HER2 Control Cell Lines

Leica BIOSYSTEMS

Why do we use control cell lines?

Oracle HER2 control cell lines are designed as assay quality controls. They ensure procedural accuracy of the Leica Bond Oracle™ HER2 IHC System.

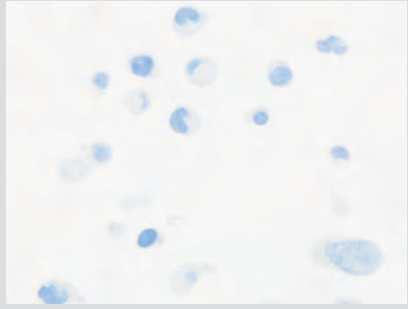
The Oracle control cells lines validate:

- Reagent optimization and performance
- Correct protocol implementation
- Instrumentation performance

The Oracle 2+ Cell line affords superior assay validation by representing the borderline 2+ expression level, the expression level most likely to be affected by any variation in an assay. Cell lines do NOT validate laboratory specimen preparation procedures or replace the requirement for appropriately fixed and processed in-house tissue controls.

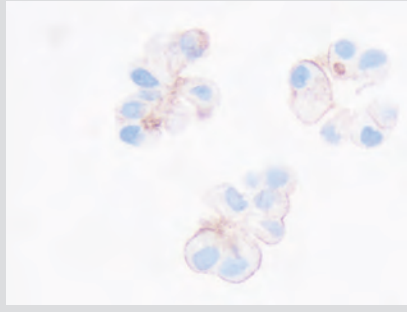
A valid assay with the Oracle HER2 Control Slide shows the following:

0



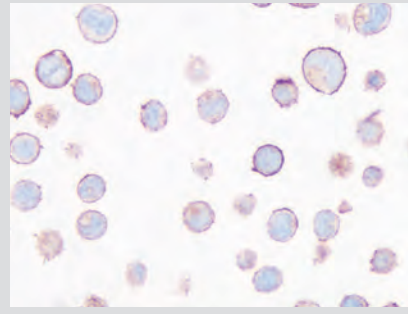
No staining in the 0 control cell line, MDA-MB-231

1+



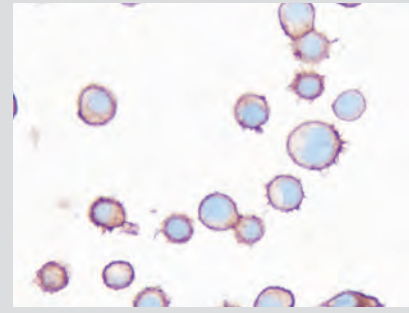
Presence of faint/barely perceptible brown, incomplete cell membrane staining in the 1+ control cell line, MDA-MB-175

2+



Presence of weak to moderate brown, complete cell membrane staining in the 2+ control cell line, MDA-MB-453

3+



Presence of strong brown, complete cell membrane staining in the 3+ control cell line, SK-BR-3

Important notes for evaluating the HER2 control cell lines

A feature of the MDA-MB-175 1+ control cell line is a distinct growth pattern in which the cells form clusters. These clusters give rise to a continuous luminal brush border region across the cell cluster. This brush border staining will be stronger than that of the cell membrane and should not be included in the HER2 staining evaluation. It is the faint/barely perceptible incomplete cell membrane staining that is the correct HER2 oncoprotein 1+ staining pattern. Dot-like immunostaining of the Golgi region in the cytoplasm may also be observed in this cell line and should not be included in the HER2 staining evaluation. (For more information see Leica Bond Oracle HER2 IHC System Interpretation Guide).

