

Product Data Sheet



Quality in Control

PRODUCT NAME:	HER2 Analyte Control ^{DR}
PRODUCT CODE:	HCL028 (1 cell microarray (CMA) block)
INTENDED USE:	Research Use Only (RUO)
STORAGE:	2°C to 8°C. Avoid freezing as this may cause the wax to crack
DESCRIPTION:	CMA which includes 4 individual cores (Diameter 2mm x Length 3-3.5mm) containing cell lines of the following tumour origin: Cell line A: Breast adenocarcinoma Cell line B: Breast adenocarcinoma Cell line C: Gastric adenocarcinoma Cell line D: Breast adenocarcinoma Fixative: 10% Neutral Buffered Formalin Embedding: 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. Over 300 sections in the hands of an experienced histologist can be achieved.

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 Lines	IHC for HER2*	FISH for HER2 gene amplification†
A	0 (Negative)	Non-amplified
B	1+ (Negative)	Non-amplified
C	2+ (Borderline)	Equivocal
D	3+ (Positive)	Amplified

*As assessed with HER2 pathway Ventana/Roche Benchmark Ultra. †Abbot PathVysion HER2 FISH

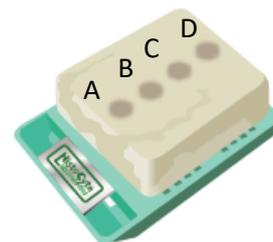


Figure 1. HER2 Analyte Control^{DR} CMA block.

DIRECTIONS FOR USE:

Material is supplied in a block (see figure 1) and designed to be used as a same-slide control. Sections should be cut and arranged as appropriate. 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.

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