Clinical Surgical Pathology - Gross Room Procedure
surgpath19.03

Specimen Accession & Preparation

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<tr>
<th>Final Approval: May 2010 Effective: May 2010</th>
<th>Next Review Date: April 2015</th>
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<td><strong>List all stakeholder(s) and dates of approval:</strong></td>
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<tr>
<td>Stakeholder Name(s): Geoffrey Werner Date: 5/3/10 Reviewed ❌ Revised ✔</td>
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<td>Stakeholder Name(s): Mark Magilner, MD Date: 5/2010 Reviewed ❌ Revised ✔</td>
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<td>Stakeholder Name(s): Geoffrey Werner Date: 12/23/11 Reviewed ❌ Revised ✔</td>
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<td>Stakeholder Name(s): M. Magilner, MD Date: 11/12/12 Reviewed ❌ Revised ✔</td>
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<td>Stakeholder Name(s): Geoffrey Werner Date: 3/26/14 Reviewed ❌ Revised ✔</td>
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Describe briefly the most recent revision made to this policy, procedure or protocol & why:
11/12/12 – Medical Director. Revision to specimen acceptance/rejection policy and procedure (part 3).
11/12/12/ - Medical Director. Revision to Specimen Deficiency Form. (attachment)

Purpose/Policy Statement:
Upon delivery of tissue specimens to the Pathology Gross Room, each case is labeled with an identifying accession number and recorded in CoPath. Case types include the following designations: L, LA and LB (outside patients), M, MA and MB (hospital patients). This is the identification by which the specimen is followed during gross examination, dissection, and placement into a tissue cassette for processing.

Definitions:
• n/a

STEPS / KEY POINTS

PROCEDURE:
1. By visualizing the type of requisition form submitted, organize received specimens into group designations:
   • M = Salem Hospital cases
   • L = Outside cases with sub groups of -
     Hospital submissions
     Physician Office submissions
2. A completed pathology requisition must accompany specimens and include the following information:
   • Patient's full name.
   • Patient unique identifying information (DOB, SSN, etc.).
   • Specific tissue identification.
   • Preoperative diagnosis/Clinical history.
   • Postoperative diagnosis
   • Physician’s full name
   • Patient’s billing information
   • Date of collection.
• Date received in pathology (time-stamp)
All tissue sample containers must be clearly labeled with:

• Patient’s full name.
• Patient unique identifying information (DOB, SSN, etc.).
• Specific tissue identification.

3. DETERMINE SPECIMEN ADEQUACY BY EXAMINATION OF ALL MATERIAL RECEIVED IN THE
DEPARTMENT FOR THE DEFICIENCIES LISTED BELOW.

a. Specimens not bagged or bagged inadequately
b. Requisition placed in bag improperly
c. Lid not sealed properly and/or fluid spill contamination
d. Inadequate amount of fixative fluid
e. No specimen source on container
f. No clinical history
g. No physician name.

FOR ALL CASES:
If deficiency “a” to “g” is encountered, the deficiency is recorded in the CoPath Deficiency Record System with all required information and the specimen is then accessioned and processed. Additional telephone contact to add missing information may be needed. All information added to a requisition by a lab assistant should include a date and initials and who was spoken to.

** FOR CASES WITH POSSIBLE SPECIMEN IDENTITY DEFICIENCIES, I.E:

h. Requisition form missing
i. Specimen container missing
j. Patient’s name not on the specimen container
k. Discordant information between requisition form and specimen container
l. Any labeling or requisition which calls into question the specimen identity

** NOTE: Surgical Pathology specimens are unique and irreplaceable. Therefore every effort should be made to correct deficiencies “h” to “l” to leave no doubt as to the identity of each specimen. A serious effort to resolve ambiguous identification must be applied. In general, a specimen is not permanently “rejected”. An ambiguous specimen may be processed at the discretion of a pathologist provided that an appropriate notation of the issue is noted in the final pathology report. At any step in the following process, a pathologist, pathologist assistant, or PPA manager may be contacted for assistance.

• If deficiency “h” to “l” is encountered, the specimen should not be accessioned until corrected.
• An entry is made in the CoPath Deficiency Record System with all required information.
• Contact by telephone the originating client to notify them of the problem.
  o Identify the contact person.
  o Explain that a specimen deficiency form must be completed prior to processing.
• The Specimen Deficiency Form will be partially completed by Pathology staff (see attached form)
• For off campus specimens: Secure the specimen in a transport bag with the requisition form and the Specimen Deficiency Form, clearly labeled with the destination and contact person visible on the outside. Forward the specimen to the SHRLS Courier Services pick-up location and recorded on the appropriate log.
• For on campus specimens: A hospital staff member or clinician may come to the pathology lab to complete the Specimen Deficiency Form.

• In ALL cases the form must be signed by the person who makes the correction and returned with the specimen and requisition.

• The Specimen Deficiency Form will be attached to the specimen requisition and scanned in to document imaging after completion of the case.

• At the discretion of the pathologist assistant or pathologist, a notation may be made in the final pathology report noting any possible identification discrepancies.

