

medac



Quality in Control

Breast Analyte Control^{DR}

medac

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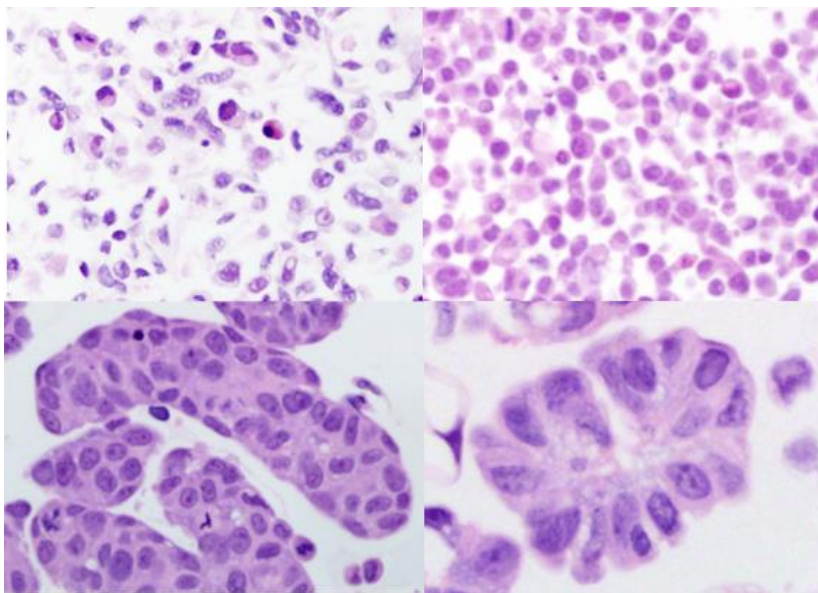
www.medac-diagnostika.de

Product Codes: HCL016, HCL017 and HCL018

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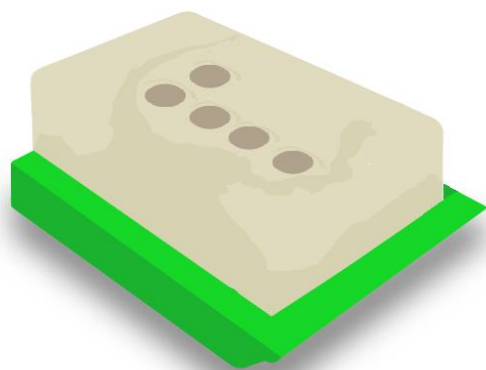
HistoCyte Laboratories Ltd is based in the heart of the Newcastle University campus. Started in 2014 by scientists with a combined experience of over 30 years in the development of reagents for immunohistochemistry and in-situ hybridization. Collaborating with pathologists locally and globally, HistoCyte Laboratories Ltd is developing a range of cost effective products designed to help scientists to maintain and develop the quality of assays within their laboratory.



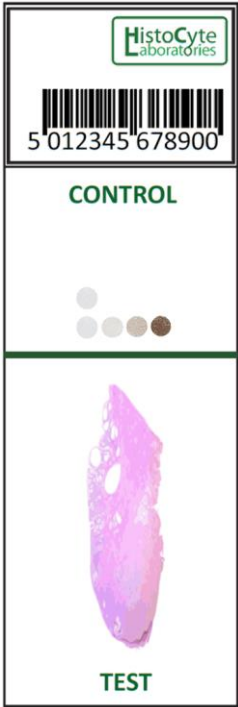
Breast Analyte Control^{DR}

Breast Analyte Control^{DR} is part of the *Dynamic Range* of HistoCyte Products. When a Dynamic Range or a control of high sensitivity is required the **Breast Analyte Control^{DR}** is ideal. This product contains four cells of varying expression for a variety of breast biomarkers, including Her2, Estrogen Receptor and Progesterone Receptor. It also includes an osteosarcoma negative control.

