Policy: Processing of Specimens for Molecular Pathology

Purpose:
1.0 To guide the staff in physician practices located outside of NYULMC in the safe and proper collection of all molecular pathology specimens.
   1.1 Internal submissions should reference the NYU Interdisciplinary Process Standard.
2.0 To provide accurate and timely information to the provider for notification of patients.

Supportive Data:
1.0 Hours of Operation:
   1.1 The Molecular Pathology laboratory is located on the third floor of Tisch Hospital TH-338 & TH-343. Address: 560 First Avenue, Tisch Hospital Room 338, New York, NY 10016.
   1.2 The Laboratory hours are 9:00 am – 5:00 pm Monday – Friday; and the laboratory is closed on weekends and holidays.
   1.2.1 Send specimens immediately when obtained from any physician offices to the laboratory room TH-338, for processing during the operating hours above.
   1.2.2 Specimens for these labs are optimally to be received during the operating hours stated. If the clinical staff anticipates that the specimens cannot/won't be delivered during the hours of 9 – 5 on weekdays, then the lab needs to be called (212-263-3905 or 212-263-5910) prior to the procedure and within the laboratory hours of operations to see what can be done. The lab may not be able to accept the specimen and this may affect the viability of the specimen and/or the timeliness of the result reporting.

2.0 Specimen Labeling and Delivery:
   2.1 Please call 212-263-5967 for courier information if needed.
   2.2 Transport all molecular pathology specimens to the laboratory in a plastic sealable biohazard bag.
   2.3 Label the specimen container with:
      2.3.1 Two patient identifiers (patient first, last name and date of birth), and
      2.3.2 Specimen information as follows:
         2.3.2.1 Specimen type,
         2.3.2.2 Site of origin (if appropriate),
         2.3.2.3 Fixative (if appropriate), and
         2.3.2.4 Referring physician.
   2.4 Submit the specimen with a completed Hematopathology & Molecular Pathology Requisition Form.
      2.4.1 Obtain the Hematopathology & Molecular Pathology Requisition Forms by calling 212-263-5967, or
      2.4.2 Download the form from the link:
      http://pathology.med.nyu.edu/files/Molecular_Pathology_Requisition_Form.pdf
   2.5 The form must be signed by an authorized requester (referring clinician) with the following information documented on the requisition:
      2.5.1 Two forms of patient identification (first/last name, date of birth),
      2.5.2 Patient demographic information,
      2.5.3 Clinical information,
      2.5.4 Type of primary sample and site origin,
      2.5.5 Date and time of collection,
      2.5.6 Name of individual who collected the specimen,
      2.5.7 Referring clinician information,
      2.5.8 Test examination(s) requested by the clinician.
   2.6 Note that the Molecular Pathology Laboratory has detailed information describing the test indication, description, and specimen requirements for each test offered in this lab. This information can be readily provided by calling 212-263-3905 with the request.
2.7 These specimens may be obtained by registered nurses, e.g., peripheral blood, or licensed independent professionals who have delineation of privileges to perform the procedure, e.g., bone marrow, or tissue biopsies.

3.0 Specimen Submission Requirements for Molecular Pathology:

3.1 The Molecular Pathology Laboratory performs PCR-based assays. The specimen requirements by test are:

3.1.1 Peripheral blood, bone marrow, fresh tissue or paraffin shavings/unstained slides are acceptable for the following:

- 3.1.1.1 B-cell gene rearrangements,
- 3.1.1.2 Bcl1,
- 3.1.1.3 Bcl2,
- 3.1.1.4 EBV,
- 3.1.1.5 T-cell receptor gene rearrangements,
- 3.1.1.6 HHV8,
- 3.1.1.7 HTLV.

3.1.2 Peripheral blood or bone marrow is acceptable for the following:

- 3.1.2.1 JAK2,
- 3.1.2.2 FLT3,
- 3.1.2.3 NPM1,
- 3.1.2.4 BCR-ABL CML (quantitative),
- 3.1.2.5 BCR-ABL CML (qualitative),
- 3.1.2.6 BCR-ABL ALL,
- 3.1.2.7 PML-RARA,
- 3.1.2.8 AML1-ETO.

