Product Data Sheet

PRODUCT NAME: ALK-Lung Analyte Control

PRODUCT CODE: HCL007 (2 unstained slides)
HCL008 (5 unstained slides)

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: 2-8°C

DESCRIPTION: Each control slide includes 2 control cell lines of a 2mm diameter:

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
Section Thickness:	3-5µm
Mounting:	Mounted on positively charged slides and dried at 37°C overnight

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.

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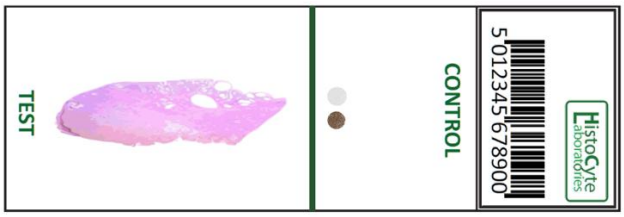
EXPRESSION PROFILE:

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 019).

INTERPRETATION OF RESULTS:



Slides are designed to be used as same-slide. Test sample should be placed below the control, in the area marked 'TEST' (see diagram above).

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.

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