Breast Analyte Control^{DR} is available as pre-cut slides (2 slide and 5 slide mailers) and cell microarray blocks.



| Format | Product Code |
|---------|--------------|
| 2 Slide | HCL016 |
| 5 Slide | HCL017 |
| Block | HCL018 |

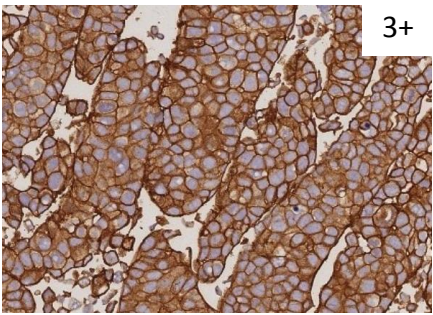
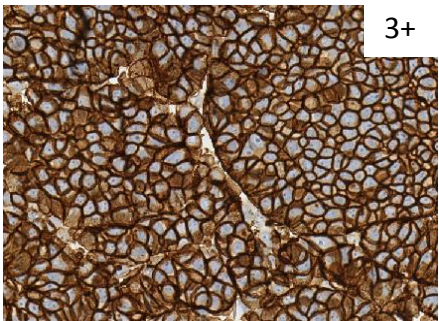


Breast Analyte Control^{DR} Her2

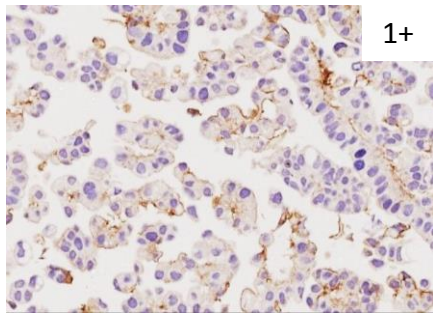
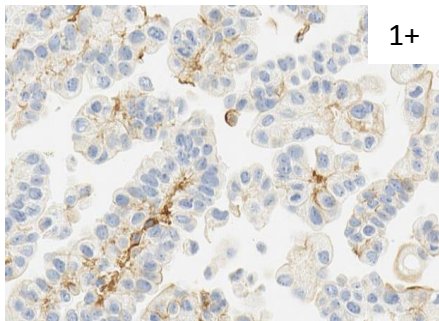
Roche (4B5)

Leica (CB11)

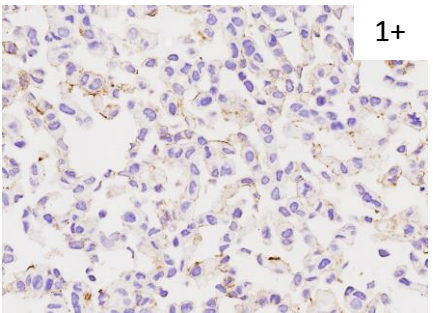
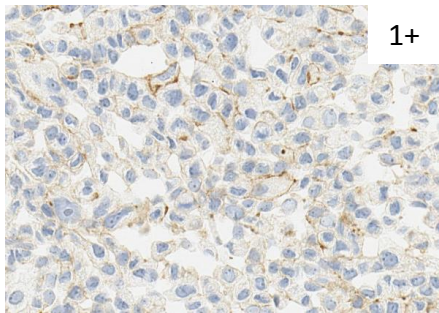
Breast Ductal
Carcinoma



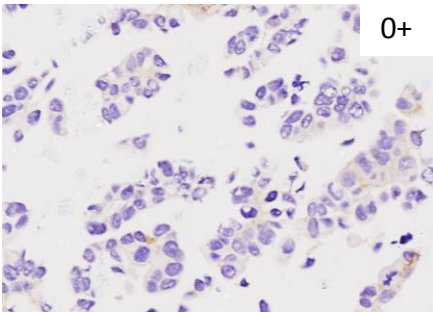
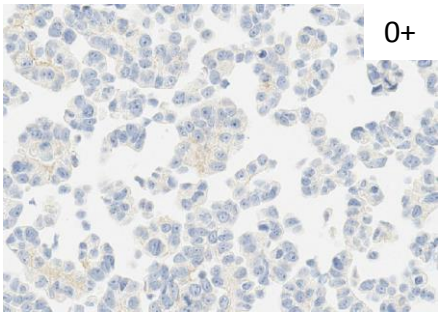
Breast Ductal
Carcinoma



