

- 3) Allison KH, Hammond EH, Dowsett M, et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. *Arch Pathol Lab Med.* 2020;144(5):545-63.

CYG.48950 Predictive Marker Testing - Decalcified Specimens

Phase I

If the laboratory performs **in situ hybridization (ISH)** for predictive markers on decalcified specimens, the assay was validated for decalcified specimens or the results include a disclaimer noting that these assays have not been validated on decalcified specimens.

NOTE: Decalcification may adversely affect patient results. If the assay has not been validated for decalcified specimens, a disclaimer must be included in the patient report, such as, "This assay has not been validated on decalcified tissues. Results should be interpreted with caution given the possibility of false negative results on decalcified specimens."

Use of decalcification solutions with strong acids is not recommended.

REFERENCES

- 1) Darvishian F et al. Impact of decalcification on receptor status in breast cancer. *The Breast Journal* 2011; 17:689-91.
- 2) Hanna W et al. Testing for HER2 in breast cancer: current pathology challenges faced in Canada. *Curr Oncol* 2012; 19:315-323.
- 3) Gertych A et al. Effects of tissue decalcification on the quantification of breast cancer biomarkers by digital image analysis. *Diag Pathol* 2014; 9:213.

DIGITAL IMAGE ANALYSIS

This section applies to laboratories using digital image analysis to evaluate specific features in a specimen or tissue section image following enhancement and processing of that image, including but not limited to morphometric analysis, ISH and cytogenetics (evaluation of metaphase chromosomes).

If predictive marker testing is performed, additional requirements in the Predictive Markers section also apply.

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of validation and calibration policies and procedures • Sampling of validation/calibration records • Sampling of specimen analysis policies and procedures • Sampling of patient digital image analysis reports for completeness
	<ul style="list-style-type: none"> • What is your course of action if calibration is unacceptable?
	<ul style="list-style-type: none"> • Select a representative case and follow the entire process from receipt to final reporting

CYG.49470 Preanalytic Testing Phase Validation

Phase II

There are records showing that the preanalytic phase of the test system has been validated for each assay, including fixation and processing.

NOTE: Applicable requirements under the "Test Method Validation and Verification-Nonwaived Tests" section of the All Common Checklist must be followed.