

Anti-Human c-erbB-2 [SP101]

Catalog No.	Description	
AN752-5M 6 ml of Ready-to-Use Antibody for use wit BioGenex Super Sensitive TM Detection Systems OR equivalent detection system		
AN752-10M	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	
NU752-UC	1 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
NU752-5UC	0.5 ml of Concentrated Antibody for use with BioGenex Super Sensitive TM Detection Systems OR equivalent detection system	
AY752-YCD	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 160 tests	
AY752-50D	Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx [®] Elite/Ultra Staining System, 50 tests	

Clone	Species	Ig Class
SP101	Rabbit	IgG

Intended Use

For Research Use only. This antibody is designed for the specific localization of c-erbB-2 in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

Summary and Explanation

c-erbB-2 is a receptor tyrosine kinase of the c-erbB family. It is closely related in structure to the epidermal growth factor receptor. Amplification or over-expression of the erbB-2 gene occurs in approximately 15-30% of breast cancers. It is strongly associated with increased disease recurrence and a poor prognosis. Over-expression is also known to occur in ovarian, stomach, and aggressive forms of uterine cancer, such as uterine serous endometrial carcinoma. c-erbB-2 oncoprotein is detectable in a proportion of breast and other adenocarcinomas, as well as transitional cell 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 <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

Rabbit Monoclonal Antibody c-erbB-2 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	Breast carcinoma tissue as available with Biogenex FB- 752N* & FG-752N*
Recommended Dilution for Concentrated Antibody	1:10-25 in HK941
Recommended Pretreatment (Manual/i6000)**	EZ-AR2 (HK522-XAK)
Recommended	EZ-AR2 Elegance
Pretreatment (Xmatrx)	(HX032-YCD)
Antibody Incubation (Manual/i6000)	30-60 Min at RT
Antibody Incubation (Xmatrx)	30-60 Min 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.	Н
Document No.	932-752N	Release Date	12-Nov-2021



***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

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 membrane 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. Mitri Z, Constantine T, et al: "The HER2 Receptor in Breast Cancer: Pathophysiology, Clinical Use, and New Advances in Therapy". Chemother Res Pract2012: 743193.
- 2. Olayioye MA. "Update on HER-2 as a target for cancer therapy: Intracellular signaling pathways of ErbB2/HER-2 and family members". Breast Cancer Res3 (6): 385–389.
- 3. Roy V, et al: "Beyond trastuzumab: small molecule tyrosine kinase inhibitors in HER-2-positive breast cancer". Oncologist14 (11): 1061–9
- 4. Suthipintawong C, et al: "Immunostaining of estrogen receptor, progesterone receptor, MIB1 antigen, and c-erbB-2 oncoprotein in cytologic specimens: a simplified method with formalin fixation". Diagn Cytopathol. 1997 Aug;17(2):127-33.
- 5. Nakapoulou LL, et al:" Prognostic significance of the coexpression of p53 and c-erbB-2 protein in breast cancer". J Pathol. 1996 May;179

2°C 8°C	Temperature Limitation	LOT	Batch Code
\boxtimes	Use By Date	[]i	Consult Instructions for Use
NON STERILE	Non-Sterile		Manufacturer

© 2020, BioGenex Laboratories. All rights reserved.

Category	Antibodies	Revision No.	H
Document No.	932-752N	Release Date	12-Nov-2021