

# **Anti-Human Ep-CAM** [EP155]

Catalog No.	Description		
AN820-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive <sup>TM</sup> Detection Systems OR equivalent detection system		
AN820-10M	10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive <sup>TM</sup> Detection Systems and i6000 <sup>TM</sup> Automated Staining Systems		
NU820-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive <sup>TM</sup> Detection Systems OR equivalent detection system		
NU820-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AY820-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx <sup>®</sup> Elite/Ultra Staining System, 160 tests		
AY820-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx <sup>®</sup> Elite/Ultra Staining System, 50 tests		

Clone	Species	Ig Class
EP155	Rabbit	IgG

#### **Intended Use**

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

# **Summary and Explanation**

Ep-CAM is a highly conserved type I transmembrane glycoprotein and is expressed on most normal and malignant epithelial cells. Ep-CAM is also known as epithelial cell adhesion molecule, MOC31, or Ber-EP4. It is detected in the membrane/cytoplasm of the majority of epithelial tissues (all simple, pseudo-stratified and transitional epithelial), with the exception of the adult squamous epithelium and some epithelium-derived cells, such as hepatocytes, epidermal keratinocytes, gastric parietal cells, myoepithelial cells, and thymic cortical epithelium. In tumors, Ep-CAM is over expressed by the majority of human epithelial carcinomas, except hepatocellular carcinomas (HCC).

# **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 Ep-CAM 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	Adenoma as available with Biogenex FB-820N* & FG-820N*	
Recommended Dilution for Concentrated Antibody	1:30-50 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 <b>OR</b> One-Step Super Sensitive <sup>™</sup> Polymer-HRP IHC Detection System/DAB; see p. 2 for more information	

<sup>\*</sup>FB: positive control barrier slides, FG: positive control nonbarrier slides. Xmatrx requires barrier slides.

<sup>\*\*</sup>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.

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Detection	Two-Step	One-Step	Link and	
System	HRP Kit	HRP Kit	Label Kit	
	QD440-XAKE			
	(1000 Test)	QD630-XAKE	QP300-XAKE	
	QD430-XAKE	(1000 Test)	(1000 Test)	
Manual	(1000 Test)			
Mailuai	QD420-YIKE			
	(500 Test)	QD620-XAKE	QP900-9LE	
	QD400-60KE	(500 Test)	(500 Test)	
	(60 Test)			
Xmatrx -	QD550-YCDE	QD610-YADE	N/A	
Automation	(200 Test)	(200 Test)	IN/A	
i6000 -	QD410-YAXE	QD610-YAXE	N/A	
Automation	(200 Test)	(200 Test)	1N/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/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 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. Osta WA, et al.: Cancer Res 2004, 64:5818-5824.
- 2. Tomita Y, et al.: Jpn J Cancer Res 2000, 91:231-238.
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- 4. Winter MJ, et al.: Am J Pathol 2003, 163:2139-2148.
- 5. 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.
- 6. Nadji M, Morales AR. Immunoperoxidase, part 1: the techniques and its pitfall. Lab Med 1983; 14:767-770.
- 7. 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.
- 8. U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
- 9. National Institute for Occupational Safety and Health, (NIOSH), Rockville, MD. Explosive azide hazard, Publication No. 78-127, 1976.

2°C 8°C	Temperature Limitation	IVD	In Vitro Diagnostic Medical Device
$\boxtimes$	Use By Date	LOT	Batch Code
NON STERILE	Non-Sterile	<u>i</u>	Consult Instructions for Use
EC REP	Representative in the European Community	***	Manufacturer

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