

Cell Control Array Receptor

REF / Cat. No.: MB-CC REZ

Instructions for use

Intended use

The Cell Control Array Receptor Block is designed for the qualitative control of immunochemical stainings and *in situ* hybridisation. It is intended to ensure a “Yes” or “NO” answer for the particular staining and to ensure a constant sensitivity. The array contains cell lines expressing different levels of Estrogen Receptor (ER), Progesterone Receptor (PR), and HER2 (ERBB2).

It is intended for research use only.

Summary and Explanation

The Cell Control Array Receptor is a homogenous paraffin block including cores of 4 human cell lines which show different expression levels of Estrogen Receptor (ER), Progesterone Receptor (PR), and HER2 (ERBB2). In addition a core of heart muscle is included which helps to find the right orientation of the sections during mounting and microscopy.

Immunochemical staining of the cell lines using anti-ER, -PR and -HER2 antibodies are showing different expression patterns. ER and PR antibodies stain in the nuclei; HER2 antibodies in the cell membrane. It is also possible to use the block for staining with cell proliferation marker antibodies which will also result in nuclear staining. In addition, the control block can be used in *in situ* hybridisation for the detection of ERBB2 (HER2).

The cells were fixed in neutrally buffered formalin, pH 7, for 12-18 h and embedded in paraffin. The paraffin has a pink dye to facilitate cutting of sections. A core of heart muscle serves for easy orientation.

The small size of the control block sections allows for simultaneous mounting of patient material sections and control block sections on the same slide. Thus, you will have an on-slide control array staining proving a regular stain even after years of storage.

Reagents provided

REF / Cat. No. MB-CC REZ

1 Block **Cell Control Array Receptor**

Storage and handling

The block should be stored in a dry place at +4° to +25°C within the provided box. Avoid freezing below -15° as the block may crack. Please insert the block in the microtome with caution because otherwise it also may crack.

The sections (3-5 µm) should be mounted on adhesive slides and dried at 37°C over-night or for 2 h at 65°C. Sections for *in situ*-hybridisation should be 5-7 µm. Each cell line core is approximately 2 mm high. Provided that the block is regularly cut at least 100 sections can be made from one block; usually one block is good for 130-170 sections. The number of sections depends on the frequency of cutting and the thickness of the sections. Sections can be stored up to 6 weeks, although we suggest using freshly prepared sections.

The cell line cores are covered with a thin paraffin layer due to production technique. As soon as the paraffin layer is cut away at all cell line cores the sections are ready for use.

A core of heart muscle tissue is included in the block to ensure easy orientation.

Precautions

Use by qualified personnel only.

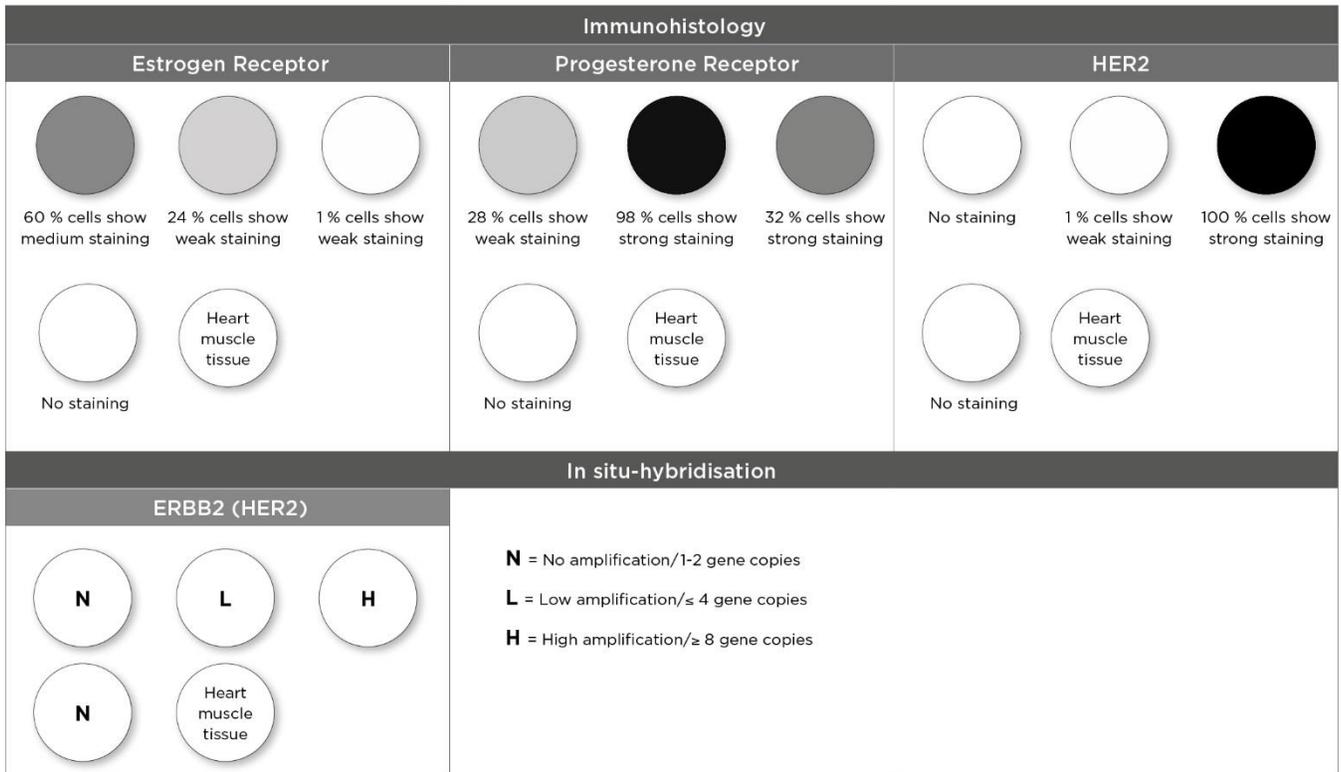
Health hazards should not be expected. However, the block should be handled as potential infectious formalin-fixed paraffin-embedded human tissue. Wear proper protection clothing. A Material safety data sheet (MSDS) is available upon request.

