Product Data Sheet

PRODUCT NAME(S): ALK Cell Line Analyte Control Slides
ALK Cell Line Analyte Paraffin Block

PRODUCT CODE:

CS-EML4-2/5	Positively Charged Slides 5 pack
CBLK-EML4-2	FFPE Block (70-100 sections per block @ 3-4 microns)
SAM-CS-EML4-2/2	Positively Charged Slides 2 pack

INTENDED USE: Research Use Only (RUO)

This product is designed to confer confidence in results obtained from the sample on the same slide. The Alk Cell Line Analyte Control slides and paraffin blocks are to be used to monitor the performance of the IHC staining assay during initial validation and for troubleshooting activities. Fixation and processing parameters may differ from the test cases and, as such provide control for all reagents and method steps except fixation and tissue processing. The clinical interpretation of any positive staining or its absence must be evaluated within the context of clinical history, morphology and other histopathological criteria. This material cannot be used independently as a means of optimizing assays in the laboratory.

QUANTITY:

CS-EML4-2/5	Five positively charged Alk Cell Line Analyte Control Slides
CBLK-EML4-2	1 each-ALK Cell Line Analyte Control TMA Block
SAM-CS-EML4-2/2	Two positively charged Alk Cell Line Analyte Control Slides

STORAGE: 2-8°C Avoid freezing as this may cause the wax to crack. Avoid Temperatures above 100° F as the paraffin block may start to melt.

Directions For Use: StatLab recommends that TMA tissue control (whether slide format or prepared slide from block) should be dried 1-2 hours at 60°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

Manufactured for:
StatLab Medical Products
2090 Commerce Drive
McKinney, TX 75069

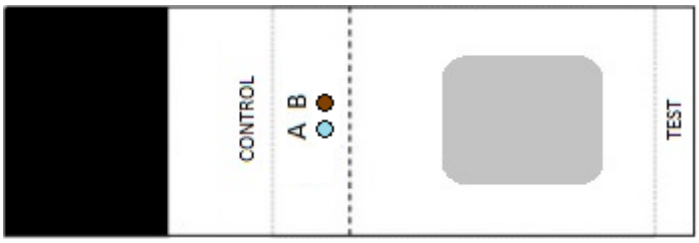
While StatLab has made every effort to assess these analyte controls with a variety of assays available on the market, it is the responsibility of the end user to determine suitability with their reagents and procedures within their laboratory.

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 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 or Interpretation Guide, contact ihctech@statlab.com or visit our website **www.StatLab.com**

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