

Progesterone Receptor (PR) [PgR636]

Prediluted Monoclonal Antibody Control Number: 901-343-081617

Catalog Number:API 343 AA, HIPI 343 G10Description:6.0, 25 ml, prediluted10 ml, predilutedDilution:Ready-to-useReady-to-useDiluent:N/AN/A

Intended Use:

For In Vitro Diagnostic Use

Progesterone Receptor (PR) [PgR636] 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.

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Summary and Explanation:

The progesterone receptor is a member of the steroid-receptor family. Steroid hormones bind to intracellular receptors, and these receptors can bind to DNA and regulate gene expression directly. Research has shown PR to reflect intact estrogen regulatory machinery. This PR antibody provides excellent staining in formalin-fixed paraffin-embedded tissues and has been shown to have superior sensitivity to most progesterone receptor antibodies (1).

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: PgR636 Isotype: IgG1/kappa

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.

<u>Protocol Recommendations (intelliPATH and manual use):</u>

Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.

Pretreatment Solution (recommended): Reveal or 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.

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Primary Antibody: Incubate for 45-60 minutes at RT. **Probe:** Incubate for 10 minutes at RT with a secondary probe. **Polymer:** Incubate for 20 minutes at RT with a tertiary polymer.

Protocol Recommendations (intelliPATH and 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.

Technical Note:

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

intelliPATHTM Automated Slide Stainer:

IPI343 is intended for use on the intelliPATHTM Automated Slide Stainer. Refer to the intelliPATH Automated Slide Stainer manual for specific instructions on its use. When using the intelliPATH, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.

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 (NaN $_3$) 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) (2)
- 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. (3)
- 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/.



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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. Press M, et al. Comparison of different antibodies for detection of progesterone receptor in breast cancer steroids. Steroids. 2002 Aug; 67(9):799-813.
- 2. 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."
- 3. 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.

