

ASCO/CAP has recently released revised scoring criteria for HER2 analysis (FISH and IHC) for breast cancer. GenPath would like to advise you of the report changes we have made (see below) to reflect these HER2 scoring changes.

Revised HER2 Guidelines available online through CAP. <http://www.cap.org/apps/cap.portal>

## IHC Report

### PATTERN ANALYSIS

ER/PgR Interpretation	
Negative or < 1%	Negative
≥1%	Positive

Ki-67 Interpretation	
<10%	Favorable
>10% & <20%	Borderline
>20%	Unfavorable

Cell Cycle by Flow Cytometry Interpretation	
1	<b>Ploidy Interpretation</b>
1.1-1.3	DNA Diploid
1.4-1.8	DNA Aneuploid (Near-diploid)
1.9-2.1	DNA Aneuploid
>2.1	DNA Aneuploid (Tetraploid)
<b>Reference Ranges:</b>	DNA Index: 1.0    DNA Ploidy: Diploid

HER2 IHC Interpretation		
Staining Pattern	Score	Assessment
No observable staining, or membrane staining that is incomplete and is faint/barely perceptible in ≤10% of invasive tumor cells.	0	Negative
Incomplete membrane staining that is faint/barely perceptible in >10% of invasive tumor cells.	1+	Negative
Circumferential membrane staining that is incomplete and/or weak/moderate in >10% of invasive tumor cells, or complete and circumferential intense membrane staining in ≤10% of invasive tumor cells.	2+	Weakly Positive / Equivocal
Homogeneous, dark, circumferential (chicken wire) pattern in >10% of invasive tumor cells.	3+	Positive

S-Phase in Infiltrating Breast Tumors			
DNA Diploid		DNA Aneuploid	
<2%	Low	<3%	Low
2%	Intermediate	3-6%	Intermediate
>2%	High	>6%	High

## FISH Report

### INTERPRETIVE INFORMATION

- \* Negative/Not Amplified: HER2/CEP17 ratio of <2.0 with an average HER2 copy number of <4.0 signals/cell.
- \* Equivocal/Borderline: HER2/CEP17 ratio of <2.0 with an average HER2 copy number of ≥4.0 and <6.0 signals/cell.
- \* Positive/Amplified: HER2/CEP17 ratio of ≥2.0 with an average HER2 copy number of ≥4.0 signals/cell, or HER2/CEP17 ratio of ≥2.0 with an average HER2 copy number of <4.0 signals/cell, or HER2/CEP17 ratio of <2.0 with an average HER2 copy number of ≥6.0 signals/cell.

### REFERENCES

- 2013 ASCO/CAP HER2 Testing Guideline Update: Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Wolff, et al. Arch Pathol Lab Med. doi: 10.5858/arpa.2013-0953-SA

If you have any questions please contact your local sales representative

Thank You