

Cell Control Array Bacteria plus Fungi

REF / Cat. No.: MB-CC BAC

Instructions for use

Intended use

The block Cell Control Array Bacteria plus Fungi is designed for the qualitative control of special stains of different pathogens. It is also suitable for specific immunochemical staining and some molecular biology methods. It is intended to ensure a “Yes” or “NO” answer for the particular staining.

The block is intended for research use only.

Summary and Explanation

The Cell Control Array Bacteria plus Fungi is a homogenous paraffin block including 3 cores of different pathogens and one core of fungi. In addition 2 cores of heart muscle are included. Staining of the cores allows for a general control of the staining method for the respective pathogen or fungi.

Mycobacterium kansasii serves as positive control for the detection of acid fast mycobacteria (e.g. Ziehl Neelsen or Auramine stain), gram positive bacteria (*Staphylococcus aureus*), and gram negative bacteria (*Escherichia coli*) for a Gram- or Giemsa-stain. *Aspergillus fumigatus* is the positive control for fungi-specific stains (e.g. PAS, Grocott).

Immunostains with antibodies against *Mycobacterium tuberculosis* stain weakly positive in the Mycobacteria cell line core. DNA of *Mycobacterium kansasii* isolated from the array can be used as a positive control e.g. in a PCR for the detection of mycobacteria.

The pathogens 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. The cores of heart muscle serve 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 Bacteria plus Fungi

Storage and handling

The block should be stored in a dry place at +4° to +25°C. 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.

Since it cannot be absolutely excluded that single bacteria cells are detached from the respective control core, cutting and mounting of the on-slide control should be done separately from cutting and mounting of the patient tissue specimen.

Microtome blade and water bath should be thoroughly cleaned after cutting controls.

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

Each pathogen core is approximately 2 mm high. Two cores of heart muscle tissue are included in the block to ensure easy orientation.

Precautions

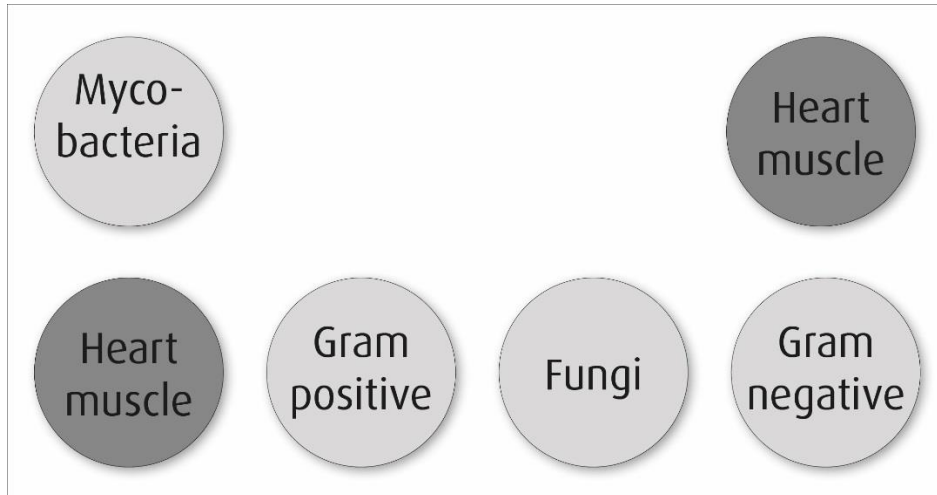
Use by qualified personnel only.

Health hazards should not be expected as fixation inactivates the pathogens contained in the control block. 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 localization and evaluation pattern of the four pathogens is shown in the figure below.



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 staining results e.g. thickness of sections, temperature during drying process, storage time of sections or staining reagents.

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.

Reference

Lee G. Luna "Histopathologic Methods and Color Atlas of Special Stains and Tissue Artifacts", Amer Histolabs Pub Dept; 1st edition 1993

Freida L. Carson "Histotechnology: A Self-Instructional Text", American Society for Clinical Pathology; 3rd edition 2009

M. Mulisch, U. Welsch (Hrsg.) „Romeis – Mikroskopische Technik“, 18. Auflage, Springer Verlag 2010

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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	
	Achtung/Gefahr Warning/Danger Attention/Danger		Gefahr Danger Danger		Achtung/Gefahr Warning/Danger Attention/Danger	
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	Achtung/Gefahr Warning/Danger Attention/Danger		Gefahr Danger Danger		Achtung/Gefahr Warning/Danger Attention/Danger
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