

# Product Data Sheet



Quality in Control

<b><u>PRODUCT NAME:</u></b>	Breast Analyte Control <sup>DR</sup>
<b><u>PRODUCT CODE:</u></b>	HCL018 (1 cell microarray (CMA) block)
<b><u>INTENDED USE:</u></b>	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°C to 8°C. Avoid freezing as this may cause the wax to crack.

**DESCRIPTION:** CMA which includes 5 individual cores (Diameter 2.0mm x Length 3.0-3.5mm) containing cell lines with a Dynamic Range (DR) of expression for a variety of biomarkers. The cell lines derive from the following tumour origin:

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

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.

Cut slides should be stored at 2°C to 8°C and used within 3 months from the time of sectioning.

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

As assessed with appropriate assays from Ventana/Roche, Leica Biosystems and Abbott Vysis. 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:**

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.

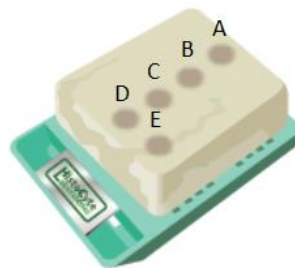


Figure 1. Breast Analyte Control<sup>DR</sup> CMA block.

For more information, contact [info@histocyte.com](mailto:info@histocyte.com) or visit our website [www.histocyte.com](http://www.histocyte.com).