

ASCO/CAP Guideline Recommendations for HER2 Testing in Breast Cancer: Reporting Elements for IHC and FISH:

When reviewing HER2 test assessments it is important to know whether the testing laboratory is CAP-accredited or whether it meets the accreditation and proficiency testing requirements set out by the ASCO/CAP guideline on HER2 testing. Additionally, whether using IHC or FISH, each HER2 status report should report the following elements:

<u>Standard Reporting Elements for IHC*</u>	<u>Standard Reporting Elements for FISH*</u>
<ul style="list-style-type: none"> <input type="checkbox"/> Patient identification information <input type="checkbox"/> Physician identification <input type="checkbox"/> Date of service <input type="checkbox"/> Specimen identification (case and block number) <input type="checkbox"/> Specimen site and type <input type="checkbox"/> Specimen fixative type <input type="checkbox"/> Time to fixation (if available) <input type="checkbox"/> Duration of fixation (if available) <input type="checkbox"/> Antibody clone/vendor <input type="checkbox"/> Method used (specifics of test/vendor and if FDA-approved) <input type="checkbox"/> Image analysis method (if used) <input type="checkbox"/> Controls (high protein expression, low-level protein expression, negative protein expression, internal) <input type="checkbox"/> Adequacy of sample for evaluation <input type="checkbox"/> Results <ul style="list-style-type: none"> <input type="checkbox"/> Percentage of invasive tumor cells exhibiting complete membrane staining <input type="checkbox"/> Uniformity of staining: present/absent <input type="checkbox"/> Homogeneous, dark circumferential pattern: present/absent <input type="checkbox"/> Interpretation [Positive (for HER2 protein expression); equivocal (FISH will be done and reported); negative (for HER2 protein expression); not interpretable] 	<ul style="list-style-type: none"> <input type="checkbox"/> Patient identification information <input type="checkbox"/> Physician identification <input type="checkbox"/> Date of service <input type="checkbox"/> Specimen identification (case and block number) <input type="checkbox"/> Specimen site and type <input type="checkbox"/> Specimen fixative type <input type="checkbox"/> Time to fixation (if available) <input type="checkbox"/> Duration of fixation (if available) <input type="checkbox"/> Probe(s) identification <input type="checkbox"/> Method used (specifics of test/vendor and if FDA-approved) <input type="checkbox"/> Image analysis method (if used) <input type="checkbox"/> Controls (amplified, equivocal, and non-amplified, internal) <input type="checkbox"/> Adequacy of sample for evaluation (adequate number of invasive tumor cells present) <input type="checkbox"/> Results <ul style="list-style-type: none"> <input type="checkbox"/> Number of invasive tumor cells counted <input type="checkbox"/> Number of observers <input type="checkbox"/> Average number of <i>HER2</i> signals/nucleus or tile <input type="checkbox"/> Average number of CEP 17 chromosome probes/nucleus or tile <input type="checkbox"/> Ratio of average <i>HER2</i> signals/CEP 17 probe signals [Note: Tile is unit used for image system counting] <input type="checkbox"/> Interpretation [Positive (amplified); equivocal; negative (not amplified); not interpretable. If IHC is being done because of problems with assay or results, this should also be indicated.]

*If an FDA- approved method is used, it should be noted. If the FDA-approved method has been modified, a statement in the report should be included indicating what modifications were made and that the changes have been validated. If the test is not FDA-approved or an FDA-approved test has been modified, a clear statement must be made that the laboratory reporting results takes responsibility for test performance.