

# CE IVD Rabbit anti-progesterone Receptor Cat. No.: AIB-30286 (1 ml Concentrate); AIB-30287 (0.5 ml Concentrate); AIB-30288 (6 ml Ready-to-use)

# Instructions for use

#### Intended use

This antibody is designed for the specific localisation of Progesterone Receptor in formalin-fixed, paraffin-embedded tissue sections. Anti-Progesterone Receptor antibody is intended for in vitro diagnostic use.

| Specifications<br>Specificity: | Progesterone Receptor   |
|--------------------------------|---|
| Immunogen:                     | Recombinant protein according to the amino acid residues 415-526 of human |
| -                              | progesterone receptor   |
| Clone:                         | SP42  |
| Isotype:                       | Rabbit IgG  |
| Species reactivity:            | Human +, others not tested  |

# Summary and Description

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

#### **Reagent provided**

Rabbit monoclonal antibody from tissue culture supernatant in buffer with carrier protein and preservative for stabilisation in the following formats:

| Concentrate:  | 1 ml   | (Cat. No. AIB-30286) |
|---------------|--------|----------------------|
| Concentrate:  | 0.5 ml | (Cat. No. AIB-30287) |
| Ready-to-use: | 6 ml   | (Cat. No. AIB-30288) |

#### **Dilution of primary antibody**

Dilution of Nordic Biosite' concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The elaboration of staining protocol should be done by an experienced specialist. For Nordic Biosite' recommendations see chapter 'Staining procedure'.

| Explanations of the symbols on the product label: |   |     |  |  |
|---|---|-----|--|--|
| REF   | Catalog Number<br>Bestellnummer<br>Reference du catalogue   | LOT | Batch Code<br>Chargenbezeichnung<br>Code du lot  | Manufacturer<br>Nordic BioSite AB  |
| $\sum$  | Use By<br>Verwendbar bis<br>Utiliser jusque   | IVD | In Vitro Diagnostic Medical Device<br>In vitro Diagnostikum<br>Dispositif médical de diagnostic in vitro | Propellervägen 4A<br>S-183 62 Täby<br>Sweden<br>Tel: +46 (0)8 5444 33 40   |
| i   | Consult Instructions for use<br>Gebrauchsanweisung beachten<br>Consulter les instructions d'utilisation |     | Temperature Limitation<br>Lagerungstemperatur<br>Limites de température                                  | Fax: +46 (0)8 756 94 90<br>info@nordicbiosite.com<br>www.nordicbiosite.com |

Explanations of the symbols on the product label:

# Storage and handling

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

Dilutions of the concentrated antibody should be done in a suitable antibody dilution buffer (e.g. BCB-20005/BCB-20006 from Nordic Bioiste). The diluted antibody should be stored at 2-8°C after use. The stability of this working solution depends on various parameters and has to be confirmed by appropriate controls.

The antibody provided is suitable for use 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 Nordic Biosite' 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. Sodium azide (NaN3), used for stabilisation, is not considered hazardous material in the concentration used. Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides. Sodium azide should be discarded in a large volume of running water to avoid formation of deposits. A material safety data sheet (MSDS) 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.

| Parameters        | Nordic BioSites recommendations  |
|-------------------|--|
| *Pre-treatment    | Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0 (BCB- |
| 20015/-20016)     |  |
| *Control tissue   | Breast carcinoma   |
| *Working dilution | 1:200-1:400 (for concentrates)   |
| *Incubation time  | 30-60 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**

This antibody stains positive in the nuclei of progesterone receptor positive cells in formalin-fixed, paraffin-embedded tissue sections. Interpretation of the staining 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, alkaline phosphatase 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. Nordic Biosite 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 Nordic Biosite be liable for any damages arising out of the use of the reagent provided.

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#### **Performance characteristics**

Nordic Biosite has conducted studies to evaluate the performance of the antibody for use with a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no crossreactivity.

#### Bibliography

Mote PA et al. J Clin Pathol (2001) 54:624-630 Leake R et al. J Clin Pathol (2000) 53:634-635 Nadji M and Morales AR (1983) Ann N.Y. Acad Sci 420:134-9 Omata M et al. (1980) Am J Clin Pathol 73(5): 626-32

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