


Standard Operating Procedure Document ID : SOP-TR-020 Version number: 2.0	
Category: Material Handling and Documentation	Effective Date : 17/Jan/2013
COLLECTION OF BREAST BIOPSY	

1. PURPOSE

This SOP is to standardize the collection, processing, handling and storage of needle core biopsy samples of breast tumour tissues.


2. SUPPLIES

- 14-gauge or 16-gauge Side-notch Tru-cut biopsy needle instrument
- Sterile tweezers
- RNAse Away
- KimWipes
- 3 barcoded cryovials empty
- 1 jar with Formalin (10%)
- 3 Sterile needles
- Gloves
- Liquid nitrogen
- Liquid nitrogen container
- Requisition form and pen
- Biohazard waste containers

3. PRECAUTIONS

Gloves must be worn at all times when handling specimens. Tissue material is considered a biohazard and should be handled using universal precautions according to local Health and Safety rules.

Liquid nitrogen must be handled carefully to avoid injury to the user. Liquid nitrogen is generally treated as a relative benign substance, but can produce serious freezing damage if trapped inside gloves, shoes or other articles of clothing. If liquid nitrogen is spilled onto bare skin, its rapid evaporation usually results in minimal damage. The gaseous form of nitrogen can be dangerous, if liquid nitrogen tank is stored in a small room without adequate ventilation.

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4. WORKING PROCEDURES

Pre-procedure:

1. Patient must have a normal coagulation profile.
2. The radiologist or surgeon must have reviewed the patients imaging scan to determine if the biopsy is feasible.
3. The patient must be advised to stop taking aspirin or any other NSAID (ex. ibuprofen or naproxen) three days prior to the biopsy.
4. The coordinator will schedule a date for the breast biopsy with the local radiologist or surgeon and will be present during the procedure to process the samples.

Biopsy Procedure


Tumour tissue from the breast lesion can be removed by needle core biopsy either by the radiologist under radiologic guidance or by the surgeon without radiological guidance. The use of radiological guidance is left to the surgeon's discretion except for the post-treatment biopsy where radiological guidance is mandatory.

The biopsy guns that can be used are listed below:

- 16-gauge Side-notch Tru-cut biopsy needle
- 14-gauge Side-notch Tru-cut biopsy needle

A total of four needle core biopsies will be performed at the periphery of the mass away from any necrotic areas.

1. The study coordinator must prepare labelled vials and the jar prior to the biopsy procedure. Containers should be well labelled with the patients' study number, initials, date of birth, biopsy date, and visit name (Banking-Pre or Banking-Post).


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2. The study coordinator must be present at the biopsy and must bring to the procedure gloves, KimWipes, RNase Away, tweezers, sterile needles, 3 empty cryovials, and 1 jar containing formalin, labels (4), a pen and the biopsy requisition form. During the preparation of the patient, the study coordinator can spray the tweezers with RNase Away and wipe any excess with KimWipes. GLOVES SHOULD BE WORN AT ALL TIMES TO PREVENT SAMPLE CONTAMINATION.

3. The radiologist or surgeon will perform the biopsy. The coordinator will note the time of biopsy #1 on the provided requisition form. The coordinator, using a sterile needle, will carefully take the biopsy specimen from the biopsy needle and deposit the sample in one empty cryovial. The cryovial should be tightly closed and immediately immersed in liquid nitrogen. The coordinator will remove the lid of the liquid nitrogen container and set to one side, and immediately will hand plunge the vial into the liquid nitrogen container. Replace the lid and close the container to avoid evaporation. The coordinator will enter the time the cryovial was placed in liquid nitrogen on the provided requisition form (REPEAT FOR BIOPSIES #2 and #3). The anatomical region where the biopsies were collected should be noted in the requisition form.

4. The radiologist or surgeon will perform the fourth biopsy. The coordinator will note the time of biopsy #4 on the provided requisition form. The coordinator, using a sterile needle, will carefully take the biopsy specimen from the biopsy needle and deposit the sample in the jar containing formalin. The sample should be gently inverted so that the biopsy is completely submerged in formalin. The coordinator will enter the time the biopsy was placed in formalin on the provided requisition form. The cryovial should be tightly closed and kept at 4°C.

5. IMPORTANT – The order of biopsy collection and processing should be respected: the FIRST, SECOND and THIRD biopsies should be snap frozen, and the FORTH biopsy should be placed in formalin and kept at 4°C.

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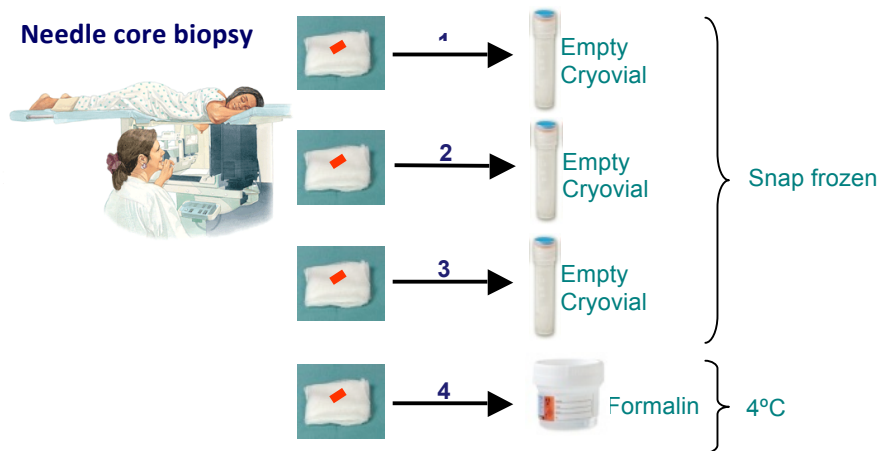


Figure 1 – Biopsy Samples

Post-Procedure:

1. Samples in the empty cryovials should be immediately transferred from the liquid nitrogen canister to a -80°C freezer or liquid nitrogen tank in a labelled box until ready for shipping. Shipping to the Jewish General Hospital can be arranged when several samples have been collected. Please contact the project manager and the CRA receiving the biopsies PRIOR to shipment to confirm proper receipt of the biopsies and follow the shipping procedure in SOP-TR-005. Samples should be shipped no later than Wednesday.
2. Biopsy sample collected in formalin should be shipped at 4°C the same day as the day of collection. If the biopsy is collected on a Friday, the sample should be stored at 4°C and shipped on the following Monday. Please contact the project manager and the CRA receiving the biopsies PRIOR to shipment to confirm proper receipt of the biopsies and follow the shipping procedure in SOP-TR-006.