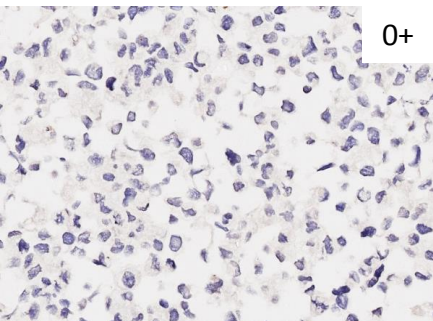
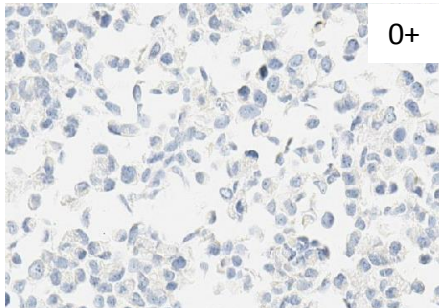
Breast Ductal
Carcinoma



Breast
Adenocarcinoma



Osteosarcoma



Her2 1+ versus 2+ Cells

Her2 2+ is difficult to obtain in laboratories and not always consistent. Tumour is often highly heterogeneous either because of the way the protein is expressed or because of the affects of fixation and processing.

2+ creates the greatest degree of inter-observer discordance¹.

“Is it a weak 2+ or a strong 1+?”



There is no linear correlation between 0/1+/2+ and 3+ (orange vs blue lines).

The linear relationship between 0, 1+ and 2+, makes 1+ cell line is the best predictor of assay drift (red line).

There are two 1+ cells in the Breast Analyte Control^{DR} allowing a laboratory to demonstrate consistency within the control.

Diagnostic algorithms are not necessarily a means to assess Quality. While Her2 are scored 0, 1+, 2+, 3+ controls in laboratories are often scored using an adapted system to convey how the assay has performed. See table below.

| Her2 | QC score | | | | | | |
|------|----------|------|----|------|----|------|----|
| | 0 | 0/1+ | 1+ | 1/2+ | 2+ | 2/3+ | 3+ |

This “grey” area is necessary to impart to the pathologist how the laboratory feel the assay has performed. This QC score can be reflected on by the pathologist scoring the case. This is where the score has to be within the 0, 1+, 2+, 3+. There can be no grey area.

1. Turashvili G, Leung S, Turbin D, Montgomery K, Gilks B, West R, Carrier M, Huntsman D, Aparicio S. Inter-observer reproducibility of Her 2 immunohistochemical assessment and concordance with fluorescent in situ hybridization (FISH): pathologist assessment compared to quantitative image analysis. BMC Cancer. 2009 May 29;9:165

2. Receptor load figures taken from Bond Oracle HER2 IHC System Interpretation Guide, Leica BioSystems, 2011.

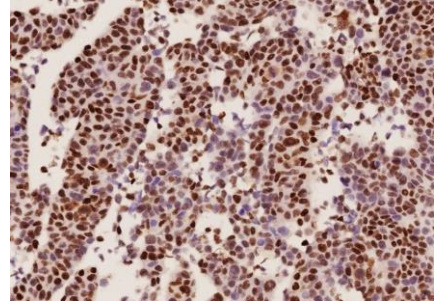
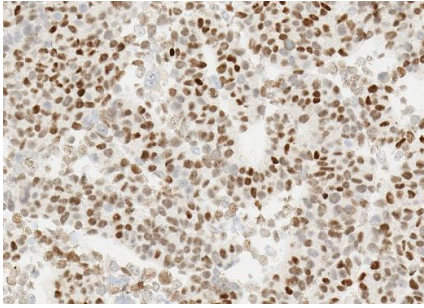
3.

