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 Estrogene Receptor (ER), Progesterone Receptor (PR), and HER2 (*c-erb*B2).
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 show different expression levels of Estrogen Receptor (ER), Progesterone Receptor (PR), and HER2 (*c-erb*B2). In addition a core of heart muscle is included which helps to find the right orientation of the sections during mounting and microscopy. Immunochemical stainings of the cell lines using ER, PR and HER2 antibodies are show different expression patterns. ER and PR are stained in the nuclei; HER2 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 for *in situ* hybridisation.
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 (OSCAR) proving a regular stain even after years of storage.

Reagents provided

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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.
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.
Each cell line core is approximately 2 mm high. A core of heart muscle tissue is included in the block to ensure easy orientation.

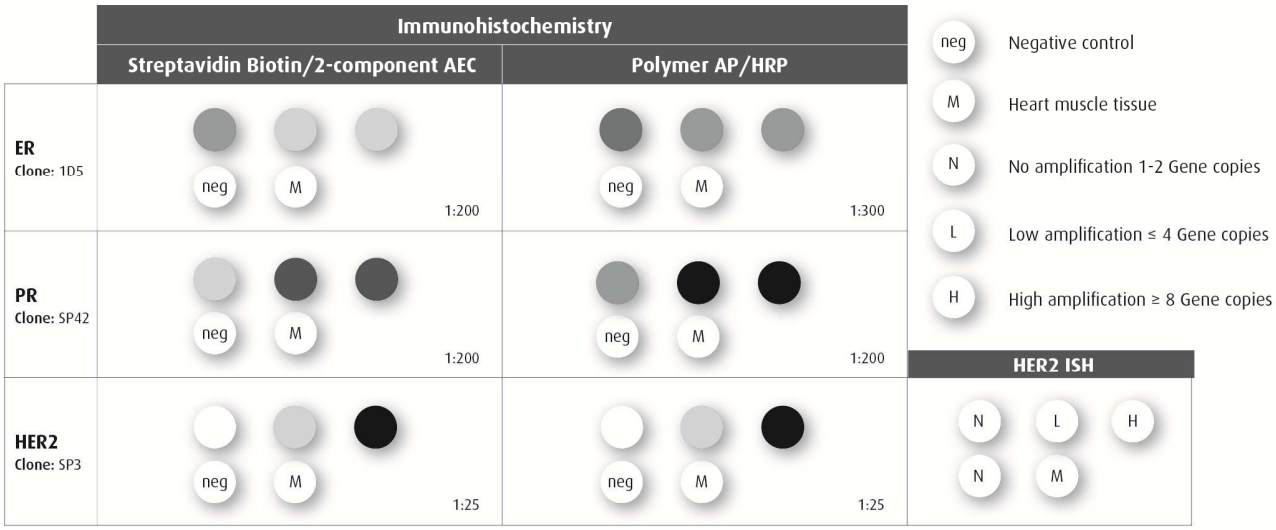
Precautions

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. If more than 10% of the cell nuclei show a medium staining intensity when stained with ER and PR antibodies this can be counted as a positive reaction with sufficient sensitivity. In case of a high staining sensitivity a medium to strong nuclear staining is to be expected in more than 60% of the cells. This analysis is illustrated in the picture.

▶ **Overview of typical staining patterns**



Used reagents
Primary antibody:
Estrogen Receptor, 1D5 (MSK001); Progesterone Receptor, SP42 (RBK020); HER2, SP3 (RBK026)
Detection system:
Streptavidin-Biotin system: ZytoChem Plus HRP (HRP125); AEC (ZUC042-050)
Polymer HRP: ZytoChem Plus Polymer (POLHRP-100); DAB (DAB057)
Polymer AP: ZytoChem Plus Polymer (POLAP-100); Permanent AP-Red (ZUC001-125)

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 stainings of this control block. The reagents employed have to be selected carefully. Especially the sensitivity of the chosen detection system and the chromogenic substrate will influence the staining intensity. Using a high-sensitive detection system ER stains might have about the same intensity on all cell line cores. An apparently paradox staining result, for example negative staining of the control block in combination with positive staining of the tumour, can occur when the tumour has a very strong positivity for ER and the overall immunohistochemical staining sensitivity is low. In such cases, the low-positive ER control cell line will show a negative result. Thus, it is always recommended to use a control block section in combination with positive tumour material of various expression levels to establish IHC reagents and dilution factors of antibodies. Furthermore thickness of tissue sections, temperature during drying process and the hematoxylin used, can influence staining intensity. 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)
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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	Hersteller / Manufacturer / Fabricant Zytomed Systems GmbH Anhaltinerstraße 16 14163 Berlin, Germany Tel: (+49) 30-804 984 990 www.zytomed-systems.de
	Achtung/Gefahr Warning/Danger Attention/Danger	Gefahr Danger Danger	Achtung/Gefahr Warning/Danger Attention/Danger		