ASCO–CAP HER2 Test Guideline Recommendations
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 HER2 to CEP17 of > 2.2 or average HER2 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:** [a,b] ● IHC 3+ based on circumferential membrane staining that is complete, intense [b,c] ● ISH positive based on: Single-probe average HER2 copy number ≥6.0 signals/cell [b,c] Dual-probe HER2/CEP17 ratio ≥2.0; [b,c] with an average HER2 copy number ≥4.0 signals/cell Dual-probe HER2/CEP17 ratio ≥2.0; [b,c] with an average HER2 copy number <4.0 signals/cell [b] Dual-probe HER2/CEP17 ratio < 2.0; [b,c] with an average HER2 copy number ≥6.0 signals/cell
	Equivocal for HER2 is defined as: IHC 2+ or FISH HER2/CEP17 ratio of 1.8–2.2 or average HER2 gene copy number 4–6 HER2 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 newtest (new specimen, if available, using same or alternative test) if: [a,b] ● IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate [a] and within >10% of the invasive tumor cells; [a] or complete and circumferential membrane staining that is intense and within ≤10% of the invasive tumor cells [a] ● ISH equivocal based on: Single-probe ISH average HER2 copy number ≥4.0 and <6.0 signals/cell [b,c] Dual-probe HER2/CEP17 ratio <2.0 with an average HER2 copy number ≥4.0 and <6.0 signals/cell [b,c]

Abbreviations: HER2, human epidermal growth factor receptor; IHC, immunohistochemistry; FISH, fluorescence in situ hybridization; ISH, in situ hybridization; QA, quality assurance; NBF, neutral buffered formalin; ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists.

Wolff AC, Hammond ME, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline update.

Asco Cap Her2 Test Guideline Recommendations

Annelies Wilder-Smith

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