4. Validate the condition of the submitted sample. The tissues submitted in 10% NBF must be submerged in an adequate amount of fixative.

• AT THIS TIME, FORMALIN MUST BE ADDED TO CONTAINERS TO PROVIDE OPTIMUM FIXATION. SPECIMENS MAY BE TRANSFERRED TO APPROPRIATELY SIZED CONTAINER TO ALLOW THE ADDITION OF SUPPLEMENTAL FORMALIN.

5. Organize the samples into an alignment that prevents accessioning of consecutive “like” specimens. This alignment must allow for samples that will be DECAL or GROSS EXAM ONLY to not be used as dividers between consecutive “like” specimens, since their handling will take them out of the normal consecutive numerical handling as processing continues.

6. Utilizing CoPath, accession each specimen and await the auto-generated print of the specimen labels.

7. Apply correctly identified printed labels to both the specimen container and the requisition form. AS EACH LABEL IS APPLIED TO A CASE REQUISITION FORM AND IT’S SPECIMEN CONTAINERS, VALIDATE THE PATIENT NAME AND/OR ID NUMBER AND THE SPECIMEN CONTAINER NUMBER.

8. Numerically align the labeled specimen containers on the counter, adjacent to the gross exam area, ERO cases are removed from numerical order and dictated on separate Job Numbers.

9. Utilizing CoPath, generate a Specimen Accession Log.

10. Utilizing the automated cassette labeler, generate processing cassettes for each accessioned case according to established department color-code criteria. AS EACH CASSETTE IS BEING PLACED WITH THE CORRESPONDING SPECIMEN CONTAINERS, VALIDATE THE PATIENT NAME AND/OR ID NUMBER AND THE SPECIMEN CONTAINER NUMBER.

Each case requiring more than one cassette must be designated with a sub-label that DISTINGUISHES IT FROM ALL OTHER CASSETTES.

a. For example:
• a single container labeled M04-1234 may result in five cassettes, sub-labeled A,B,C,D,E,
• multi-container cases with one cassette each will be sub-labeled as 1,2,3,4,5.
• multiple containers with multiple cassettes will be labeled per container and per resulting cassette (1A, 1B, 2, 3A, 3B, 3C, etc.) and WITH NO DUPLICATIONS.

b. Special handling is also recorded on the tissue cassette;
• “DEC” for samples treated for decalcification,
• “ANHYDROUS” processing,
• “STR” stereotactic breast biopsies
• “VAS” or “FTS” for vas deferens or fallopian tubes.

11. Set out dissection instruments; ruler, forceps, scalpel, strainer, etc.

12. Fill cassette-storage receptacles with fresh 10% Neutral Buffered Formalin.

13. When laboratory staff assist at the grossing bench:

• By individual case, present specimen containers to the pathologist/pathologist assistant accompanied by the requisition form and the pre-labeled tissue cassettes in sequential order for the case; prepare additional cassettes as needed.
• As each case is placed onto the Gross Board, the assistant will match the identification number of the
specimen container with the corresponding numbered embedding cassettes.

- As the dissected tissue is placed into the embedding cassette, the pathologist/pathologist assistant will verify the identification of the case.

- Any tissue specimen where size (following dehydration in alcohol during the processing cycle) and/or consistency (mucoid, friable) may compromise the sample's integrity must be additionally be secured inside the cassette by enclosure in tissue paper, nylon specimen bag or placement between two embedding sponges.

- As each case is completed and prior to release of their work the assistant will:
  a. validate the accession number and sub-labeling on the cassettes
  b. for small biopsies and dissections, on the right side of the cassette write the number of sample pieces contained within.
  c. for accountability documentation, the assistant will write their initials on the right side of each cassette.

14. Upon completion of each grossing session, tissue remains from each case are either prepared for wet-tissue storage:

- Specimens originally submitted in snap-top containers are transferred to and secured in a heat-sealed bag with 10% Neutral Buffered Formalin (NBF) and the original accession label is also transferred to identify the sample.

- Specimens originally submitted in screw-top jars are secured in their original container with 10% Neutral Buffered Formalin (NBF) and the original accession label is also transferred to identify the sample.

- The containers are arranged somewhat numerically in bins that are labeled by accession group and date. These are retained in the Gross Room storage cabinets for approximately one month.

Transfer tissue cassettes to their designated VIP Tissue Processors for processing according to the policy, VERIFICATION OF TISSUE PROCESSOR OPERATION AND TIME SCHEDULE.

15. To decontaminate instruments and work area use a solution of at least 10% Sodium Hypochlorite (chlorine bleach) to immerse all instruments and accessories, and to thoroughly drench the dissecting area and wipe down all other possibly contaminated work surfaces. Detergent may be added to this solution as a surfactant. Additionally, 100% ethyl alcohol or disinfectant cleanser may be utilized as a cleaning aid and decontaminant.