Breast Analyte Control^{DR} ER

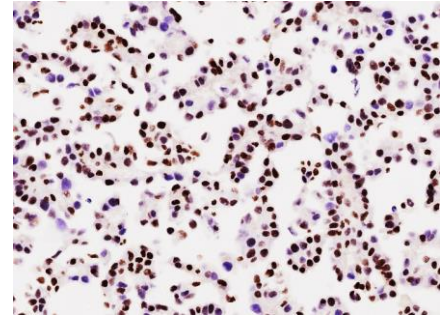
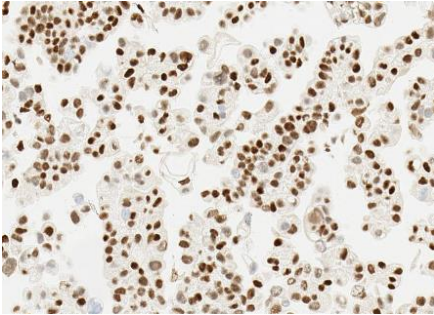
Roche (SP1)

Leica (6F11)

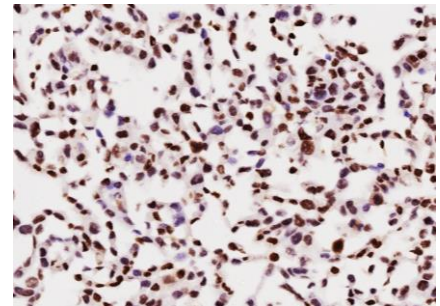
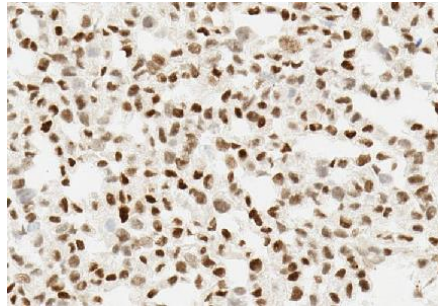
Breast Ductal
Carcinoma



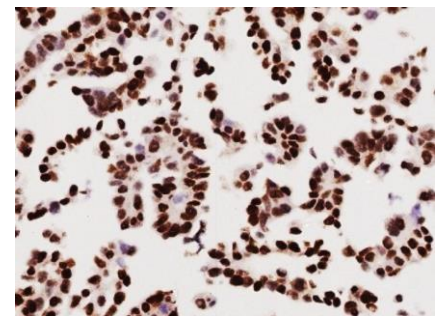
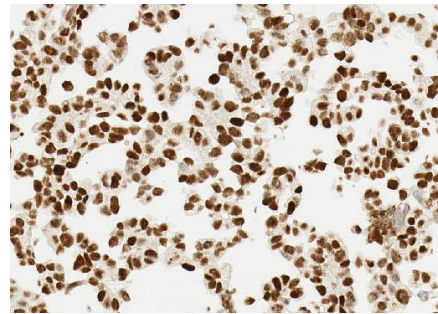
Breast Ductal
Carcinoma



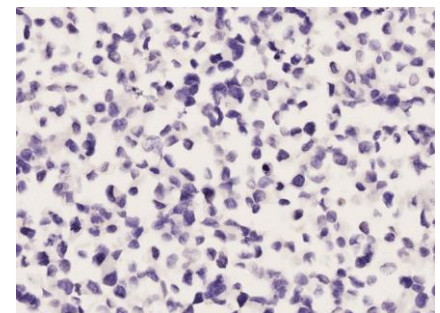
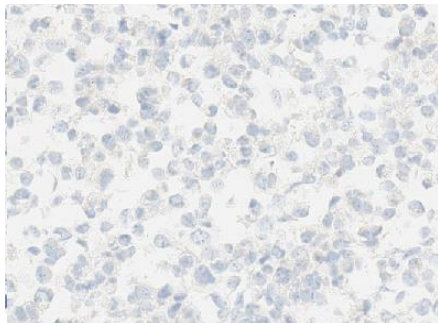
Breast Ductal
Carcinoma



