

**Optimal tissue handling for specimens that will potentially be utilized for assessment of breast CA prognostic markers.**

It is important that all biopsy material that is potentially to be assayed by IMMUNOHISTOCHEMISTRY (IHC) for breast cancer prognostic markers ER, PR, and HER2 be handled in a way that optimizes the sensitivity and specificity of the assay. Specimens subject to these tests should be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours. The volume of formalin should be at least 10 times the volume of the specimen.

The following procedures should be observed:

1. Specimens should be immersed in fixative within one hour of the biopsy or resection.
2. The TIME of removal of the tissue FROM the PATIENT (TFP) must be recorded on all specimens. This will be documented in the final surgical pathology report.
3. Similarly, the TIME tissue was placed IN FORMALIN (TIF) must be recorded on all specimens. In many cases this will be performed by laboratory personnel helping in the accessioning of the specimens and will follow appropriate inking and sectioning of the lumpectomy or mastectomy. The interval from the time the tissue was removed from the patient to the time the tissue was inked, sectioned and placed in formalin (TFP - TIF) is referred to as COLD ISCHEMIA TIME. This needs to be as short as possible as autolytic changes begin to become clinically significant after 1 hour. Therefore, the maximum time interval for TFP - TIF should be LESS THAN 1 hour. Similarly, for needle core biopsies, the artifact induced by desiccation of the specimen can occur within much less than 1 hours. Therefore, the radiologists and other providers that procure these types of biopsies should be placing them in formalin immediately, prior to transporting the specimen to the laboratory.
4. If delivery of a resection specimen to the pathology department is delayed (e.g., specimens from remote sites), the surgeon that has removed the specimen can make a single section through a tumor if it is palpable prior to the specimen being placed in 10% buffered formalin. That provider should record the time of the sectioning as TIME IN FORMALIN (TIF). This should be done in a way that does not compromise the orientation of the specimen or the ability of a prosector to paint margins for documentation of orientation. Alternatively, the margins may be separately submitted.