QUALITY CONTROL:
1. Tissue cassette labeling discrepancies are documented in the Continuous Quality Improvement record book.
2. For accountability documentation, each staff member will write their initials on the right side of each tissue cassette and the number of sample pieces contained within prior to the release of their work.
3. All saved wet tissue and/or specimen remnants are discarded into a BIOHAZARD BOX on a rotational basis after approximately one month and documented in the WET TISSUE DISPOSAL record book. Exceptions are specimens that require long-term wet tissue retention for additional testing or medicolegal considerations as directed on the Pathology Requisition form, by the pathologist assistant or by a pathologist. The specimens in this long-term storage are retained in the Pathology Gross Room within designated locked storage cabinets OR IN AN ALTERNATIVE LOCKED LABORATORY STORAGE LOCATION. Specimen RETENTION for breast implant cases is three years.
4. Limb amputation specimens are stored in a designated refrigerator storage area until the completion of the Gross Exam, at that time they are returned to the same designated refrigerator storage and retained until the pathology report is finalized. They are disposed into a BIOHAZARD BOX.
5. The technical staff assigned to the decalcification task records a list of all tissue cassette accession numbers each morning. At the end of the workday, this list will be reconciled against the remaining requisition forms and the CoPath Tissue Processing Batch Log and accountability documentation will be recorded for all cassettes from that day.

PROFICIENCY TESTING: College of American Pathologists HistoQIP, IHC Survey.

RESULTS: N/A

PROCEDURE NOTES:
1. Tissue samples submitted for ANHYDROUS processing are placed into 100% Ethyl Alcohol (EtOH) reagent for
fixation and remain in the Gross Room until the end of the day and transported to the Histology Department for appropriate anhydrous processing.

2. Tissue samples that are calcified require special handling:
   - Cassettes containing calcified tissue are placed into DECAL F (Formic Acid) reagent following Gross Examination and remain in the Gross Room. Following examination by the technical staff to determine that complete sample decalcification has been achieved, the decalcifying solution is removed by a 10 minute wash in running tap water and the cassettes are transferred to 10% NBF in the Gross Room. More calcified specimens will be transferred to a Hydrochloric Acid solution following 24 hours in Formic Acid, until such time is deemed by the pathologist assistant, that the tissue has been adequately decalcified and appropriate for histological processing.
   - The technical staff assigned to the decalcification task records a list of all tissue cassette accession numbers each morning. At the end of the workday, this list will be reconciled against the remaining requisition forms and the CoPath Tissue Processing Batch Log and accountability documentation will be recorded for all cassettes from that day.

**LIMITATIONS OF PROCEDURE:** N/A

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**Equipment/Supplies (If Applicable):**
- Disposable gloves
- Laboratory coat
- Eye protection

**SPECIMEN:** Human whole organ specimens, tissue biopsies submitted “fresh” or in 10% Neutral Buffered Formalin (NBF).

**MATERIALS, REAGENTS:**

| Decalifying Solution F - Richard Allan Cal-Rite | 10% Neutral Buffered Formalin (NBF) |
| CAUTION – CORROSIVE, IRRITANT. Wear appropriate protective equipment. |
| 100% Ethyl Alcohol | CAUTION – FLAMMABLE LIQUID, IRRITANT, SUSPECTED CARCINOGEN. Wear appropriate protective equipment. CONTAINS FORMALDEHYDE. Toxic by inhalation and if swallowed. Irritating to the eyes, respiratory system, and skin. May cause sensitization by inhalation or skin contact. Risk of serious damage to eyes. May cause cancer. Repeated or prolonged exposure increases the risk. |

**INSTRUMENTATION OR EQUIPMENT:**
- Laboratory Information System
- Pathology Gross Room Printer

**Form Name & Number or Attachment Name (If Applicable):**
surgpath19

**Author Position:**
Histology Supervisor

**Review/Revision Authority (Position Not Individual Name):**
Medical Director, Operation Manager, Histology Supervisor, Pathologist Assistant
Expert Consultant Position/s (Not Individual Name/s):
IS Manager

References (Required for Clinical Documents):

MANUFACTURER'S PACKAGE BROCHURES/INSERT: N/A

Is there a Regulatory Requirement? Yes ☐ No ☐
If yes, insert requirement information here:

Review History (No Changes):
n/a

Revision History (Note changes in area under header):
n/a

Computer Search Words:
n/a

Policy, Procedure or Protocol Cross Reference Information:
n/a
PATHOLOGY SPECIMEN DEFICIENCY FORM
Pacific Pathology Associates

DATE:

TO:

AT:

RE:

Problem:

☐ Requisition Form missing
☐ Specimen container missing
☐ Patient name not on the specimen container
☐ Discordant information between requisition form and container
☐ Other:

Please correct the problem cited above and return this form with corrected specimen and requisition to pathology

Resolved by (printed name):______________________________

Resolved by (signature):______________________________

Resolution:__________________________________________

Pacific Pathology Associates

Pacific Pathology Associates: 503.561.5350  fax 503.561.4781
Salem Health Courier Service phone: 503.561.5390 or 1.800.562.7542

Thank You