3.1.3 Peripheral blood and tissue biopsy are both required for:

- 3.1.3.1 1p19q LOH.

3.2 The requirements by specimen category are:

3.2.1 Peripheral blood (PB) or Bone marrow (BM):

- 3.2.1.1 2 to 5 ml Purple or Green top tubes < than 7 days old,
- 3.2.1.2 Preferably refrigerated,
- 3.2.1.3 Volumes < 1 ml might not yield satisfactory reportable results.

3.2.2 Paraffin embedded specimens:

- 3.2.2.1 Paraffin shavings (PS) 4x10 micron scrolls, or
- 3.2.2.2 4x10 microns Unstained slides, or
- 3.2.2.3 Paraffin Block.

3.2.3 Fresh Tissue (FT):

- 3.2.3.1 Saline, or
- 3.2.3.2 Culture media, and
- 3.2.3.3 Refrigerated.

3.3 The Molecular Pathology Laboratory performs Fluorescence in situ hybridization (FISH) assays. The specimen requirements by test are:

3.3.1 Her 2 FISH

- 3.3.1.1 Time from tissue acquisition to fixation should be as short as possible.
- 3.3.1.2 Samples should be placed in sufficient volume of neutral buffered formalin.
- 3.3.1.3 Fixation for <6 hours or >48 hours is not recommended prior to FISH.
- 3.3.1.4 Time to fixation and duration of fixation, if available should be recorded for each sample.
- 3.3.1.5 Exposure of the specimens to acids, strong bases, or extreme heat, should be avoided.
- 3.3.1.6 Selection of tissue for testing should be performed by a trained pathologist. The pathologist will use a corresponding H&E slide to identify and mark the tumor region.
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3.3.1.7 Paraffin-embedded tissue specimens should be mounted in sections between 4 and 6 microns thick onto positively charged or organosilane-coated slides.

3.3.2 **UroVysion FISH**

3.3.2.1 The UroVysion Kit should be used; it is designed for use on **voided urine specimens**.

3.3.2.2 Perform urine collection (≥33 mL).

3.3.2.3 Mix voided urine 2:1 (v:v) with preservative; Carbowax (2% polyethylene glycol in 50% ethanol) or PreservCyt® preservatives (available within a Urine Collection Kit) are recommended.

3.3.2.4 Transfer to a 50 mL centrifuge tube(s) or other tightly-capped plastic container.

3.3.2.5 If urine is not shipped immediately after collection, refrigerate immediately and ship via overnight courier within 24 hours.

3.3.2.6 The preferred storage and shipping conditions are on ice packs, but specimens may be stored and shipped at temperatures up to 25°C. Urine stored in Carbowax or PreservCyt under these conditions has been shown to be stable for 1 week.

3.3.2.7 However it is recommended that specimens be processed to the point of fixed cell pellets within 72 hours of collection. Performance characteristics of the UroVysion test under any other conditions must be determined and validated by the user.

4.0 **Inadequate or Inappropriate Specimens:**

4.1 Specimens are designated inadequate or inappropriate and therefore rejected if any of the following conditions exist:

4.1.1 Requisition is not filled out correctly and/or not signed by an authorized person.

4.1.2 Incomplete or unclear labeling of the specimen.

4.1.3 Name or birth date on the specimen container or slide does not match the name or birth date on the requisition.

4.1.4 Peripheral blood or bone marrow specimens are older than 1 week.

4.1.5 Insufficient volume (Less than 1 ml of peripheral blood)

4.1.6 Specimens are clotted or hemolyzed.

4.1.7 Urine specimen is older than 72 hours

4.1.8 Urine specimen is not fixed in recommended preservatives

4.1.9 Specimen not prepared appropriately as described in specimen submission instructions

4.1.10 Specimen preparation and/or storage are not optimal.

4.2 When any of the unsatisfactory conditions are noted as above, the Molecular Pathology Laboratory notifies the physician by telephone and the condition is documented in the final report.

4.3 Notify the laboratory at 212-263-3905 or 212-263-5910 if

4.3.1 There is a question concerning either the availability of a particular test or

4.3.2 The suitability of a specimen.

4.3.3 Do not discard any specimens without this verification.