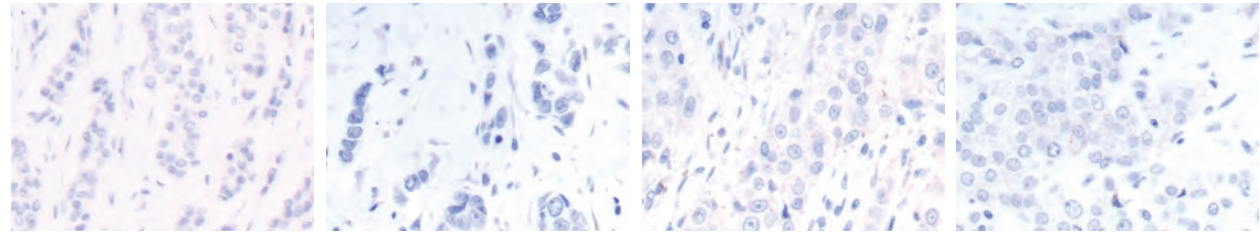
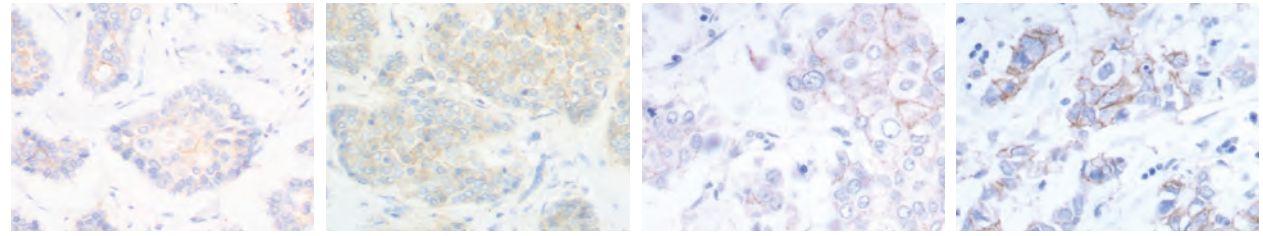
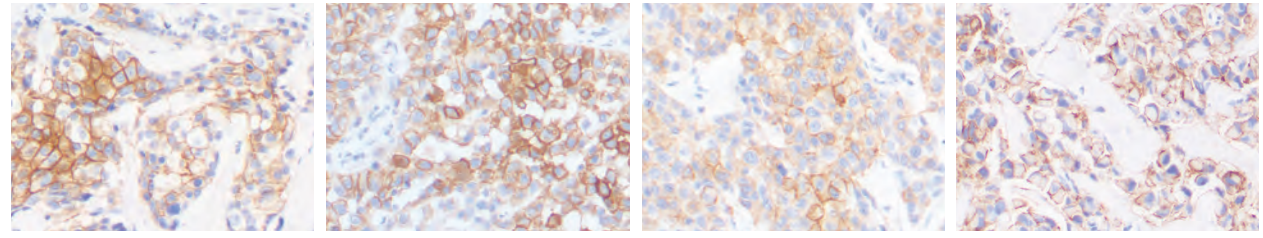
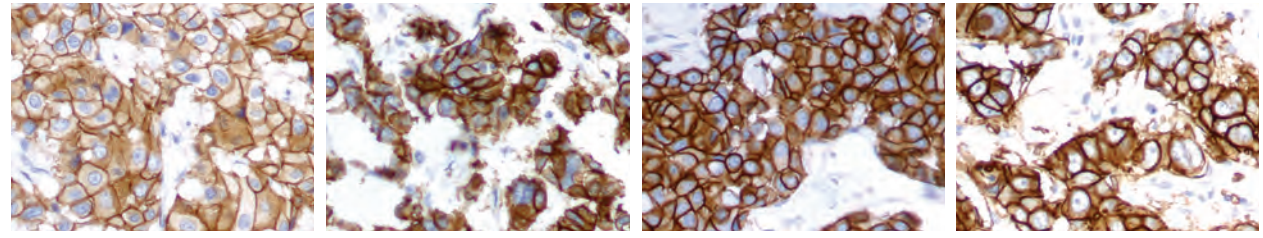
Minimal natural variation of immunohistochemical profile will be seen between growth batches of cell lines utilized within the Leica Bond Oracle HER2 IHC System. This natural variation is well within acceptable tolerance levels of a biological entity and does not affect the evaluation or performance of the system.

The Oracle HER2 control cell lines display consistent homogeneous staining as they are manufactured from a clonal population whose cells have a consistent gene/protein expression profile. When evaluating the HER2 control cell lines the observer must be aware that the percentage rules applying to tissue (overleaf) do not apply to cell lines.

Leica Bond™ Oracle™ HER2 IHC System – Interpretation of Staining on Breast Cancer Tissue

HER2 Scoring Guidelines

- Appropriate areas for interpretation should be assessed in conjunction with a corresponding H&E stained section. Cytoplasmic staining should not to be included in the assessment of membrane staining intensity[1].
- Only specimens from patients with invasive breast carcinoma should be scored. In cases with carcinoma in situ and invasive carcinoma in the same specimen, only the invasive component should be scored.

Immunohistochemical Staining Pattern	Score	Assessment	Tissue Examples
No staining is observed or membrane staining is observed in less than 10% of the tumor cells.	0	Negative	
Faint/barely perceptible membrane staining is detected in more than 10% of the tumor cells. Staining of the cell membrane may not be continuous.	1+	Negative	
Weak to moderate complete membrane staining is observed in more than 10% of the tumor cells.	2+	Equivocal (Weakly Positive)	
Strong complete membrane staining is observed in more than 10% of the tumor cells.	3+	Strongly Positive	

1. Press MF, Cordon-Cardo C, Slamon DJ. Expression of the HER-2/neu proto-oncogene in normal human adult and fetal tissues. Oncogene 1990; 5: 953–62.