

Product Data Sheet



Quality in Control

PRODUCT NAME: Breast Analyte Control^{DR}

PRODUCT CODE: HCL016 (2 unstained slides)
HCL017 (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 5 control cell lines with a Dynamic Range (DR) of expression for a variety of biomarkers. Each core has a 2mm diameter:

Cell line A:	Breast ductal carcinoma
Cell line B:	Breast ductal carcinoma
Cell line C:	Breast ductal carcinoma
Cell line D:	Breast adenocarcinoma
Cell line E:	Osteosarcoma

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.

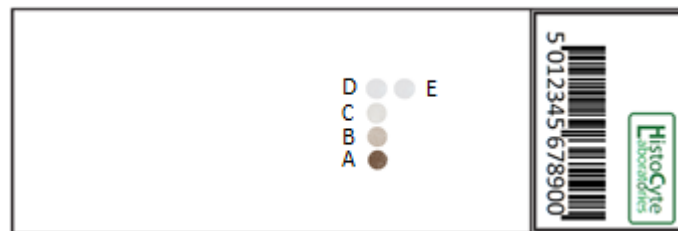
EXPRESSION PROFILE:

Cell Line	Estrogen receptor Protein	Progesterone receptor Protein	Her2 Protein	Her2 Gene
A	Moderate/High Positive (Heterogeneous)	Moderate/High Positive (Heterogeneous)	3+ Positive (Homogeneous)	Amplified
B	Moderate/High Positive (Heterogeneous)	Moderate/High Positive (Heterogeneous)	1+ Positive (Heterogeneous)	Non-amplified
C	Moderate/High Positive (Heterogeneous)	High Positive (Heterogeneous)	1+ Positive (Heterogeneous)	Non-amplified
D	High Positive (Homogenous)	Moderate Positive (Heterogeneous)	Negative	Non-amplified
E	Negative	Negative	Negative	Non-amplified

As assessed with appropriate assays from Ventana/Roche, Leica Biosystems and Abbott Vysus. Homogeneous implies that >99% of the cells stained positive for the biomarker. Heterogeneous confers a variable staining pattern in terms of percentage positivity and intensity. Negative means all cell had an absence of any staining. For FISH assessment cells were amplified if they had a ratio of over 2.2 Her2 gene to CEP17.

DIRECTIONS FOR USE:

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



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