Purpose/Policy Statement:
The purpose of this policy and procedure is to provide increased patient safety with a standardized process for handling pathology (tissue) specimens, in addition to an electronic pathology requisition as part of the patient's electronic medical record.

Definitions:
• n/a

POLICY CONTENT

It is Salem Hospital policy to provide increased patient safety by utilizing a standardized process for handling pathology (tissue) specimens, in addition to an electronic pathology requisition as part of the patient's electronic medical record. A standardized chain of custody process and a consistent hand-off/drop-off location for all pathology specimens will also help create a stable and reliable method of delivering and receiving pathology specimens in the laboratory.

STEPS / KEY POINTS

I. All Specimens
   A. Retrieve the specimen(s) at a sterile field:
      1. Obtain a verbal order from the surgeon as to the specimen name and intended test;
      2. Enter the appropriate EPIC order for the specimen;
      3. Read back the surgeon order from the EPIC screen before signing the order; and
      4. Affix the printed patient identification label to the body (not the lid) of the specimen container.

   B. Obtain the specimen from the sterile field as soon as possible—(the specimen is not to be left on the back table):
      1. The circulating nurse receives the specimen in a manner which protects both the circulator and the specimen from contamination; and
      2. Depending on the type and size of the specimen, the circulating nurse may wear protective gloves, select appropriate container size, or engage in other behaviors which support safe collection.

   C. Place the specimen container into a specially designated plastic bag, and place a requisition form (for pathology) in the pouch in the plastic bag; make certain that the lid is on tightly.

   D. Be sure to advise the surgeon to obtain 2 separate specimens at the time of collection, when both pathology and microbiology are required; the laboratory will not accept a single specimen for both.
II. Tissue for Pathology

A. For frozen section/gross exam specimens for stat exam by a Pathologist:
   1. Do not use formalin;
   2. Do not immerse the specimen in saline—you may place it on saline-moistened telfa;
   3. Call an SA to transport the specimen directly to pathology;
   4. The SA will confirm the patient name and MRN with the circulator, assuring that the O.R. white board, the labeled specimen container and the pathology requisition all match;
   5. The SA will deliver the specimen to the designated collection area in pathology—(the target time is within 8 minutes of EPIC order signing);
   6. The SA will time-stamp the paper requisition, and the SA and the Laboratory Assistant will both sign, on the specimen log, the receipt of the specimen in pathology—this must be a person-to-person hand-off;
   7. After regular hours, (e.g., between 1700 and 0800 Mon.-Fri. and on weekends and holidays):
      a. The O.R. desk must notify the laboratory of a pending need for a pathologist—(call the laboratory supervisor at ext. 1-7475);
      b. The laboratory supervisor will notify the pathologist on call;
      c. The pathologist notifies the OR desk (ext. 1-5285) upon his/her arrival;
      d. The SA will transport the specimen to pathology and time stamp the requisition; and
      e. The SA and the pathologist will complete the log-in sheet.

B. For a routine pathology exam:
   1. Cover well with 10% formalin—use a prefilled formalin container whenever possible;
   2. Confirm the patient name, MR #, and source on the label of the specimen container and completed pathology requisition, with another source, (i.e., a white board, patient chart, etc.);
   3. The SA will take the specimen to the designated collection area in pathology, and will time-stamp and log it into the specimen log, including his/her employee number; and
   4. The work flow for routine specimens will be the same at all times, 24/7.

C. For oversized specimens, including amputated limbs:
   1. Deliver the specimen directly to pathology in a covered container or double plastic bags—clearly label both bags, and use a red bio-hazard bag for the outer bag;
   2. When pathology is not staffed, (nights, weekends and holidays), place the specimen and pathology requisition in the refrigerator in pathology—(contact the laboratory supervisor at ext. 1-7475 if access is needed); and
   3. Time-stamp the requisition and log specimen into the lab on the designated specimen log sheet.

