

Progesterone Receptor (PR) [16]
Concentrated and Prediluted Monoclonal Antibody
Control Number: 901-424-081617

Catalog Number:	ACI 424 A, C	API 424 AA	OAI 424 T60
Description:	0.1, 1.0 ml, concentrated	6.0 ml, prediluted	60 tests, prediluted
Dilution:	1:100-1:200	Ready-to-use	Ready-to-use
Diluent:	Van Gogh Yellow	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use
Progesterone Receptor (PR) [16] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of progesterone receptor (PR) 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.

FOR DISTRIBUTION OUTSIDE THE UNITED STATES ONLY.

Summary and Explanation:

Progesterone Receptor (PGR) content of breast cancer tissue is an important parameter in the prediction of prognosis and response to endocrine therapy (5). Studies have shown PGR clone 16 is directed against the human progesterone receptor molecule (1-5). A prokaryotic recombinant protein, corresponding to the N-terminal region of the A form of human progesterone receptor, was used as the immunogen. Antibody characterization studies demonstrated that PGR clone 16 reacts with both A and B forms of human progesterone receptor by Western blotting procedure (4).

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 secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: 16

Isotype: IgG1

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.

Epitope/Antigen: Progesterone receptor

Cellular Localization: Nuclear

Positive Tissue Control: Progesterone receptor positive 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. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted Reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations (manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidized I.

Pretreatment Solution (recommended): Diva

Pretreatment Protocol:

Heat Retrieval Method:

Preheat the retrieval solution to 95°C for 30 minutes in Biocare's Decloaking Chamber. Then, place slides into the preheated solution and retrieve under pressure at 95°C for 40 minutes; alternatively, steam tissue sections for 45-60 minutes or use a water bath at 95°C for 40 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 30-45 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10 minutes at RT with a tertiary polymer.

Protocol Recommendations (manual use) Cont'd:

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

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

Protocol Recommendations (ONCORE Automated Slide Staining System):

OAI424 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Protocol Name: PR

Protocol Template (Description): Ms HRP Template 1

Dewaxing (DS Option): DS Buffer

Antigen Retrieval (AR Option): AR2, low pH; 103°C

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

Technical Note:

This antibody has been optimized for use with Biocare's MACH 4 Universal HRP-Polymer Detection and ONCORE HRP Detection. Other Biocare polymer detection kits may be used; however, users must validate incubation times and protocols for their specific application. Use TBS buffer for washing steps.

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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

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) (6)
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. (7)

Progesterone Receptor (PR) [16]

Concentrated and Prediluted Monoclonal Antibody
Control Number: 901-424-081617

Precautions Cont'd:

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/>.

References:

1. Qiu J, *et al.* Effect of delayed formalin fixation on estrogen and progesterone receptors in breast cancer: a study of three different clones. *Am J Clin Pathol.* 2010 Nov; 134(5):813-9.
2. Arihito K, *et al.* Comparison of evaluations for hormone receptors in breast carcinomas using two manual and three automated immunohistochemical assays. *Am J Clin Pathol.* 2007 Mar; 127(3):356-65.
3. Press M, *et al.* Comparison of different antibodies for detection of progesterone receptor in breast cancer steroids. *Steroids.* 2002 Aug; 67(9):799-813.
4. Mote P, *et al.* Detection of progesterone receptor forms A and B by immunohistochemical analysis. *J Clin Pathol.* 2001 Aug; 54(8):624-30.
5. Bevitt D, *et al.* New monoclonal antibodies to oestrogen and progesterone receptors effective for paraffin section immunohistochemistry. *J Pathol.* 1997 Oct; 183(3):228-32.
6. 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."
7. 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.

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.