

# **CE** IVD Rabbit anti-Progesterone Receptor Cat. No.: BRB038 (16 ml Ready-to-use)

### Instructions for use

#### Intended Use

This antibody is designed for the specific localization of progesterone receptor antigen in formalin-fixed, paraffinembedded tissue sections.

Anti-Progesterone receptor antibody is intended for in vitro diagnostic use.

Specifications Specificity:	Human Progesterone receptor
İmmunogen:	Recombinant protein corresponding to the amino acid residues 400-550 of the
	human progesterone receptor
Clone:	SP42
Isotype:	Rabbit IgG
Species reactivity:	Human +, others not tested

#### Summary and explanation

The determination of steroid hormone receptors is of great importance for therapy of patients with hormone receptor expressing tumours. Progesterone and estrogen receptor positive breast carcinoma patients have demonstrated a better response to endocrine therapy than receptor negative patients.

Expression of progesterone receptors in tumour cells of human breast carcinoma points to an intact estrogen receptor and to sensitivity of this tumour to endocrine therapy. The progesterone receptor content is therefore a marker for response to hormone therapy.

Several studies have shown that progesterone receptor is a better prognostic marker than estrogen receptor.

#### **Reagent provided**

Rabbit monoclonal antibody in TBS with carrier protein and preservative for stabilisation in the following format: **Ready-to-use:** 16 ml (Cat. No. BRB038)

Dilution of primary antibody

None

#### Storage and handling

The antibody should be stored at 2-8°C without further dilution.

If necessary, dilutions of the antibody should be done with a suitable antibody dilution buffer (e.g. ZUC025 from Zytomed Systems). The diluted antibody should be stored at 2-8°C after use. Stability of this working solution depends on various parameters and has to be confirmed by appropriate controls.

The antibody provided is stable until the expiry date indicated on the label, if stored at 2-8°C. Do not use product after the expiry date. Positive and negative controls should be run simultaneously with all specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Zytomed Systems' technical support or your local distributor.

#### Precautions

Use through qualified personnel only. Wear protective clothing to avoid contact of reagents and specimens with eye, skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with large amounts of water.

Microbial contamination of the reagent must be avoided, since otherwise non-specific staining may occur. ProClin300 and sodium azide (NaN<sub>3</sub>) are used for stabilisation. Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides. Discard the antibody solution in a large volume of running water to avoid formation of deposits. A material safety data sheet (MSDS) for the pure substances is available upon request.

#### **Staining procedure**

Refer to the following table for conditions specifically recommended for this antibody. Also refer to detection system data sheets for guidance on specific staining protocols or other requirements.

<u>Parameters</u>	Zytomed Systems recommendations
*Pre-treatment:	Heat Induced Epitope Retrieval (for example in Citrate buffer pH 6.0)
*Control tissue	Breast carcinoma
*Working dilution	None
*Incubation time	60 minutes

#### **Quality control**

The recommended positive control tissue for this antibody is a breast carcinoma. We recommend carrying out a positive and a negative control with every staining run. Please refer to the instructions of the detection system for guidance on general quality control procedures.

#### Troubleshooting

If you observe unusual staining or other deviations from the expected results please read these instructions carefully, refer to the instructions of the detection system for relevant information or contact your local distributor.

#### **Expected results**

The antibody stains positive in nuclei of progesterone receptor positive cells in formalin-fixed, paraffin-embedded tissue. The interpretation of the results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

#### Limitations of the Procedure

Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining, for example variations in fixation and embedding or the inherent nature of the tissue can cause inconsistent results (Nadji and Morales, 1983). Endogenous peroxidase, pseudoperoxidase activity in erythrocytes or biotin may cause non-specific staining depending on the detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive results with HRP (horse radish peroxidase) detection systems (Omata *et al*, 1980). Inadequate counterstaining and mounting can influence the interpretation of the results.

Zytomed Systems warrants that the product will meet all requirements described from its shipping date until the expiry date is reached, if the product is stored and utilised as recommended. No additional guarantees can be given. Under no circumstances shall Zytomed System be liable for any damages arising out of the use of the reagent provided.

#### **Performance characteristics**

Zytomed Systems has conducted studies to evaluate the performance of the antibody utilising a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no cross-reactivity.

#### **Bibliography**

Nadji M. et al. Am J Clin Pathol 123(1):21-27, 2005 Leake R et al. J Clin Pathol 53:634-635, 2000 Kaufmann O. et al. Mod Pathol 11(4): 357-363, 1998 Ravdin PM et al. J Clin Oncol 10(8): 1284-1291, 1992 Mote PA et al. J Clin Pathol 54:624-630, 2001 Ravn V. et al. Mod Pathol 11(8): 709-715, 1998 Omata M et al. Am J Clin Pathol 73: 626-32, 1980 Nadji M and Morales AR Ann N.Y. Acad Sci 420:134-9, 1983



www.zytomed-systems.de Zytomed Systems GmbH • Anhaltinerstraße 16 • 14163 Berlin, Germany • Tel: (+49) 30-804 984 990

## Explanations of the symbols on the product label

Symbols are used in accordance with ISO 15223-1. Further symbols on the product label might be:



GSH07: Warning / Attention

For Research Use Only