

Client Communication

Specimen Collection Instructions: Cytology and Histology (Tissue) Specimens

This Client Communication provides guidance as to the proper submission of Cytology and Histology (tissue) specimens in the best interest of patient care. Pathology Laboratories, Inc. (PathLabs) values your referrals and desires to work closely with providers and their medical staff to assure that quality reporting is achieved by following these recommended guidelines for specimen submission.

This communication covers a range of topics highlighted below:

- Cytology-Gynecological and Non-Gynecological Specimens
 - Labeling of Specimen Containers and Requisitions
- Histology (Tissue) Specimens
 - Labeling of Specimen Containers and Requisitions
 - Specimen Tissue Site Labeling
 - Routine Tissue
 - Breast Related Tissue Any breast tissue including breast biopsy, breast excision, breast skin biopsy, and axillary biopsy. (See also Prognostic/Predictive Marker Testing and Special Instructions)
 - Tissue Other Than Routine Tissue including lymph node biopsy, skin biopsy for Direct Immunofluorescence, tissue for Cytogenetics. (See also Prognostic/Predictive Marker Testing and Special Instructions)
 - Prognostic/Predictive Marker Testing and Special Instructions
 - Clinical History Submission
 - Checklist for Histology / (Tissue) Biopsy Submission



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Client Communication

Labeling: Containers and Requisitions

Regulatory institutions and programs, overseeing the laboratory industry, such as the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA), require that proper labeling criteria be met, without exception. These governing bodies require proper specimen labeling with matching requisition information to protect patients from adverse events due to improperly labeled specimens.

Every specimen referred to the laboratory must have a label on the container in which it is held, along with matching identification on the requisition. It is not acceptable to label only the lid, transport bag, or other container used to transport the specimen.

Please ensure the specimen is labeled according to instructions given below, and double check that the information on the specimen container matches the related requisition.

CYTOLOGY - Gynecological and Non-Gynecological Specimens:

The CONTAINER label on each specimen must specify the following legible information:

- Patient full first and last name
- Patient date of birth
- Specimen site(s) on each container

The REQUISITION must also specify the following legible information:

- Patient full first and last name
- Patient date of birth
- Date of service

- Ordering physician
- Specimen site(s) on each container
 Patient demographic sheet (Site of collection must match container exactly)
- Diagnosis code(s)
 - and insurance information

HISTOLOGY - Tissue Specimens

The CONTAINER label on each specimen must specify the following legible information:

- Patient full first and last name
- Patient date of birth
- Specimen site(s) on each container

The REQUISITION must also specify the following legible information:

- Patient full first and last name
- Patient date of birth
- Date of service
- Time of collection

- Ordering physician
- Specimen site(s) on each container
 Clinical History (Site of collection must match container exactly)
- Diagnosis code(s)
- - Patient demographic sheet and insurance information



Specimen Tissue Site Labeling - Histology (Tissue)

<u>Tissue from multiple different sites should be submitted in multiple separate containers. Multiple is defined</u> <u>as anything greater than one (1) specimen. It is not advisable to put multiple specimens in a single container</u> <u>from a patient safety perspective, i.e., one (1) specimen per container.</u>

Examples of Specimen Site:

- Routine Tissue Submit in a leakproof container of formalin at room temperature:
 - ECC (Endocervical curettage is acceptable to abbreviate "ECC".)
 - Endocervical or Cervical Polyp
 - Endometrial/Endometrium
 (EMB is an acceptable abbreviation. It is NOT acceptable to abbreviate as "ENDO".)
 - Cervix
 - Labia
 - Vulva
 - Perineum
 - Skin biopsy/excision

(Please be as specific as possible, e.g., Right Arm, Left Hand index finger, etc.)

