QA.SPEC.2.0 UNACCEPTABLE SPECIMENS—IDENTIFICATION AND RECOLLECTION

PURPOSE

To establish a procedure for evaluating specimen acceptability, requesting a recollection, processing and tracking the new specimen request. This policy addresses the pre-analytical process for evaluating specimen acceptability. Handling of mislabeled and unlabeled specimens is covered in MACL policies QA.SPEC.3.0 and QA.SPEC.4.0.

SCOPE

This policy applies to all MACL laboratory and PCC facilities.

POLICY OWNERS

QA and Safety Officer

RELATED DOCUMENTS

QA.SPEC.1.0 Specimen Collection—Verification of Patient Identification
QA.SPEC.3.0 Specimen Labeling—Mislabeled and Unlabeled—Hospital Registered Patients
QA.SPEC.4.0 Processing Mislabeled and Unlabeled Specimens for Non Hospital-Registered Patients

TEXT

A. Specimen Rejection—Specimens may be rejected whenever there is a reason to suspect that the test results will be compromised or inaccurate due to specific conditions. Each specimen should be evaluated before testing.

1. Evaluate specimen for integrity and correct labeling. If the specimen that is being evaluated is unacceptable, determine whether multiple tubes were drawn on the patient with the same collection time. These specimens, if acceptable, may be utilized to complete testing.
2. In the event that testing cannot be performed on an irreplaceable specimen, the physician, nursing unit or other authorized patient care giver should be notified immediately. If unable to contact an appropriate individual, the physician must be paged. An Everest concern should also be initiated. MACL's System Medical Director and QA and Safety Officer should also be notified if the inability to perform testing on an irreplaceable specimen results in a life threatening situation.

Irreplaceable Specimens

- Cultures, any source (Note: CT/GC, BV and other DNA probe tests are not considered irreplaceable)
- Body cavity fluids: amniotic, pleural, peritoneal, pericardial
- Cerebrospinal fluid (CSF)
- Timed Specimens (eg, pre and post TDM, stimulation testing; excludes easily recollected samples such as post-prandial glucose)
- Pediatric Venipunctures
- Microtainer Venipunctures
- Stone analysis
- Products of Conception (POC) for chromosome analysis
- Biopsies and Other Surgical Specimens
- Bone Marrow
- All fine needle biopsies or aspirations including synovial
- Lavages, washings and brushings (bronchial, esophageal, bladder, etc)
- Cytology Specimens

B. Specimen Rejection Criteria—The laboratory may reject

specimens with improper specimen handling or processing or specimens that were collected improperly.

1. The following specimen types are not acceptable for testing and may be rejected
    a. Clotted CBC tubes
    b. Coagulation tubes with insufficient volume
    c. Urinalysis specimens in gray top tubes (microscopics may be performed)
    d. Specimens drawn in the incorrect anticoagulant
    e. Clotted blood gas specimens
    f. Insufficient volume to perform ordered testing (QNS)
    g. Specimens that were improperly processed
        (1) Ammonia
        (2) Lactic acid
    h. Grossly hemolyzed specimens
    i. Microbiology specimens not in proper collection media

C. Department Specific Rejection Criteria
1. Chemistry
    a. Refer to specific instrument methodology for specimen requirements.
2. Hematology
    a. Lavender tubes should have a minimum of 2 mL of blood in a 5 mL tube.
    b. Blue top coagulation tubes should be full, well mixed and contain no clots. Unspun tubes should be kept at room temperature delivered to the laboratory within 24 hours of collection.
    c. Blue top coagulation tubes collected on patients with a hematocrit of 55% or greater should be recollected using a different blood to anticoagulant ratio. Contact Regional Special Coag or hospital site where the specimen was collected for further information.
    d. Urinalysis specimens
        i. If received in a gray top culture tube will only be tested for microscopic analysis.
        ii. Urinalysis specimens with no preservative should be tested within two hours of collection if kept refrigerated.
        iii. Urinalysis specimens with preservatives should be tested within 72 hours of collection if kept at room temperature.
    e. Reticulocyte counts should be kept at room temperature and tested within 36 hours of collection.
    f. Urine Eosinophil counts should be kept at room temperature and tested within 24 hours.
3. Immunology
    a. ANA, RPR and HIV test specimen rejections
        i. Hemolyzed specimens
4. Microbiology
    a. Specimens received in grossly contaminated containers may be rejected.
    b. Diapers submitted for O & P and fecal culture will be rejected.
    c. Formed stools submitted for Cryptosporidium testing will be rejected.

d. Stool cultures, O & P, and fecal polys not collected in transport media will be rejected.
e. Anal swabs for O & P will be rejected.
f. Sputum specimens will be rejected if the sample contains >25 epithelial cells per low power field. Sputum specimens submitted on swabs will be rejected.