Expected results

The special selection of cell lines helps to control the method employed. It provides the answer “Yes” or “NO” for the particular staining. Because cell lines with different ER/PR expression levels are included in the block it will also be possible to differentiate high and low staining intensities.

The image shows typical staining patterns when the specified reagents were used. Other antibodies and/or other detection systems lead to different staining patterns. High staining sensitivity provided, the cells show staining according to the values given in the image. Even if always the same reagents are used the percentage of positively stained cells varies about +/- 10%.

► Overview of typical staining patterns



Used reagents

Primary antibodies: Estrogen Receptor (clone SP1, RBK018); Progesterone Receptor (clone SP42, RBK020); HER2 (clone SP3, RBK026)
 Detection system: ZytoChem Plus (HRP) Polymer Kit (POLHRP-100) in combination with DAB Substrate Kit (DAB530)

Troubleshooting

If you observe unusual staining or other deviations from the expected results which could possibly be caused by the product, please read these instructions carefully, contact Zytomed Systems' technical support or your local distributor.

Limitations of the procedure

A large number of factors can considerably influence the immunohistochemical staining of this control block. Thickness of tissue sections and the temperature during the drying process can influence the staining intensity. The reagents have to be selected carefully as well. Especially the sensitivity of the chosen detection system and the chromogenic substrate will influence the staining intensity.

When new antibodies are to be established it is always recommended to use a control block section in combination with positive tumour material of various expression levels.

Zytomed Systems guarantees that the product will meet all requirements described from its shipping date until its expiry date, as long as the product is correctly stored and utilized. 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 product. The product has been found to be suitable for the intended use.

References

- Sharpe R et al. Clin Cancer Res 17:5275-86 (2011)
 Subik K et al. Breast Cancer: Basic Clin Res 4:35-41 (2010)
 Dabbs D Immunohistochemistry, Elsevier 2006 ISBN 0-443-06652-3
- Horwitz et al. Cancer Res 38:2434-37 (1978)
 Leitlinie Mammaphathologie S3, 3. Auflage 2012, BVDP und DGP

May 21, 2019

Rev: A0519

Doc: DBE_MB-CC REZ

Explanation of the symbols on the product label:

REF	Bestellnummer Catalog Number Reference du catalogue		Verwendbar bis Use By Utiliser jusque		Gebrauchsanweisung beachten Consult Instructions for use Consulter les instructions d'utilisation
LOT	Chargenbezeichnung Batch Code Code du lot		Lagerungstemperatur Temperature Limitation Limites de température	RUO	Nur für Forschungszwecke For Research Use Only Pour la recherche uniquement
IVD	In vitro Diagnostikum In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro		Achtung/Gefahr Warning/Danger Attention/Danger		Achtung Warning Attention
	Achtung/Gefahr Warning/Danger Attention/Danger		Gefahr Danger Danger		Achtung/Gefahr Warning/Danger Attention/Danger
					<p>Hersteller / Manufacturer / Fabricant Zytomed Systems GmbH Anhalterstraße 16 14163 Berlin, Germany Tel: (+49) 30-804 984 990 www.zytomed-systems.de</p>