Product Data Sheet

HistoCyte Laboratories
Quality in Control

PRODUCT NAME: HPV/p16 Analyte Control[DR]

PRODUCT CODE: HCL001 (2 unstained slides)
HCL002 (5 unstained slides)

INTENDED USE: Research Use Only (RUO)

N.B. 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.

STORAGE: 2-8°C

DESCRIPTION: Multi-purpose, high-risk human papilloma virus (HPV) 16 and 18 control slides each slide containing 4 control cell lines:

Cell line A:	human breast adenocarcinoma
Cell line B:	human cervical squamous cell carcinoma
Cell line C:	human cervical adenocarcinoma
Cell line D:	human epidermoid carcinoma

Fixative:	10% Neutral Buffered Formalin
Embedding:	In paraffin wax
Section Thickness:	4µm
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.

EXPRESSION PROFILE:

Cell Line	HPV Gene Copy*	mRNA E6/E7 Copy†	p16 Expression‡
A	Negative	Negative	Negative
B	Low (1-2 copies/cell)	Low	High
C	Medium	High	High
D	High	High	High (heterogeneous)

*As assessed with Ventana INFORM® HPV III Family probe and Leica BOND™ Ready-to-Use HPV probe. †As assessed with Advanced Cell Diagnostics RNAscope® HPV HNC assay. ‡As assessed with Ventana CINtec® p16 Histology Kit

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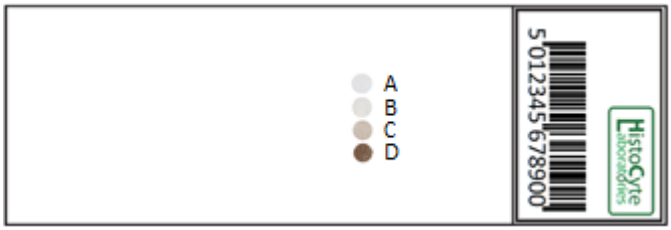
INTERPRETATION OF RESULTS:



Slides are designed to be used as same-slide. Test sample should be placed below the control (see diagram above).

Cell Lines	Expected HPV (DNA) Result	Expected HPV E6/E7 (mRNA) Result	Expected p16 (protein) Result
A	Negative	Negative	Negative
B	Occasional cells demonstrating 1-2 punctate signals in the nucleus*	Intense punctate signals, typically located in the cytoplasm. Can appear nuclear due to the number of signals or clusters and the orientation that the cell is sectioned.	Majority of cells demonstrate intense nuclear and cytoplasmic staining
C	Majority of cells demonstrate moderate punctate nuclear staining. Multiple gene copies create intense clusters in many of the cells.	The majority of cells demonstrate intense punctate staining. Typically cytoplasmic but in some cells there are signals in the nuclei too. This is likely due to mRNA being transcribed but also, with some cells, the plane in which the cells have been sectioned.	Majority of cells demonstrate intense nuclear and cytoplasmic staining
D	The cells demonstrate a variety of staining patterns, from single punctate nuclear staining to multiple foci of signals in the nucleus.	The majority of cells demonstrate intense punctate staining. Typically cytoplasmic but in some cells there are signals in the nuclei too. This is likely due to mRNA being transcribed but also with some cells the plane in which the cells have been sectioned.	Heterogeneous pattern with the majority of large cells demonstrating intense nuclear and cytoplasmic staining,†

*Presence of the genes is sporadic depending on the orientation of the section taken through the cell and the sensitivity of the assay used. It is recommended that the slide is viewed with a x40 objective minimum. † CaSki cells are typically more homogeneously positive for p16 by IHC. HistoCyte Laboratories Ltd have manipulated the cells to provide a heterogeneous analyte control.

For more information, contact info@histocyte.com or visit our website www.histocyte.com and download our Interpretation Guide.

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