



Cell Control Array ALK (IHC)

REF / Cat. No.: MB-CC ALK

Instructions for use

Intended use

The Cell Control Array ALK (IHC) block is designed for the qualitative control of immunochemical staining. It is intended to ensure a “Yes” or “NO” answer for immunohistochemical staining. Furthermore, the Cell Control Array ALK (IHC) can be used for certain RT-PCR techniques. The array contains an ALK protein expressing cell line and an ALK negative cell line.

It is intended for research use only.

Summary and Explanation

Most mature tissues do not express the ALK gene and therefore no ALK protein is produced. A rearrangement of the ALK gene, like in ALCL (anaplastic large cell lymphoma) or in non-small cell lung cancer (NSCLC), leads to an activation of the gene and to ALK protein expression. The Cell Control Array ALK (IHC) block serves as a positive control for the detection of ALK protein in these and other tissues.

The Cell Control Array ALK (IHC) is a homogenous paraffin block including one ALK positive, one ALK negative cell line and two cores of muscle tissue. The block serves as a general control for the detection of ALK protein. ALK antibodies lead to staining in immunohistochemistry with the ALK positive cell line. The negative cell line shows no staining.

The Cell Control Array ALK can also be used for the detection of mRNA of an EML4-ALK fusion (fusion EML4 Exon 13 with ALK Exon 20 [E13;A20]) using real-time PCR. RNA should be extracted from sections having a total thickness of approximately 80 µm (e.g. 4 x 20 µm).

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 and mounting. Two cores of heart muscle serve as an 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 ALK (IHC)

Storage and handling

The block should be stored in a dry place at room temperature 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 may crack as well.

The sections (3-5 µm) should be mounted on adhesive slides and dried at 37°C overnight or for 2 h at 65°C.

Provided that the block is regularly cut, one block is good for at least 130-170 sections; up to 400 are possible. 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 at least 2 mm high and can differ slightly in length from array to array. Two cores of heart muscle tissue are included in the block to facilitate orientation during mounting and microscopy.

Precautions

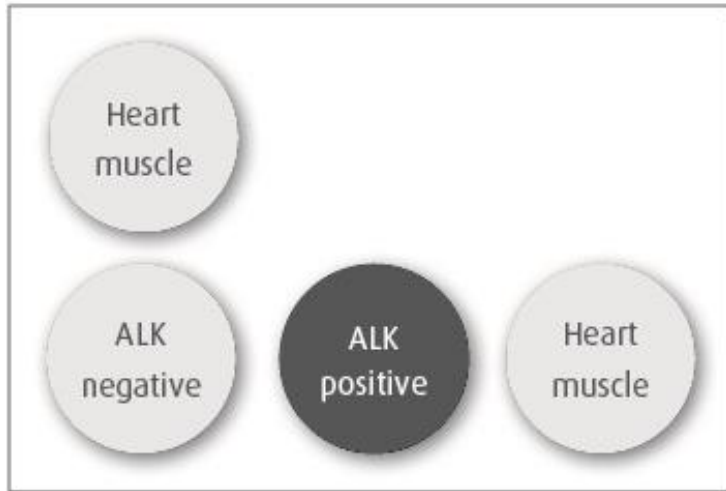
Use by qualified personnel only.

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 orientation of the different cores of the Cell Control ALK (IHC) block is shown in the picture. Not all cells express the ALK protein in the same quantity. Therefore immunohistochemistry can show different staining intensities in different cells. Depending on the sensitivity of the immunohistochemical staining, few cells may show no staining. In general, the block is suited as a positive control for ALK immunohistochemistry on lymphatic tissue and lung tissue.



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 the MB-CC ALK. The reagents employed, like the antibody and the pre-treatment buffer (Citrate or Tris-EDTA buffer) have to be selected carefully. Especially the sensitivity of the chosen detection system, and the chromogenic substrate will influence the staining intensity. 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

Shaw A et al. Nature 13:772-787 (2013) Omata M et al. Am J Clin Pathol 73:626-632, 1980
 Dabbs D Immunohistochemistry, Elsevier 2006 ISBN 0-443-06652-3 Nadji M, Morales AR. Ann N Y Acad Sci 420:134-138, 1983

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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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