Title	Specimen Collection and Handling
Document ID	Quality-SOP-00012
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PURPOSE

To provide guidelines to ensure that laboratory tests are correctly ordered and specimens are correctly collected and handled so the integrity of specimens is maintained to ensure the delivery of results, which are accurate, reliable and reflective of a patient's condition.

REGULATORY GUIDELINES

College of American Pathologists Checklist 06/04/2020

- Requirement ID
    - GEN.40016, GEN 40050, GEN.40100, GEN.40125, GEN.40460, GEN.40470GEN.40490, GEN.40491, GEN.40492, GEN.40499, GEN.40501, GEN.4052to GEN.40509, GEN.40511 to GEN.40545, GEN.40700 to GEN.40942, COM.06000 to COM.6300

New York State Department of Health: Clinical Laboratory Standards of Practice

- Standard
    - QMS S1, QMS S3, LS S7, LIS FS, PRS FS, TR S1, TR S4, SP S1 to SP S8, RCL S1 to RCL S4, TPC S1

SCOPE

This document applies to all samples collected for testing within the Clinical Laboratory.

RESPONSIBILITIES

Personnel involved in collecting, transporting, and testing specimens within the Clinical Laboratory, follow these procedures.

REFERENCES

CLSI Document H42-A2 Vol 27 No. 16. Enumeration of Immunological Defined Cell Populations by Flow Cytometry; Approved Guidelines – Second Edition 2007.

SAFETY PRECAUTIONS

All procedures are performed under Universal Safety Precautions.

PROCEDURE

Patient Preparation

1. No specific conditions or preparations of the patient are required.

Laboratory Test Orders

1. Clinical Laboratory test orders will be done through Amerimmune Laboratory Network Website https://www.amerimmune.com/amerimmune-laboratory-network . Order tests from the Laboratory Sample will be processed at. When form is submitted it is automatically input into Simplified Laboratory Information Management System (SLIMS) before specimens are delivered to the Laboratory.
2. Please make sure forms are not done in ALL CAPS as our Interpretation reports are pulled directly from SLIMS.
3. Both the website and SLIMS are readily available on the desktop of computers in the Laboratory, medical service areas, workstations, and physician workspaces.
4. Orders for all tests require an electronic or paper requisition to accompany the specimen. Specimen must have label affixed.

Specimen Labeling

2. All specimens are labeled at time of draw with:
    a. Last Name, First Name or First Name, Last Name (please check with your reference Laboratories how they require their samples to be labelled)
    b. Date of Birth.
    c. Dated Collected and Time
3. In the event a sample is received with a label that is incorrect, the following actions must be applied:
    a. Investigate.
    b. Document in our Nonconforming Events Report.
    c. Contact Ordering Practitioners Office.
    d. Correct and update the Nonconforming Events Report if required.
    f. Run, cancel, or requesting a redraw, depends on the findings of an investigation. Due to the nature of the testing, these samples are irreplaceable. Every reasonable attempt is made to avoid a redraw. There are instances when a redraw cannot be avoided. Should there be any doubt about the integrity of the sample, cancellation and a redraw is always the best course of action.

Specimen Type

1. Defined in the Technical Testing SOP and on Electronic Requisition Form.

CBC and Differential

1. As indicated by the Technical Testing SOP, a complete blood count, (CBC), with differential, is required to be done on the patient's blood:
    a. Must be Drawn the same day.
    b. Preferably, obtained from the same draw as the blood for Flow.

Criteria for Sample Rejection

1. Samples older than 48 hours.
2. Refrigerated or frozen samples.
3. Unlabeled samples.
4. Clotted samples:
    a. This may cause selective loss or alteration of certain subpopulations.
5. Draws that are less than the minimum volume:
    a. This has a deleterious condition on the cells.
6. Samples that are grossly hemolyzed:
    a. This indicates the red cells have been damaged, suggesting the WBCs may also have been damaged.
7. If known, Absolute lymphocyte count is less than 0.2 K/uL
    a. Due to low number of lymphocytes.
8. Samples collected in an inappropriate anti-coagulant.
9. Shipped samples that have been altered due to extreme temperatures.

Notification for Sample Rejection

1. The sample will be accessioned and then canceled.
2. A nonconforming event report will be generated documenting the reason for the sample rejection.

3. The client will be notified of the sample rejection, cancellation, and a request for a new sample will be given, if clinically necessary.

Collection of Specimens

1. Specimens are collected using accepted phlebotomy technique. Please refer to Quality-SOP-00052 Specimen Collection Procedure.

Specimen Handling Conditions

1. After collection, samples are to be handled at room temperature during transportation and storage.

Sample Transport

1. Specimens may be hand delivered by staff where available AND approved by the laboratory.
2. All samples must be transported in the biohazard labeled specimen bag pouches.
3. All samples are considered infectious and should be treated as such.
4. Staff in clinical areas:
    a. Ensure that accession labels are attached to the specimens.
    b. Extra labels and accompanying paperwork must be placed in the specimen bag pouch.
5. Courier Transport:
   Courier service is utilized for specimen transport from Satellite clinical areas.
    a. Pickups are made according to a schedule as well as on demand.
    b. Date and time log entries are completed by staff members at pick-up locations and at final drop-off points.
    c. The Laboratory Spill Response Procedure is followed for any spills occurring during transit.

Sample Request Form

1. A written or electronic test request form must accompany the sample.
2. The test request form must state the following:
    a. Patient: Last Name, First Name
    b. Patient: Date of Birth
    c. Patient: Sex
    d. Tests Requested
    e. Date of collection
    f. Date test was ordered
    g. Physician ordering test
    h. Physician address
    i. Physician signature
3. Forms without signatures are returned to the requestor for a signature delaying testing.
4. Any changes or additions will require a new request form.
5. The physician’s signature is the mechanism in which the laboratory ensures that specimens are analyzed only at the request of the authorized person.
6. Unclear test requests are clarified, a new requisition form that is current and correctly filled out, including signature, is to be resubmitted before testing.
7. Requisition forms are emailed to Laboratory Technician. Laboratory Personnel need to follow Quality-SOP=00046 Patient Identification Process to save form.

Sample Receipt in the Lab

1. All samples received in the laboratory were logged and assigned an accession number that is unique to that sample when submitted.
2. Laboratory Sample Receiving form to be completed at time of delivery, we need a copy of sample label, Date received, Time received and initials (if a label is not provided name and DOB of patient must be written in on form. Please refer to Quality-Form-00058
3. All samples must have date and time received logged in SLIMS.
4. The SLIMS accession label will be printed and added to sample tube and Conical Tubes. It will display, Patients Name, Medical Record Number (MRN) Date of Birth (DOB), Age, Date and Time received, Date collected, and time collected, Ordering Practitioner and Test Requested.

Sample Storage

1. Samples will be stored as indicated in the Quality Management Program.

Extended Downtime

1. In the event of an extended downtime due to a catastrophic event, all requestors will be notified and, redraws will be coordinated.

Sample Handling Feedback

1. In the event any sample handling issues continue to be a constant, action will be taken to reach out to the person or parties responsible.
2. This meeting will be documented in the error and deviation log.

Sample Tracking

1. Samples sent from remote sites are tracked through a FedEX, or equivalent, tracking number. Should there be an error in the delivery of a sample, customer service will reach out to the site, and the incident will be documented in the error and deviation log.

Sample Transport

1. Samples are inspected upon receipt in the laboratory for issues and all issues are documented and tracked in the error and deviation log.
2. In the event any sample transport continues to be a constant, action will be taken to reach out to the person or parties responsible.
3. This meeting will be documented in the error and deviation log.