



MEMO

Date: January 13, 2012

To: RML Clients – Surgeons, Nursing Staff and Department of Surgery

From: Dr. Michael Harvey, Anatomic Pathology Section Chief
Dr. James Taylor, Immunohistochemical Lab Section Chief
Dr. James Palmer, Specialist in Breast Pathology

RE: Surgical Breast Specimen New Fixation Requirements

The College of American Pathology (CAP) and American Society for Clinical Oncology (ASCO) has established standards for fixation of breast tissue which will undergo ER/PR and HER-2/neu testing. At Regional Medical Laboratory, our established procedures are in compliance with regard to optimal formalin fixation time, which has been established as greater than six hours and less than 96 hours. As of January 1, 2012, CAP has added an additional requirement to have formalin in contact with all breast tumors within one hour of its removal from the patient (i.e. less than one hour of cold ischemia time). In order to be in compliance with the policy, our pathologists will process breast specimens in accordance with the new guidelines upon receipt in the laboratory.

The guidelines require documentation in the report of time tissue is removed from the patient, time tissue is placed in fixative, duration of fixation, and fixative type including the time the tumor is in contact with the fixative.

Please document the time the specimen is removed from the patient and also the time placed in formalin on the requisition for ALL breast specimens including biopsies, lumpectomies, resections and mastectomies.

Thank you for your compliance with this requirement to allow for the very best quality of specimens for ER/PR and HER-2/neu testing.

If you have questions about this or other surgical pathology issues, please contact us at 918-744-2553.