D. For breast tissue:
   1. For a specimen for biopsy/lumpectomy/mastectomy:
      a. Process as a routine or frozen section, as ordered by the surgeon; and
      b. For needle placements (needle localizations):
         I. Use a grid card to collect the specimen—place a patient sticker on the card and a printed patient label on the bag—
            • The circulator will call mammography/ultrasound as indicated on their sheet; and
            • The SA will take the specimen, films and pathology requisition from the circulator to mammography/ultrasound and then to pathology—(should this occur when pathology is not staffed, the SA must return this specimen to the O.R. for the addition of formalin).
         II. If the surgeon chooses to send the specimen directly to pathology, follow the frozen section or routine specimen directions in sections II, A or B—(send the needle/wire in the specimen cup).
   2. Reduction tissue:
      a) When tissue is to go to pathology, handle it as a routine specimen (II, B) or oversized specimen (II, C);
      b) If liposuction contents are to be included with the tissue, divide equally or per the surgeon’s direction—(it is acceptable to add formalin to this mixture); and
      c) When tissue is discarded, double bag the tissue with a red exterior bio-hazard bag for disposal by housekeeping.
E. For “Lymph Node/Lymphoma Protocol,” (i.e., to rule out lymphoma, metastasis or an infectious process):
   1. Do not use formalin;
   2. Place the specimen in a sterile specimen cup—do not immerse the node in saline, although you may
      place it on saline-moistened telfa:
         a) Place the EPIC pathology order, and select the lymph node/lymphoma protocol; and
         b) Be certain to include indications for the protocol.
   3. Deliver the nodes to the pathology area immediately; this requires a person-to-person hand-off.
   4. After hours, refer to section II, A, 7, a-e.

F. For a sentinel node biopsy, (i.e., to look for metastatic breast cancer or a melanoma—usually with dye or a
   radioactive tracer):
   1. Do not use formalin;
   2. Do not immerse the node(s) in saline, although you may place it/them on saline moistened telfa;
   3. Use yellow radioactive tape on all specimens;
   4. Deliver the node(s) to the pathology/grossing area immediately; this requires a person-to-
      person hand-off.
   5. After hours, refer to section II, A, 7, a-e.

G. When moles or other small specimens are removed at the same time another, larger specimen is removed,
   send them to pathology in a separate, appropriately labeled specimen container.

H. For nerve/muscle biopsy:
   1. Inquire if the specimen needs special testing performed at OHSU—if it does not, handle it as you would
      any routine specimen for pathology.
   2. If the specimen needs special testing at OHSU:
      a) Confirm with the SH pathology department that the specimen will be transported to OHSU
         immediately after the procedure—the procedure should be completed before 10:30, and received
         in pathology by 11:00 so that the specimen can go to OHSU before 14:00;
      b) Place the specimen on telfa moistened with physiosol or normal saline;
      c) Place the specimen in a sterile specimen container; and
      d) Complete the pathology requisition slip and have the SA deliver the specimen directly to
         pathology; this requires a person-to-person hand-off.
      e) NOTE: Specimen can stay refrigerated overnight in saline moistened gauze (squeeze off any
         excess) and ship the next day. (Per Mary North – OHSU)

   **Procedure performed at Outside Institutions – can be sent to PPA for processing or sent directly to OHSU

   Send to: OHSU must receive by 14:00

   OHSU
   LAB CENTRAL – ROOM 3020 3RD FLOOR
   DILLEHUNT HALL (ACROSS THE STREET FROM MAIN HOSPITAL)
   3181 SW SAM JACKSON PARK RD
   PORTLAND, OR 97239

   NOTIFY OHSU - FLORENCE; 1.503.494.6781 X46781 TO LET HER KNOW YOU ARE SENDING A BIOPSY.
   FOR RESULTS CALL: 1.503.494.6775

I. Uterine contents from a suction machine:
   1. Collect the specimen;
   2. Plug the bottom of the disposable receptacle and place the specimen inside a second specimen
      container;
   3. Pour 10% formalin into the disposal receptacle, after placing it inside the second container;
   4. Plug the other end of the disposable receptacle; and
   5. Proceed with routine processing—(see section II, B).

III. Microbiology
   A. Surgical cultures: (All Surgical Cultures are to have an order entered into EPIC.)
   1. When specimens are sent for “surgical culture,” three studies are routinely done: aerobic, anaerobic and gram
      stain.
2. A gram stain alone may be ordered by the surgeon—(the surgeon may request aerobic and anaerobic studies to follow, if the gram stain contains organisms).

3. The best cultures come from tissue culture or syringe/fluid collection—encourage these, whenever possible:
   a) For a tissue culture:
      I. The scrub nurse places the tissue in a sterile container; and
      II. The circulating nurse:
         - Generates the order in EPIC;
         - Places the printed patient label on the container, including the date, the time, his/her initials, and the source;
         - Places the container in a specimen bag; and
         - Immediately delivers the specimen to specimen management in the laboratory; this requires a **person-to-person hand-off**.
   b) For syringe/fluid collection:
      i. The scrub nurse:
         - Removes the tip from an appropriately sized syringe;
         - Collects the fluid;
         - Tightly caps the tip of the syringe with a luer lock cap; and
         - Does not use a needle to cap the syringe.
      ii. The circulating nurse:
         - Generates the order in EPIC;
         - Places the printed patient label on the syringe, including the date, the time, his/her initials, and source;
         - Places the syringe in a specimen bag; and
         - Immediately delivers the specimen to specimen management in the laboratory; this requires a **person-to-person hand-off**.

