UNACCEPTABLE / SUBOPTIMAL SPECIMEN PROTOCOL

**Purpose:** To provide a protocol for management of unacceptable/suboptimal specimens, relating to deficiencies in identification and/or physical properties.

**Policy:** The Department of Pathology may reject requests for analysis of a specimen not meeting criteria based on issue(s) with specimen integrity or specimen identification. Alternately, a process is provided by which specimens deemed irreplaceable by the physician, but can still be processed without damaging equipment, must be handled including, but not limited to, appropriate notification/documentation.

I. Specimen Rejection Criteria:

1. **Specimen Labeling:**
   a. Any specimen received unlabeled or improperly labeled.
   b. Specimen labeling requirements include, but are not limited to, the following:
      - Patient Name
      - Medical Record Number
      - Patient Date of Birth or Age
      - Identification Information for LSUHSC-S must agree with the HIS data.
      - Collect Date and Time (*)
      - Initials or Tech Code of person collecting specimen (*)
      - Specimen Source - On applicable specimen types i.e., cultures, biopsies, etc. (*)
   c. Clinical Pathology: All elements are addressed on the specimen container.
   d. Anatomic Pathology: Designated elements (*) are listed on the requisition form, other elements on the specimen container.
   e. Blood Bank specimens require use of a Typenex label according to Nursing Policy and Procedures Manual, Policy B-12, Typenex ID Bands.
   f. If label on specimen is incomplete, mislabeled, or missing (unlabeled), Pathology Central Processing personnel will notify one of the following via telephone that the specimen will be rejected due to a labeling irregularity:
      a. Nurse
      b. Ordering Physician
      c. Person Collecting Specimen
   g. If challenged by physician, the challenge will be referred to the Medical Director, Technical Director, Supervisor, or Senior Technical Staff. This person will make the final decision on the rejection of the specimen.
2. Specimen Container / Tube Type / Fixative:
   a. Specimen collected in an inappropriate container (e.g., test requiring sterile container but submitted in non-sterile container).
   b. Specimen collected in an inappropriate tube type (e.g., blood submitted in red-top tube when test requires tube containing anticoagulant).
   c. Specimen collected in inappropriate fixative (e.g., saline instead of formalin).
      1) Specimens placed in formalin need to be labeled with formalin label.
      2) Specimen submitted in saline should be noted on container.
      3) Specimen not in contact with fixative (e.g., specimen dried out).

3. Specimen Volume:
   a. Insufficient specimen / tissue to meet minimum specimen requirements.
   b. Inadequate volume such that blood to anticoagulant ratio is incorrect.

4. Specimen Special Handling:
   b. Specimen exposed to light when light sensitive.
   c. Specimen failed to be maintained at required temperature.

5. Specimen Integrity:
   a. Criteria affecting viability and accuracy of analysis are assessed within technical areas.
   b. Appropriateness of testing is a technical judgment of licensed staff. Specimens assessed as unsuitable for testing will be rejected.
   c. Broken or crushed slides sent for consultation are unacceptable in providing accurate analysis / consultation.
   d. Fresh Specimens submitted to Anatomic Pathology:
      a) Sputum, bronchial aspirate, or mucocele fluid: Specimens with high mucus content may be preserved for 12 to 24 hours, if refrigerated. Specimens without thick mucus or specimens diluted with saliva are not as well protected and may deteriorate more rapidly if not immediately transported.
      b) Pleural, peritoneal, or pericardial fluids: Specimens with high protein content may be preserved for 24 to 48 hours without refrigeration.
      c) Urine or cerebrospinal fluid: Specimens with low mucus or protein content will endure only a 1 to 2 hour delay, even if refrigerated. Note: Refrigeration may inhibit bacterial growth but does not protect the cells.
      d) Gastric material: Specimens with low pH must be collected on ice and be prepared within minutes of collection to prevent cellular destruction by hydrochloric acid.
6. Specimen Transport Time:
   a. Specimens should be transported to Pathology Central Processing within the acceptable time frame for the specific test ordered.
   b. Preferred Collect to Receipt Time for Clinical Pathology specimens is one hour or less to ensure specimen preservation, facilitate proper handling, and improved TAT’s. Exception: Specimens submitted for tests requiring extremely rapid transport to preserve specimen integrity.
   c. Customers should refer to the Pathology Policy and Information Manual on the LSUHSC website for specific testing information or call listed contacts and/or specific technical sections for assistance.

