COLLEGE of AMERICAN PATHOLOGISTS

FAQs

Topic: **Quantitative Image Analysis of HER2 Immunohistochemistry for Breast Cancer**

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Do laboratories have to use quantitative image analysis (QIA) for interpretation of HER2 Immunohistochemistry (IHC) for breast cancer guideline?[1]
No, laboratories do not have to use QIA. This guideline was developed for laboratories already using or considering using QIA for HER2 IHC for breast cancer.

Why was this guideline developed?
The field of digital pathology has been around for decades, but overall, many laboratories have not embraced the advances digital pathology has to offer for a number of reasons. The CAP Laboratory and Pathology Quality Center responded to a proposal to develop a guideline that would help laboratories understand what is needed in order to improve the accuracy and reproducibility of their QIA IHC results. In doing so, the hope is that laboratories will have concrete recommendations to help them understand the principles involved in QIA analysis and produce accurate, reproducible results.

Is QIA really superior to manual interpretation for HER2 immunohistochemistry for breast cancer?
A growing body of literature has shown the value of QIA for breast biomarkers improving accuracy, precision, and reproducibility of diagnostic interpretation by pathologists[2-6] however, this was not the focus of the guideline. The purpose of the guideline is help laboratories already using or considering using QIA for HER2 IHC achieve accurate and reproducible results.

What is the most important recommendation(s) of the guideline?
The recommendations dealing with validation of the QIA system for clinical use (recommendations 1 and 2) are probably the most important. While the guideline does not discuss the details of validation at length, proper validation helps provide a high degree of assurance that a process, system or test method will consistently produce a result that meets predetermined acceptance criteria. The guideline refers readers to the College of American Pathologists Laboratory Accreditation Program and the Principles of Analytic Validation of Immunohistochemical Assays guideline for more information on validation.

What kind of training or expertise is needed for those involved in operating the QIA system and interpreting the results?
The guideline has addressed training over 3 recommendations based on the role/responsibility of the person involved.

Personnel involved in the QIA process should be trained specifically in the use of the technology. This training can be conducted by a QIA vendor, the laboratory, or by a qualified trainer (as defined by the laboratory director).

The pathologist who oversees the QIA process should have expertise in QIA. This pathologist(s) may be the laboratory director or a designee. The pathologist overseeing QIA should have the ability to problem-solve any issues related to validation, pre-imaging processes (such as staining), functionality of the system (eg, calibration, analysis of the software, etc.), and generation of the pathology report. This pathologist must be able to critically assess all areas involving the system.

The pathologist who only uses QIA to finalize a case should be knowledgeable of the QIA system, but does not bear the same burden as the pathologist who oversees the entire process. The pathologist using QIA to finalize a case should be qualified to interpret HER2 test results, including being familiar with American Society of Clinical Oncology (ASCO)/CAP HER2 testing guideline, HER2 IHC interpretation criteria, and be able to recognize unusual or discordant results. This pathologist does not need expertise in items such as image acquisition, calibration, etc.

In terms of digital image (slide) retention, what does our laboratory need to retain and for how long?

QIA results and the algorithm metadata should be retained in accordance with local requirements and applicable regulations. These data components should all be treated like other laboratory testing "assets" and subject to local/institutional requirements, as well as those requested for accreditation.

The length of retention should be comparable to the current requirements for similar image assets and based on documented standard operating procedures and policies. In the United States, the latest accreditation standard for data sets from ex-vivo microscopic imaging systems is 10 years.

How will the guideline be enforced? What happens if a laboratory doesn't follow the guideline?

As with any clinical evidence-based guideline, following the recommendations is not mandatory. Recommendations may be incorporated into future versions of the CAP Laboratory Accreditation Program checklists; however, they are not currently required by LAP or any regulatory or accrediting agency. It is only highly encouraged that laboratories adopt these recommendations.

REFERENCES

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