- Breast Related Tissue Submit in a leakproof container with formalin at room temperature:
 - Includes any tissue related to the breast:
 - Breast biopsy
 - Breast excision
 - Breast skin biopsy
 - Axillary biopsy
- Tissue Other Than Routine Submit in a leakproof container with the appropriate media type:
 - Includes any tissue other than routine or breast related:
 - Lymph node biopsy
 - Skin for Direct Immunofluorescence testing
 - Tissue for Cytogenetic testing

Prognostic/Predictive Marker Testing and Special Instructions

Prognostic/Predictive Marker Testing:

Breast Tissue and any Breast Related Tissue – Prognostic and/or predictive marker testing refers to specific tests (e.g., ER, PR, HER2), which predict the course of the diagnosed disease, illness or problem and determine treatment or outcome. It is a CAP and CLIA requirement that all breast tissue for prognostic and/or predictive marker testing be handled in the following manner as to ischemic time and total formalin fixation time:



To determine ischemic time and total fixation time, the following is required to be recorded on the requisition:

- Record the <u>Time Excised</u> on the requisition
- Record the <u>Time Placed in Formalin</u> on the requisition

Ischemic and Total Formalin Fixation Time for prognostic and/or predictive marker testing will be reflected on the final report:

- Ischemic time must be less than 1 hour
- Total formalin fixation time must be more than 6 hours but less than 72 hours NOTE 1: It does not matter if there is a clinical suspicion for breast cancer or not, as there is always a

chance of breast cancer in any breast related tissue.

NOTE 2: Performing these types of biopsies on Saturday is discouraged given the time by when the specimen will arrive and be processed in our laboratory (Monday overnight to Tuesday morning).

Special Instructions for Tissue Other Than Routine:

 Client Service will provide instructions on media type and days this special testing is offered. Please phone Client Service 419.255.4601 / 800.281.8804 for further instruction.

Clinical History Submission - Histology (Tissue)

"Clinical History" provides pertinent and accurate information for a pathologist to review specimens.

Pertinent information includes but is not limited to:

- Patient history
- Procedure notes
- Notes from previous surgeries
- Radiology reports
- Previous Pap Test results for specimen(s) NOT performed at PathLabs
- Past surgical pathology report(s) for specimen(s) NOT performed at PathLabs

"Clinical History" must be provided with the following specimen types (but is not limited to):

- Skin excisions
- Skin re-excisions
- LEEP excisions
- Any ENT related biopsy or excision
- Oral biopsies or excisions

- Axillary biopsies
- Axillary excisions
- Breast biopsy
- Breast excision



ORATORIES

Checklist for Histology (Tissue) Biopsy Submission

CONTAINER:

Formalin container is labeled with PATIENT'S FULL FIRST AND LAST NAME

Formalin container is labeled with **PATIENT'S DOB**

Formalin container is labeled with THE SITE OF COLLECTION*

*SITE examples: ECC (Endocervical), Endometrial (EMB), Cervix, Labia, Vulva, Perineum (*indicate right or left*)

Formalin container houses only one (1) specimen from a single site.

REQUISITION:

Requisition must have PATIENT FULL FIRST AND LAST NAME

Requisition must have **PATIENT DOB**

Requisition must have THE DATE/TIME OF COLLECTION

Requisition must have **ORDERING PHYSICIAN**

Requisition must have **SITE OF COLLECTION AND IT MUST MATCH THE CONTAINER EXACTLY NOTE: TIME EXCISED FROM BODY AND TIME PLACED IN FORMALIN** (**Required for BREAST TISSUE and TISSUE RELATED to the BREAST**)

Requisition must have **DIAGNOSIS CODE(S)**

Requisition must have **CLINICAL HISTORY**

NOTE: Clinical History includes patient history, procedure notes, notes from previous surgeries, radiology reports and past Pap Test/surgical pathology reports (*if NOT performed at PathLabs*). Requisition must be accompanied by **PATIENT DEMOGRAPHIC SHEET AND INSURANCE INFORMATION**

This Client Communication will be posted to our **website** for reference, **within the Clinicians area; specifically, under the Cytology Testing and Surgical Pathology sections.**

Please review this information with your medical staff. Thank you for incorporating this important criteria into your future specimen submissions enabling PathLabs to enhance the quality of our Cytology and Surgical Pathology reporting.

