratified squamous epithelia express 10% to 30% of their total protein as keratin. Cytokeratin 14 (CK14) is a 50-kDa keratin expressed in abundance in stratified epithelial cells, epidermal cells, basal cells, mesothelial cells, and myoepithelial cells in various tissues including breast and prostate. CK14 is helpful in the identification of breast cancer with basalphenotype.

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 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 BiogenexFB-831N*& FG-831N*
Recommended Dilution for Concentrated Antibody	**1:20-50 in 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)	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 barrier slides, FG: positive control non-barrier slides. Xmatrx requires barrier slides.
**Pretreatment times will vary based on individual microwave power.

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***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)	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 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. 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.
2. 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.
3. Marchuk D, et al.: “Complete sequence of a gene encoding a human type I keratin:sequences homologous to enhancer elements in the regulatory region of the gene”.Proc Natl Acad Sci U S A 1985, 82:1609-1613
4. Betz RC, et al.: “Loss-of-function mutations in the keratin 5 gene lead to Dowling- Degos disease”.Am J Hum Genet 2006, 78:510-519

2°C 8°C	Temperature Limitation	IVD	In Vitro Diagnostic Medical Device
	Use By Date	LOT	Batch Code
NON STERILE	Non-Sterile		Consult Instructions for Use
EC REP	Representative in the European Community		Manufacturer