



According to College of American Pathologists' laboratory regulations for breast tissue submission, the cold ischemic time* must be documented so there is standardization in the measurement level of protein expression for clinically relevant targets such as HER2 and estrogen/progesterone receptor expression by immunochemistry. This measurement ensures results are biologically meaningful and are not artifacts related to the manner in which the tissue was handled.

CAP Requirements:

Incyte Diagnostics is required to follow and document adherence to this regulation, and asks for your assistance in this documentation. The following breast tissue submissions are included in this regulation:

- *Core Needle Biopsies*
- *Breast Biopsies*
- *Lumpectomies*
- *Partial Mastectomies*
- *Mastectomies*

Documentation:

The time the specimen was removed and the time placed in formalin can be documented on the Incyte Diagnostics Requisition or by using an Incyte provided stamp.

COLD ISCHEMIA TIME Time Removed: _____ Time Into Formalin: _____

REQUIRED BREAST SPECIMEN INFORMATION				
DATE OF COLLECTION	TIME	BREAST TISSUE REMOVED	TIME	BREAST TISSUE PLACED IN FORMALIN
		□ □ : □ □		□ □ : □ □

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* Cold ischemic time refers to the time the specimen is removed from the body to the time it is placed in formalin. The surgical interruption of blood flow leads to tissue ischemia, acidosis, and enzymatic degradation.