COLLEGE of AMERICAN PATHOLOGISTS

ASCP STRONGERTOGETHER

ASCO American Society of Clinical Oncology

CAP-ASCP-ASCO HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma Guideline

Statements and Strength of Recommendations

Summary of Recommendations

	Guideline Statement	Strength of Recommendation*
1.	In patients with advanced gastroesophageal adenocarcinoma (GEA) who are potential candidates for HER2-targeted therapy, the treating clinician should request *HER2* testing on tumor tissue.	Strong Recommendation
2.	Treating clinicians or pathologists should request *HER2* testing on tumor tissue in the biopsy or resection specimens (primary or metastasis) preferably prior to the initiation of trastuzumab therapy if such specimens are available and adequate. *HER2* testing on FNA specimens (cell blocks) is an acceptable alternative.	Recommendation / Moderate
3.	Treating clinicians should offer combination chemotherapy and HER2-targeted therapy as the initial treatment for appropriate patients with *HER2*-positive tumors who have metastatic or recurrent GEA.	Strong Recommendation
4.	Laboratories/pathologists must specify the antibodies and probes used for the test and ensure that assays are appropriately validated for HER2 immunohistochemistry (IHC) and in-situ hybridization (ISH) on GEA specimens.	Strong Recommendation
5.	When GEA HER2 status is being evaluated, laboratories/pathologists should perform/order IHC testing first, followed by ISH when IHC result is 2+ (equivocal). Positive (3+) or negative (0 or 1+) HER2 IHC results do not require further ISH testing.	Strong Recommendation
6.	Pathologists should use the Ruschoff/Hofmann method in scoring HER2 IHC and ISH results for GEA.	Strong Recommendation
7.	Pathologists should select the tissue block with the areas of lowest grade tumor morphology in biopsy and resection specimens. More than one tissue block may be selected if different morphologic patterns are present.	Recommendation / Moderate
8.	Laboratories should report HER2 test results in GEA specimens in accordance with the CAP "Template for Reporting Results of *HER2 (ERBB2)* Biomarker Testing of Specimens From Patients With Adenocarcinoma of the Stomach or Esophagogastric Junction."	Strong Recommendation
9.	Pathologists should identify areas of invasive adenocarcinoma and also mark areas with strongest intensity of HER2 expression by IHC in GEA specimen for subsequent ISH scoring when required.	Strong Recommendation
10.	Laboratories must incorporate GEA HER2 testing methods into their overall laboratory quality improvement program, establishing appropriate quality improvement monitors as needed to ensure consistent performance in all steps of the testing and reporting process. In particular, laboratories performing GEA HER2 testing should participate in a formal proficiency testing program, if available, or an alternative proficiency assurance activity.	Strong Recommendation
11.	There is insufficient evidence to recommend for or against genomic testing in GEA patients at this time.	No Recommendation

*The strength of recommendations used for the statements are based on the CAP rating system (Strong Recommendation, Recommendation, Expert Consensus Opinion, and No Recommendation) and the GuideLines Into DEcision Support (GLIDES) methodology rating system (Strong, Moderate, and Weak).

Bartley AN, Washington K, Ventura CB, et al. *HER2* testing and clinical decision making in gastroesophageal adenocarcinoma: guideline from the College of American Pathologists, American Society for Clinical Pathology and the American Society of Clinical Oncology. *Arch Pathol Lab Med.* 2016;140(12):1345-1363. doi: 10.5858/arpa.2016-0331-CP

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