4. Port-a-cul (for anaerobes) or when not enough fluid or tissue is present to obtain a specimen otherwise.
   a. The scrub nurse:
      i. Does not use the port-a-cul if the media in the port-a-cul has a purple color; otherwise,
      ii. Uses two swabs from the port-a-cul to obtain the specimen;
      iii. Places the swabs deeply into the port-a-cul media; and
      iv. Breaks off the ends of the swabs and replaces the cap.
   b. The circulating nurse follows the procedures in section III, A, 3, a&b, ii.

B. Urine cultures: order a “urine culture,” unless the surgeon specifies anaerobes and/or gram stain.

IV. Cytology
   A. Pap smears (slides), brushings, diaphragm, etc. –
      1. Write the patient’s name and MR # on the frosted end of the slide with a #2 pencil (no pen).
      2. Fixation – do not allow slides to dry in air:
         a. Place the slides in 95% ethanol as soon as possible;
         b. Place the slides back-to-back, so that the specimen is in contact with ethanol;
         c. Place the EPIC order;
         d. Place the printed patient label with the date, time, your initials and source on the container;
         e. **Also note** the last menstrual period and previous history on the order for cervical vaginal smears; and
         f. Deliver the specimen to the specimen management area in the lab at once—this requires a **person-to-person hand-off**.
   B. Fluids –
      1. Place the fluid in a sterile container.
      2. Estimate the amount of specimen (mls of liquid), and add an equal amount of saccomanno solution to it; place a "saccomanno" label on the container.
      3. If the specimen is also to be cultured, separate it and add the saccomanno solution only to the portion that is not to be cultured.
      4. For bronchial washings that go for culture as well as cytology, separate the specimen as indicated above, and add the saccomanno solution to the portion to be sent for cytology.
      5. Generate a computer order in EPIC.
      6. Deliver the specimen to the specimen management area in the laboratory at once—this requires a **person to- person hand-off**.
V. Rapid Sequence, Multi-Specimen Procedures
A. The charge nurse will, on a daily basis, identify scheduled procedures that routinely require many specimen order entries to be placed within a very short time frame, (i.e., bladder biopsies, sentinel node breast cases, etc.).
B. The charge nurse will plan for additional help to be in the room during the specimen collection/order entry portion of the procedure.
C. Additional help will arrive to the room, (any person assigned to help should communicate with the circulator as to how to be notified when the help is imminently needed), to attend to the needs at the sterile field or for anesthesia assistance while the primary assigned circulator performs the duties of specimen collection/order entry.
   1. If the above should occur during a procedure when it was not predicted, the circulator should make one phone call to the charge nurse and use the words, “I have multiple specimens and need assistance.”
   2. The charge nurse will find immediate help or be the person who arrives to the room to help.
   3. If this should occur during a procedure when no extra resource is available, (i.e., on a night shift when the circulator is the charge nurse), the option of using the downtime procedure may be considered.
D. In extreme circumstances, it is acceptable to use a permanent marker to temporarily number specimen containers, and paper to write the specimen order for read-back, and then perform the computer order entry as soon as the procedure will allow.

VI. Miscellaneous
A. Cerebrospinal Fluid (CSF) –
   1. Collect the CSF in a sterile tube.
   2. Generate a computer order in EPIC.
   3. The circulating nurse shall follow the procedure for syringe collection listed in III, A, 4, b.
   4. Deliver the sample at once to the specimen management area in the lab—this requires a person-to-person hand-off.
B. Kidney & ureteral stones (separate computer entry) –
   1. Place in a dry container.
   2. Label “for chemical analysis.”
   3. Generate a computer order in EPIC.
   4. Deliver the specimen to specimen management in the lab.
C. Sperm motility specimens –
   1. Place a drop of semen onto a sterile slide.
   2. Place a drop of sterile normal saline or physiosol on the specimen and hand it to the circulating nurse.
   3. Place a small glass slide cover on the slide and place the slide in a cardboard slide holder.
   4. Place the printed patient label on the cardboard slide holder and carefully place the cardboard holder inside a biohazard specimen bag—make sure to note the side, (Right or Left), on the label.
   5. Generate a computer order in EPIC—(Sperm Check Post Vas).
   6. Call x1-2234 to alert them that a vas reversal specimen is coming and ask for the name of the person that should receive this specimen—communicate this name to the SA doing the transport and ensure that there is a person-to-person hand-off to this “named” person in Hematology.
In order to ensure accurate disposition of tissue and/or foreign bodies removed in surgery, use the following guidelines:

I. Tissues to be Sent to the Pathology Laboratory

   A. Send all tissues removed in the operating room for gross and/or microscopic examination, with the following exceptions, which may be discarded or handled at the surgeon’s discretion:

   1. Arthroscopic shavings;
   2. Bone removed for exposure;
   3. Carotid plaque;
   4. Foreign bodies—(this includes bullets that, for legal reasons, are given directly to law enforcement representatives, to preserve chain-of-custody-see section III);
   5. Foreskin of a child less than 15 years old, removed at circumcision;
   6. Hernia sac;
   7. Intervertebral disc;
   8. Joint tissue removed during total hip or knee, or femoral head replacements, (excluding tissue from pathological fractures);
   9. Nasal bone and cartilage;
   10. Normal skin, bone or fatty tissue;
   11. Opaque lens, (cataract);
   12. Orthopedic appliances, (which may go home with the patient after terminal cleaning);
   13. Teeth, (which may go home with the patient);
   14. Therapeutic radioactive sources, the removal of which is guided by radiation safety monitoring requirements;
   15. Toenails;
   16. Tonsils or adenoids from a patient under 16 years old; and
   17. Varicose veins.

   B. Explanted Prostheses/Medical Devices:
      1. Send all explanted breast prostheses to pathology, where they are secured and retained for 3 years.
      2. Handle other explanted prostheses/medical devices at the surgeon’s discretion—(who may send them home with the patient).
      3. Documentation: Ensure that an explant form (Attachment B) is completed for all explanted prostheses/medical devices listed on the FDA’s list of tracked devices (Attachment C).

   C. In addition to the above-noted exceptions, the only tissues/body parts that may be sent home with patients are those requested for religious reasons—to facilitate this:
      1. Write the patient’s request on a pathology slip;
      2. Call the Hospital Medical Director; and
      3. Call the Director of Laboratory Services.

II. Tissue Submission – submit bilateral specimens separately.

III. Bullets Removed in Surgery

   A. Bullets could be evidence in potential lawsuit cases.
   B. The O.R. nurse who observes removal of a bullet must transfer same directly to the police officer, (if available or, if not, to the surgeon).
EXPLANT FORM
Medical Device Tracking Report

Patient’s Name: ,

Last, First M.I.

Patient’s Address:

City: , State: Zip:

Patient’s Telephone Number:

Patient’s Social Security No.

Explanted Device Description (as much information as possible)

Explanted Device Manufacturer
Name:

Explanted Device Model No.:

Explanted Device Serial No.:

Explanted Device Lot No.:

Explanting Surgeon:

Explanting surgery Date:

If Known,

Implanting Surgeon’s Name:

Implanting Facility:

Implanting Surgery Date:
FDA has issued orders to manufacturers who are required to track the following implantable devices:

- Glenoid Fossa prosthesis
- Mandibular condyle prosthesis
- Temporomandibular Joint (TMJ) prosthesis
- Abdominal Aortic Aneurysm Stent Grafts
- Automatic implantable cardioverter/defibrillator
- Cardiovascular permanent implantable pacemaker electrode
- Implantable pacemaker pulse generator
- Replacement heart valve (mechanical only)
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pumps
- Silicone Gel-Filled Breast Implants
- Cultured Epidermal Autografts

FDA has issued orders to manufacturers who are required to track the following devices that are used outside a device user facility:

- Breathing frequency monitors
- Continuous Ventilators
- DC-defibrillators and paddles
- Ventricular Bypass (assist) Device

**Equipment/Supplies (If Applicable):**

na

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

Surgpath01.01

**Author Position:**

Operation Manager

**Review/Revision Authority (Position Not Individual Name):**

Medical Director, Operation Manager, Safety Officer, Pathologist Assistant

**Expert Consultant Position/s (Not Individual Name/s):**

na

**References (Required for Clinical Documents):**

na

**Is there a Regulatory Requirement? Yes □ No □**

If yes, insert requirement information here:

**Review History (No Changes):**

na

**Revision History (Note changes in area under header):**

na

**Computer Search Words:**

na

**Policy, Procedure or Protocol Cross Reference Information:**

na