

- 1) Wolff AC, Somerfield MR, Dowsett M, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologist Guideline Update. *Arch Pathol Lab Med.* Published online June 7, 2023. doi: 10.5858/arpa.2023-0905-SA.
- 2) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11):1346-63.
- 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.

ANP.22985 Predictive Marker Testing - Decalcified Specimens

Phase I

If the laboratory performs in situ hybridization (ISH) and/or immunohistochemistry 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 tissue section image following enhancement and processing of that image, including but not limited to, IHC (eg, HER2 and ER), morphometric analysis, and ISH. This checklist section does not apply to laboratories that are imaging slides for manual scoring or review by an individual.

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

VALIDATION AND CALIBRATION

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of validation and calibration policies and procedures • Sampling of validation/calibration records
	<ul style="list-style-type: none"> • What is your course of action if calibration is unacceptable?

ANP.23004 Preanalytic Testing Phase Validation

Phase II