5. Molecular
   a. BD ProbeTec (SDA) *Chlamydia trachomatis* and *Neisseria gonorrhoeae* test specimen rejections
      i. No swab in tube
      ii. White swab in tube
      iii. Two swabs in tube
      iv. Non-BD swab in tube
      v. Sources other than endocervical, male urethra, Urine, or self-collected vaginal
      vi. Urine tube overfilled or underfilled
      vii. Leaking specimen
      viii. Improper collection device for specimen source submitted
      ix. Any expired specimen
   b. Digene Hybrid Capture 2 HPV DNA test specimen rejections
      i. Pap smear liquid based media vials with less than 2 mL of fluid and/or received 21 days post collection.
      ii. Any non-ThinPrep or non-Digene DNA collection device
      iii. Any expired specimen
   c. BD Affirm VPIII (BVV) test specimen rejections
      i. Any non-BD Affirm tube
      ii. Any non-BD swab in tube
      iii. Specimens containing glass fragments from ampule used during collection
      iv. Incorrect source
      v. Any expired specimen
      vi. No swab in tube
   d. Group B Strep PCR and MRSA PCR specimen rejections
      i. Incorrect collection device
      ii. Incorrect specimen source
      iii. Any expired specimen
   e. *C difficile* by PCR test specimen rejections
      i. Frozen specimen
      ii. Specimen in vial containing preservative
      iii. Formed stool (does not take the shape of the container
      iv. Any expired specimen
   f. Factor V Leiden and Factor II PCR test specimen rejections
      i. Spun specimen
      ii. Incorrect specimen tube
      iii. Any expired specimen
   g. Respiratory Virus Panel (RVP) PCR test specimen rejections

i. Incorrect collection device
ii. Nasal source, bronchial washing
iii. Incorrect collection device
iv. Any expired specimen
v. No swab in tube

h. HSV 1 and 2 PCR, CMV PCR specimen rejections
i. Plasma spun from tube > 6 hours from collection
ii. Incorrect collection device
iii. Any expired specimen

i. Group A Strep Direct test specimen rejections
i. Incorrect collection device
ii. Any expired specimen

6. Cytology
a. PAP Specimens may be rejected if
i. Specimens not collected in FDA approved liquid based pap collection media
ii. Glass slide specimens broken beyond repair

7. Flow Cytometry
a. Green top tubes should be kept at room temperature

D. Notification of specimen rejection and recollection requests
1. Inpatients (all units within a given hospital).
a. Laboratory processing or testing personnel will contact the nursing unit to explain why testing could not be performed on the submitted specimen and to request a new order and a new specimen.
b. The order for which an unacceptable specimen was submitted will be credited in Sunquest, by laboratory personnel with an appropriate comment.
c. The tests will be re-ordered by the nursing unit in the appropriate hospital computer system.

2. Outpatient, non-hospital registered and discharged inpatients analyzed at an HBL.
a. Hospital based PCC associates will notify the physician's office or the patient directly to explain why testing could not be performed and to request a new specimen. If applicable, a new order must also be requested. The original accession number should be credited in Misys and the tests reordered when the recollected specimen is received. If applicable, the test should be resulted out as Test Not Performed (TNP'd) in QLS.
c. If the physician requests that the test be cancelled, credit the accession number in Sunquest with an appropriate comment.

3. Outpatient, non-hospital registered and discharged inpatient specimens analyzed at Regional Laboratory.
a. If the wrong specimen or wrong media is submitted, the Regional testing department will order a Test in Question (TIQ). For all other rejections, Regional Specimen Management, Client Services, or testing personnel will complete a Request for Recollect Form.

b. The test that cannot be performed will be credited in Sunquest with an appropriate comment and/or TNP'd in QLS as applicable.

c. The Request for Recollect Form will be forwarded to the appropriate area (either a MACL draw site or Client Services to notify client and patient within 24 hours of original specimen collection (and no later than 72 hours of collection time for "no specimen received:" in testing department).

   i. If the recollect involves a send-out test, the Referral Testing Department will complete the Request for Recollect Form and notify the client or draw site where the original specimen was collected. The Referral Testing Department will also TNP the test in QLS and credit in Sunquest as applicable.

   ii. If the patient was originally drawn at a MACL draw site and involves a non-send-out test, CRC will TNP in QLS if applicable, call and fax the form to the draw site. The draw site will notify the physician of the need for a recollect (if Client Services, TIQ, or testing department have not already done so), explain the reason (i.e., hemolysis, QNS, wrong specimen), apologize and proceed to contact the patient.

   iii. If the patient was originally drawn by the client and involves a non-send-out test, Client Services will notify the physician of the cancellation (if TIQ or testing department have not already done so), and explain the reason of the recollect. However, if the cancellation is due to possible lab error (i.e., specimen poured off, broken in transit, missed test), Client Services will also proceed to contact the patient for a recollect. Client Services will then call and fax the recollection request to the appropriate draw site.

d. The test will be reordered when the recollected specimen is received.

E. Hospital registered patients (inpatient and outpatient) must be credited in Misys within three days of registration.

F. If the physician requests that testing be performed on the existing questionable specimen, testing will be performed with appropriate computer documentation of the requesting physician and the condition of the specimen.