Breast
Adenocarcinoma



Osteosarcoma

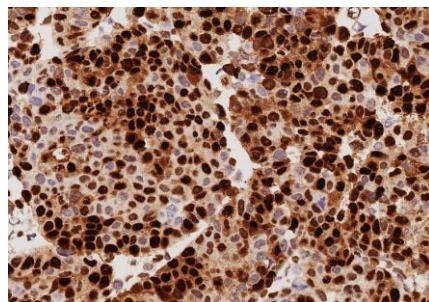
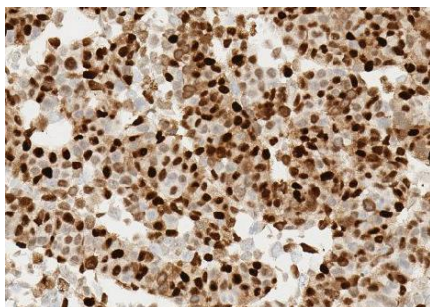


Breast Analyte Control^{DR} PR

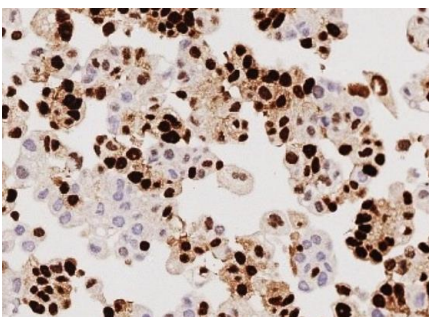
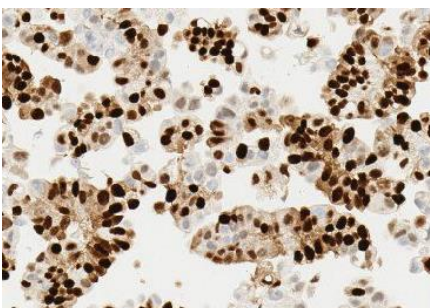
Roche (1E2)

Leica (16)

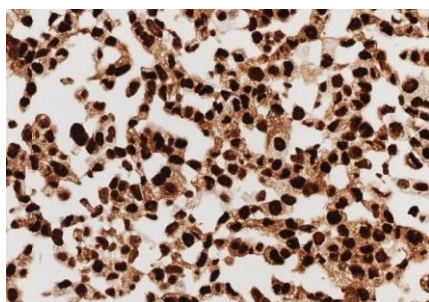
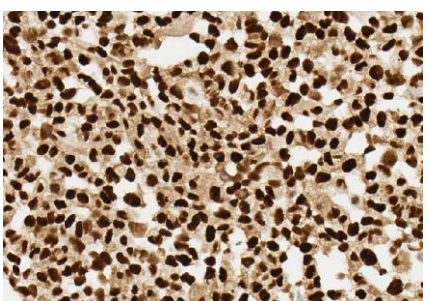
Breast Ductal
Carcinoma



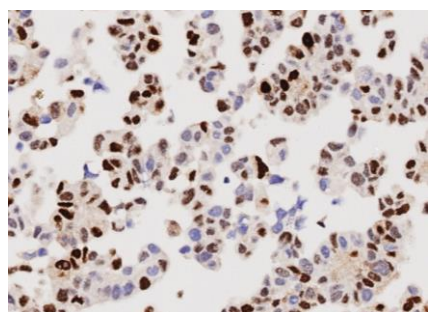
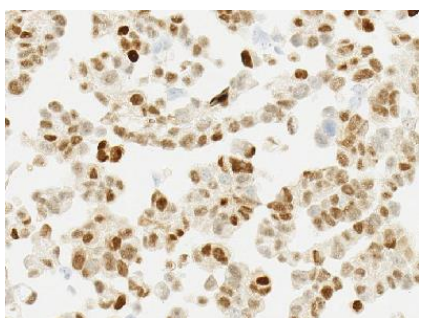
Breast Ductal
Carcinoma



