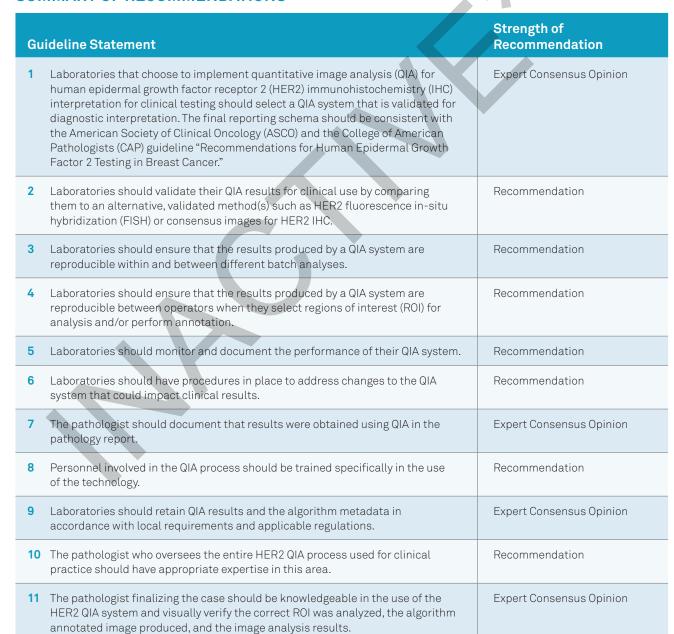# Quantitative Image Analysis of HER2 Immunohistochemistry for Breast Cancer

Statements and Strengths of Recommendations

SUMMARY OF RECOMMENDATIONS

	Guideline Statement	Strength of Recommendation
1	Laboratories that choose to implement quantitative image analysis (QIA) for human epidermal growth factor receptor 2 (HER2) immunohistochemistry (IHC) interpretation for clinical testing should select a QIA system that is validated for diagnostic interpretation. The final reporting schema should be consistent with the American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP) guideline "Recommendations for Human Epidermal Growth Factor 2 Testing in Breast Cancer."	Expert Consensus Opinion
2	Laboratories should validate their QIA results for clinical use by comparing them to an alternative, validated method(s) such as HER2 fluorescence in-situ hybridization (FISH) or consensus images for HER2 IHC.	Recommendation
3	Laboratories should ensure that the results produced by a QIA system are reproducible within and between different batch analyses.	Recommendation
4	Laboratories should ensure that the results produced by a QIA system are reproducible between operators when they select regions of interest (ROI) for analysis and/or perform annotation.	Recommendation
5	Laboratories should monitor and document the performance of their QIA system.	Recommendation
6	Laboratories should have procedures in place to address changes to the QIA system that could impact clinical results.	Recommendation
7	The pathologist should document that results were obtained using QIA in the pathology report.	Expert Consensus Opinion
8	Personnel involved in the QIA process should be trained specifically in the use of the technology.	Recommendation
9	Laboratories should retain QIA results and the algorithm metadata in accordance with local requirements and applicable regulations.	Expert Consensus Opinion
10	The pathologist who oversees the entire HER2 QIA process used for clinical practice should have appropriate expertise in this area.	Recommendation
11	The pathologist finalizing the case should be knowledgeable in the use of the HER2 QIA system and visually verify the correct ROI was analyzed, the algorithm annotated image produced, and the image analysis results.	Expert Consensus Opinion

*Inactive guidelines are no longer updated with systematic literature reviews, but the recommendations may still be useful for educational, informational, or historic purposes.