

Anti-Carcinoembryonic Antigen (CEA) [CEA88]

Catalog No.	Description		
AM365-5M	6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AM365-10M	10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive TM Detection Systems and i6000 TM Automated Staining Systems		
MU365-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
MU365-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AX365-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 160 tests		
AX365-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests		

Clone	Species	Ig Class
CEA88	Mouse	IgG1

Intended Use

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

Summary and Explanation

CEA consists of a heterogeneous family of related oncofetal 200 kD glycoproteins that is secreted into the glycocalyx surface of gastrointestinal cells. Usually CEA is demonstrated as a linear labeling of the apical poles of cells lining the glandular lumen and, occasionally, as weak staining near the apex of colonic epithelial cells. CEA, however, should not be used as a marker of differentiation because many colon and lung tumors actually show increased staining with differentiation. Pancreatic carcinomas, testicular tumor, gall bladder neoplasms and granular cell myoblastomas stain positive, whereas malignant tumors of brain, prostate, skin, lymphoreticular tissues, hepatocellular carcinomas, oesophageal squamous cell carcinomas, and mesothelioma fail to stain for CEA.

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 <u>primary antibody</u> 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 to Carcinoembryonic antigen (CEA) 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	Colon Cancer as available with Biogenex FB-365M* & FG-365M*	
Recommended Dilution for Concentrated Antibody	1:50-100 in HK156	
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 TM 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. ***For automation systems (Xmatrx-Elite, Xmatrx-Ultra & i6000 Diagnostics), refer to the factory protocols provided with the instrument.

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CE	Emergo	Europe, Prinsessegracht	20, 2514AP	The Hague, The	e Netherlands
EC RE	P				

Detection	Two-Step	One-Step	Link and
System	HRP Kit	HRP Kit	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 -	QD550-YCDE	QD610-YADE	N/A
Automation	(200 Test)	(200 Test)	
i6000 -	QD410-YAXE	QD610-YAXE	N/A
Automation	(200 Test)	(200 Test)	

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

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- 10. U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
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2°C 8°C	Temperature Li mitation	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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