II. Specimen Rejection Procedure
   1. Pathology personnel will notify one of the following via telephone that the specimen will be rejected along with reason for rejection:
      a. Nurse
      a. Ordering physician or
      b. Person collecting specimen
   2. Pathology personnel will instruct individual to key in a new order and recollect the specimen where appropriate.
   3. Computer Documentation:
      a. Order received in LIS (Sunquest or CoPath).
      b. Order credited in LIS with documentation via appropriate English text code or free text indicating reason rejected, person notified, and of personnel rejecting the specimen.
      c. A Variance report should be completed by Pathology staff when applicable.

III. Irreplaceable Specimens

1. Specimen Acceptability:
   a. Irreplaceable specimens will not be rejected.
   b. Challenge by physician regarding irreplaceable status:
      a) Will be referred to Medical Director, Technical Director, Supervisor, or Pathology Senior Technical Personnel.
      b) One of the above will make the final decision on rejection of specimen.
      c) If rejected, challenging physician is notified of decision.
      d) If accepted, Acceptance of Responsibility form must be completed.

2. Irreplaceable specimen types:

| Abdominal Fluid | CSF | Suprapubic Aspiration |
| Abdominal Fluid | CSF | Suprapubic Aspiration |
| Amniotic Fluid  | Cyst Aspirate | Surgical /Biopsy Specimen |
| Ascitic Fluid   | Cytology Biopsy | Synovial Fluid |
3. Specimen Processing Responsibility:
   a. Acceptance of Responsibility form (attached to this policy) is provided by Anatomic or Clinical Pathology Central Processing areas (as appropriate).
   b. Form must be signed in appropriate Anatomic Pathology Central Processing area or appropriate clinical laboratory section; e.g., Central Processing, Out Patient Laboratory, Trauma Laboratory, by the person accepting responsibility for specimen.
   c. In extenuating circumstances when the person who collected the sample is not available, the form may be signed by other appropriate health care provider.
   d. Completed forms are maintained:
      a) Anatomic Pathology – attached to requisition and is retained in Patient Client Service area.
      b) Clinical Pathology – retained in applicable technical sections.
      c) Documentation is retained for a minimum of two (2) years.

4. Documentation:
   a. Irreplaceable specimens requiring an Acceptance of Responsibility signature are documented in appropriate LIS via English Text Code(s) and/ or free texting:
      a. Anatomic Pathology – at the time of accessioning in Co-Path.
      b. Clinical Pathology - at the time of test resulting.
      c. Note reason, name of person who signed form, and individual’s name that authorized form be signed.

License Director Approval:

____________________________ ____________________________
Stephen M. Bonsib, M.D./Director, Department of Pathology Date

Division Approval:

____________________________ ____________________________
Jaiyeola Thomas, M.D./Medical Director, Anatomic Division Date

____________________________ ____________________________
James Cotelingam, M.D./Medical Director, Clinical Division Date
LSUHSC-S, Department of Pathology Laboratories

ACCEPTANCE OF RESPONSIBILITY

Date: ___________   Patient Name: __________________________________  Medical Record No._________________

Specimen Type: ______________________ Test(s) Ordered: ________________________________________________

Describe the Labeling Identification Error:
Types of Identification Errors:
☐ (a) mislabeled specimen: (wrong patient name/medical record number, etc.)

☐ (b) incompletely labeled specimen (missing information, e.g. DOB/age, collect date/time, collector initials) 

☐ (c) unlabeled specimen: 

☐ (d) requisition/specimen patient ID disagreement

_________ I collected this sample(s) and accept full responsibility for the identity of this specimen. The Clinical Laboratory accepts responsibility for validity of test results ONLY.

___________________________ collected this sample(s), but due to extraneous circumstances, is unavailable to sign this form. Though I did not actually collect this sample(s), I am knowledgeable about its collection and accept full responsibility for its identity. The Clinical Laboratory accepts responsibility for validity of test results ONLY.

Print Name                                                                                          Signature
Physician _______   RN _______   LPN _______

Describe the Transport Error.
Types of Transport Errors:
☐ (a) failure to meet critical transport times affecting test results, e.g. Ammonia, Lactic Acid, CSF cell count.

☐ (b) failure to meet special handling requirements, e.g. placed on ice, protected from light.

Describe Suboptimal Specimen Integrity with a potential to affect test results

Examples of suboptimal specimen integrity
☐ (a) hemolysis
☐ (b) lipemia
☐ (c) under-filled / over-filled specimen container tube
☐ (d) other (please specify) ______________

I acknowledge ☐ transport errors and/or ☐ suboptimal specimen integrity issues possibly affecting test results. However, testing is requested. I accept responsibility for use of the resulting information in care of the patient.

Print Name _______________________________________      Signature ____________________________________
Physician _______   RN _______   LPN _______

Authorized by:  ____________________________________    ____________________________________________

Print Name                                                          Signature
Lab Staff____  Supervisor_____  Senior Technical Staff_____  Medical Director_____  Technical Director_____