

Estrogen Receptor (ER) [SP1]

Concentrated and Prediluted Rabbit Monoclonal Antibody
901-301-052523

BIOCARE
M E D I C A L

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Concentrate	ACI 301 A, B, C	0.1, 0.5, 1.0 mL	Renoir Red	1:50 – 1:100
Predilute	API 301 AA	6.0 mL	Ready-to-use	N/A
ONCORE	OAI 301 T60	60 tests	Ready-to-use	N/A
ONCORE Pro	OPAI 301 T60	60 tests	Ready-to-use	N/A

Intended Use:

For In Vitro Diagnostic Use

Estrogen Receptor (ER) [SP1] is a rabbit antibody that is intended for laboratory use in the qualitative identification of estrogen receptor (ER) 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:

Human estrogen receptor (ER) is a 66 kDa protein that acts as an estrogen-dependent, nuclear hormone receptor. Studies have shown ER is present in the nuclei of epithelial cells in normal breast and endometrial tissues, as well as a subset of breast carcinomas. The SP1 clone is a high affinity rabbit monoclonal antibody directed against an epitope of the C-terminus of the ER protein (1). SP1 has been shown to stain formalin-fixed paraffin-embedded tissues. The robustness of SP1 has been demonstrated by successful immunohistochemistry using lower temperatures for antigen retrieval (e.g. 80 or 95°C), and in some instances, staining can be obtained even without antigen retrieval (2-3).

FOR DISTRIBUTION OUTSIDE THE UNITED STATES ONLY.

Principle of Procedure:

This antibody product may be used as the primary antibody in immunohistochemistry testing of formalin-fixed, paraffin-embedded tissue sections. In general, immunohistochemical (IHC) staining techniques allow for the visualization of antigens via the sequential application of a specific antibody to the antigen (primary antibody), a secondary antibody to the primary antibody (optional link antibody/probe), an enzyme complex and a chromogenic substrate with interposed washing steps. The enzymatic activation of the chromogen results in a visible reaction product at the antigen site. The specimen may then be counterstained, and cover slipped. Results are interpreted using a light microscope and aid in the differential diagnosis of pathophysiological processes, which may or may not be associated with a particular antigen.

Source: Rabbit Monoclonal

Species Reactivity: Human; others not tested

Clone: SP1

Isotype: IgG

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: Estrogen receptor protein

Cellular Localization: Nuclear

Positive Tissue Control: Breast carcinoma

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 (intelliPATH FLX® and manual use):

Peroxide Block: Block for 5 minutes with Peroxidized 1.

Pretreatment: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions

Protein Block (Optional): Incubate for 5-10 minutes at RT (room temperature) with Background Punisher.

Protocol Recommendations (intelliPATH FLX® and manual use) Cont'd:

Primary Antibody: Incubate for 30 minutes at RT.

Probe: N/A

Polymer: Incubate for 30 minutes at RT with a secondary-conjugated polymer.

Chromogen: Incubate for 5 minutes at RT with Biocare's DAB -OR- Incubate for 5-7 minutes at RT with Warp Red.

Counterstain: Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:

This antibody, for intelliPATH FLX and manual use, has been standardized with MACH detection system. Use TBS for washing steps.

Protocol Recommendations (ONCORE™ Automated Slide Staining System):

OAI301 is intended for use with the ONCORE. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

Protocol Name: ER Rb

Protocol Template (Description): Rb HRP Template 1

Dewaxing (DS Option): DS2

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

Reagent Name, Time, Temp.: ER Rb, 30 min., 25°C

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

OPAI301 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: ER Rb

Protocol Template (Description): Rb HRP template 1

Dewaxing (DS Option): DS2-50

Antigen Retrieval (AR Option): AR2, low pH; 101°C

Block Option: Buffer

Reagent Name, Time, Temp.: ER 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



60 Berry Drive
Pacheco, CA 94553
USA



TP V2 (10/26/2021)

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080



Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Estrogen Receptor (ER) [SP1]

Concentrated and Prediluted Rabbit Monoclonal Antibody
901-301-052523

BIOCARE
M E D I C A L

Precautions Cont'd:

build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (5)

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. (6)

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. Cheang MC, et al. Immunohistochemical detection using the new rabbit monoclonal antibody SP1 of estrogen receptor in breast cancer is superior to mouse monoclonal antibody 1D5 in predicting survival. *J Clin Oncol.* 2006 Dec;24(36):5637-44.

2. Rossi S, et al. Rabbit monoclonal antibodies: a comparative study between a novel category of immunoreagents and the corresponding mouse monoclonal antibodies. *Am J Clin Pathol.* 2005 Aug;124(2):295-302.

3. Cano G, et al. Estimation of hormone receptor status in fine-needle aspirates and paraffin-embedded sections from breast cancer using the novel rabbit monoclonal antibodies SP1 and SP2. *Diagn Cytopathol.* 2003 Oct;29(4):207-11.

4. Rocha R, et al. Rabbit monoclonal antibodies show higher sensitivity than mouse monoclonals for estrogen and progesterone receptor evaluation in breast cancer by immunohistochemistry. *Pathol Res Pract.* 2008; 204(9):655-62.

5. 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."

6. 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.



60 Berry Drive
Pacheco, CA 94553
USA



TP V2 (10/26/2021)

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080



Westervoortsedijk 60
6827 AT Arnhem
The Netherlands