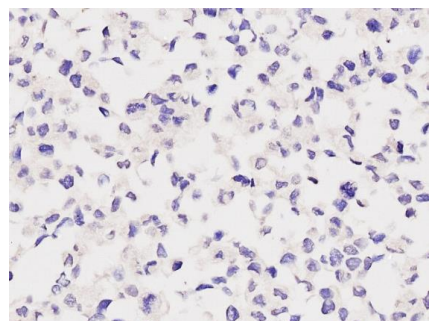
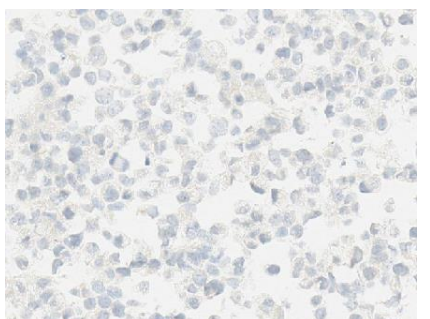
Breast Ductal
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Osteosarcoma



QC Scoring: ER/PR

The heterogeneous cells are the key to determining how significantly the assay performance fluctuates. If the assay over stains or under stains, more or less of the cells in the heterogeneous cores will stain. For both ER and PR there are three cores with heterogeneous expression.

Due to the heterogeneous expression in the cores Quickscore or Allred scoring is not useful in assessing the cells. This is specifically for clinical assessment in tissue.

As the heterogeneous cell cores provide the utility for the control, a QC scoring method needs to be applied rather than a clinical one.

The table below has an example of a scoring method that easily conveys assay performance to the pathologist.

| QC score | Result | Definition |
|----------|----------------|---|
| 1 | Query/ fail | Control not staining as normal. Too weak. Repeat if necessary upon review of test sample. |
| 2 | Pass | Performance lower than expected but within tolerance |
| 3 | Pass | Performance as expected |
| 4 | Pass | Performance higher than expected but within tolerance |
| 5 | Query/ fail | Control not staining as normal. Too strong. Repeat if necessary upon review of test sample. |



Also Available from HistoCyte Laboratories Ltd

| Targets | Product Name | Format | Code |
|------------------------|---|-----------|--------|
| HPV/p16 | HPV/p16 Analyte Control^{DR} (Four core with dynamic range of HPV gene copies) | Slide (2) | HCL001 |
| | | Slide (5) | HCL002 |
| | | Block | HCL003 |
| | HPV/p16 Analyte Control (Three core with standard range of HPV gene copies) | Slide (2) | HCL004 |
| | | Slide (5) | HCL005 |
| | | Block | HCL006 |
| ALK | ALK-Lung Analyte Control (Two core positive and negative for the EML4-ALK translocation) | Slide (2) | HCL007 |
| | | Slide (5) | HCL008 |
| | | Block | HCL009 |
| | ALK-Lymphoma Analyte Control (Two core positive and negative for the NPM-ALK translocation) | Slide (2) | HCL010 |
| | | Slide (5) | HCL011 |
| | | Block | HCL012 |
| Breast Analyte Control | Breast Analyte Control (Two cores, one positive for Her2, ER and PR. The other negative) | Slide (2) | HCL013 |
| | | Slide (5) | HCL014 |
| | | Block | HCL015 |
| | Breast Analyte Control^{DR} (Five cores with a dynamic range of expression of Her2, ER and PR. Including negative control) | Slide (2) | HCL016 |
| | | Slide (5) | HCL017 |
| | | Block | HCL018 |

Contact us for more information or a FREE SAMPLE*

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*Subject to availability

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