

Product Data Sheet

PRODUCT NAME: HPV/p16 Analyte Control^{DR}

PRODUCT CODE: HCL003

INTENDED USE: Research Use Only (RUO). To be used by professionals experienced in the field of histology.

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.

QUANTITY: 1 cell microarray (CMA) block

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

DESCRIPTION: Multi-purpose, high-risk human papilloma virus (HPV) CMA which includes 4 cores (diameter 2.0mm x length 3.0-3.5mm) the following 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

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	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

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. 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.

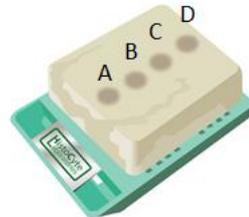


Figure 1. HPV/p16 Analyte Control^{DR} CMA block.

INTERPRETATION OF RESULTS:

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.