

Product Data Sheet



PRODUCT NAME: ALK-Lung Analyte Control

PRODUCT CODE: HCL009 (1 cell microarray (CMA) block)

INTENDED USE: Research Use Only (RUO)

N.B. Once validated in the laboratory, this product is designed to confer confidence in results obtained from the sample on the same slide. If the control has worked appropriately then the assay has worked and any staining, or lack thereof, present within the sample is genuine. This material cannot be used independently as a means of optimising assays in the laboratory.

STORAGE: 2°C to 8°C. Avoid freezing as this may cause the wax to crack

DESCRIPTION: CMA which includes 2 individual cores (Diameter 2mm x Length 3mm) containing cell lines of the following tumour origin:

Cell line A: Negative for EML4-ALK fusion by immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH).

Cell line B: Positive for EML4-ALK fusion by immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH).

Fixative: 10% Neutral Buffered Formalin

Embedding: In paraffin wax

HistoCyte Laboratories Ltd recommend cutting sections at 3-5µm and mounted on positively charged slides and dried at 37°C overnight with 1-2 hrs incubation at 60°C.

The number of slides obtained is variable depending on the skill of the histologist, the temperature of the block when cut and frequency of use. Up to 300 sections in the hands of an experienced histologist can be achieved.

N.B. While HistoCyte Laboratories Ltd has made every effort to assess these analyte controls with a variety of assays available on the market, it is the responsibility of the end user to determine suitability with their reagents and procedures within their laboratory.

EXPRESSION PROFILE:

Cell Line	IHC for EML4-ALK*	FISH for EML4-ALK translocation†
A	Negative	Negative
B	Positive	Positive

*As assessed with Ventana/Roche anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody (Product code 790-4843). †Abbott Molecular, Vysis ALK Break Apart FISH Probe Kit (Product code 06N38-020) and CytoCell Aquarius® Pathology probes, ALK Breakapart (LPS

DIRECTIONS FOR USE:

Material is supplied in a block (see figure 1 below) and designed to be used as a same-slide control. Sections should be cut and arranged as appropriate. HistoCyte Laboratories Ltd recommend samples are arranged in a straight line across the slide as illustrated in the diagram below (figure 2). When placed appropriately on a slide, a test sample should fit easily below the cell cores. The use of Superfrost Plus or HistoBond+ slides is recommended as a minimum. Other slides may be used but need to be validated in conjunction with the automated platform employed in the laboratory.

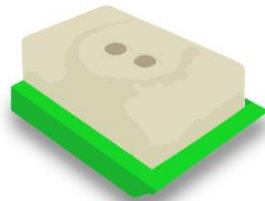


Figure 1. ALK-Lung Analyte Control CMA block.

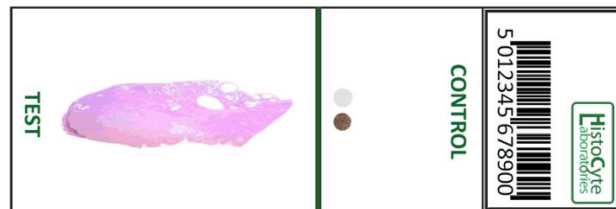


Figure 2. ALK-Lung Analyte Control appropriately placed on a slide.

INTERPRETATION OF RESULTS:

Cell Lines	IHC for EML4-ALK	FISH for EML4-ALK translocation†
A	Negative	Negative
B	Strong cytoplasmic staining	Clear break apart green and red signals indicative of ALK translocation.

For more information, contact info@histocyte.com or visit our website www.histocyte.com.