

c-erbB-2/HER2

Prediluted Rabbit Monoclonal Antibody
901-342-060223

BIOCARE
M E D I C A L

Available Product Formats

Format	Catalog Number	Description	Dilution	Diluent
ONCORE Pro	OPAI 342 T60	60 tests	Ready-to-use	N/A

Intended Use:

For In Vitro Diagnostic Use

c-erbB-2/HER2 [EP3] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of c-erbB-2 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:

This antibody recognizes a protein of 185 kDa, identified as the second member (cerbB-2/HER-2) of the c-erbB family. This rabbit monoclonal antibody is directed against the cytoplasmic domain of the human c-erbB-2 protein. The c-erbB-2 is closely related in structure to the epidermal growth factor receptor. The c-erbB-2 protein is overexpressed in a variety of carcinomas, especially those of breast and ovary. Immunohistochemical staining correlates with gene amplification. Studies have shown that c-erbB-2 positive breast cancer usually correlates with negative staining for estrogen and progesterone receptors; thus a poorer predictive outcome is correlated with c-erbB-2 staining.

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Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, a one-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Rabbit monoclonal

Species Reactivity: Human

Clone: EP3 (previously known as EP1045Y)

Isotype: IgG

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: c-erbB-2 protein

Cellular Localization: Cell membrane

Positive Tissue Control: Breast cancer

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):

OPAI342 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

Protocol Name: c-erbB-2 Rb

Protocol Template (Description): Rb HRP template 1

Dewaxing (DS Option): DS Buffer

Antigen Retrieval (AR Option): AR2, low pH, 95°C

Block Option: Buffer

Reagent Name, Time, Temp.: c-erbB-2 Rb, 30 min, 25°C

Limitations:

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

Quality Control:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Precautions:

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (3)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (4)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at <http://biocare.net>.

Troubleshooting:

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. 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.
2. Nakapoulou LL, et al. Prognostic significance of the co-expression of p53 and cerbB-2 protein in breast cancer. J Pathol. 1996 May; 179(1):31-8
3. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
4. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.