

ASCO–CAP HER2 Test Guideline Recommendation Summary of Guideline 2007 and 2013 Recommendations

Topic	2007 Recommendation	2013 Recommendation
Specimens to be tested	All primary breast cancer specimens and metastases should have at least one HER2 test performed.	All newly diagnosed patients with breast cancer must have a HER2 test performed. Patients who then develop metastatic disease must have a HER2 test performed in a metastatic site, if tissue sample is available.
Optimal algorithm for HER2 testing	Positive for HER2 is either IHC HER2 3+ (defined as uniform intense membrane staining of > 30% of invasive tumor cells) or FISH amplified (ratio of <i>HER2</i> to <i>CEP17</i> of > 2.0 or average <i>HER2</i> gene copy number > six signals/nucleus for those test systems without an internal control probe	Must report HER2 test result as positive for HER2 if: ^{1*} <ul style="list-style-type: none"> • IHC 3+ based on circumferential membrane staining that is complete, intense^{1*} • FISH positive based on: <ul style="list-style-type: none"> • Single-probe average <i>HER2</i> copy number ≥ 6.0 signals/cell^{1*} • Dual-probe <i>HER2/CEP17</i> ratio ≥ 2.0,^{1*} with an average <i>HER2</i> copy number ≥ 4.0 signals/cell • Dual-probe <i>HER2/CEP17</i> ratio ≥ 2.0,^{1*} with an average <i>HER2</i> copy number < 4.0 signals/cell^{1*} • Dual-probe <i>HER2/CEP17</i> ratio < 2.0,^{1*} with an average <i>HER2</i> copy number ≥ 6.0 signals/cell
	Equivocal for HER2 is defined as: IHC 2+ or FISH <i>HER2/CEP17</i> ratio of 1.8-2.2 or average <i>HER2</i> gene copy number 4-6 <i>HER2</i> signals/nucleus for test systems without an internal control probe	Must report HER2 test result as equivocal and order reflex test (same specimen using the alternative test) or new test (new specimen, if available, using same or alternative test) if: ^{1*} <ul style="list-style-type: none"> • IHC 2+ based on circumferential membrane staining that is incomplete and/or 'weak/moderate' and within >10% of the invasive tumor cells,^{1*} or complete and circumferential membrane staining that is intense, and within $\leq 10\%$ of the invasive tumor cells^{1*} • FISH equivocal based on: <ul style="list-style-type: none"> • Single-probe FISH average <i>HER2</i> copy number ≥ 4.0 and < 6.0 signals/cell^{1*} • Dual-probe <i>HER2/CEP17</i> ratio < 2.0 with an average <i>HER2</i> copy number ≥ 4.0 and < 6.0 signals/cell^{1*}

Abbreviations: HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; FISH, fluorescence in situ hybridization; CE17, centromere 17; ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists.

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