Title	Quality Management Systems - Specimen Handling
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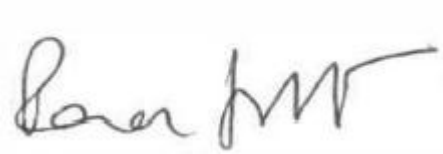
Written By	Matthew Plassmeyer & Raavi Gupta M.D.
Approved By	 **09/08/2021** **Raavi Gupta M.D.** **Laboratory Director**

NYAIRL
NEW YORK
ALLERGY & IMMUNOLOGY
RESEARCH LAB

Contents

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 NYAIRL Website https://www.amerimmune.com/nyairl when submitted and is automatically input into Simplified Laboratory Information Management System (SLIMS) before specimens are delivered to the Laboratory.
2. Both the website and SLIMS are readily available on the desktop of computers in the Laboratory, medical service areas, workstations, and physician workspaces.
3. Please make sure forms are not done in ALL CAPS as our Interpretation reports are pulled directly from SLIMS.
4. Orders for all tests require an electronic or paper requisition to accompany the specimen. Specimen must have label affixed.

Completing Cognito Forms for NYAIRL Samples

1. Go to NYAIRL Website https://www.amerimmune.com/nyairl
2. Select Step 3: Order Tests Online for all Standard Immunophenotyping Panels to be completed at NYAIRL Laboratory
3. Complete following Fields (those with a red asterisk * are mandatory fields)
   a. Patient Information
      i. Name: First and Last
      ii. Legal Gender (select from drop down menu)
      iii. Address: Address Line 1, City, State (select from drop down menu). ZIP Code
      iv. Date of Birth: type MM/DD/YYYY or use calendar function
      v. Phone
      vi. Email
      vii. Medical Record Number
   b. Testing Menu
      i. Test Requested (will also show you which tube to collect blood in and how much blood is required)
   c. Sample Management
      i. Tentative Blood Collection Date type MM/DD/YYYY or use calendar function
      ii. Blood Sample (select from drop down menu)
      iii. Draw Location (select from drop down menu)
      iv. Comments
   d. Provider information
      i. Is this your first-time ordering from NYAIRL (select Yes or No)
      ii. If NO complete
      iii. Ordering Practitioner (select from drop down menu)
      iv. Practice Name (select from drop down menu)
      v. Email for Copy of Laboratory Requisition
      vi. Providers Signature (sign with Mouse)
      vii. Date of Signature (order date)
   e. Attachments
      i. You can upload any relevant information you deem necessary for the test if required
   f. Do you need to view Blood Collection Options and Procedures (Select Yes or No)
   g. Then Click on Next
   h. Review Form
      i. This is where you can check patients name and demographics are all correct.
      ii. Name is not in All Caps
      iii. All Names should be Capitalized in English.
      iv. Names and Date of Births should match what's on the Specimen Label.

Completing Cognito Forms for Amerimmune Research Samples

1. Go to NYAIRL Website https://www.amerimmune.com/nyairl
2. Select Amerimmune Order Form for all samples being processed at Amerimmune Laboratory
3. Complete following Fields (those with a red asterisk * are mandatory fields)
   a. Patient Information
      i. Name: First and Last
      ii. Legal Gender (select from drop down menu)
      iii. Address: Address Line 1, City, State (select from drop down menu). ZIP Code
      iv. Date of Birth: type MM/DD/YYYY or use calendar function
      v. Phone
      vi. Email
      vii. Medical Record Number
   b. Testing Menu
      i. Test Requested (will also show you which tube to collect blood in and how much blood is required)
   c. Sample Management
      i. Tentative Blood Collection Date type MM/DD/YYYY or use calendar function
      ii. Blood Sample (select from drop down menu)
      iii. Draw Location (select from drop down menu)
      iv. Comments
   d. Provider information
      i. Is this your first-time ordering from NYAIRL (select Yes or No)
      ii. If NO complete
      iii. Ordering Practitioner (pre-filled with Dr Shah)
      iv. Practice Name (pre-filled with New York Food Allergy & Wellness Center)
      v. Email for Copy of Laboratory Requisition (prefilled with nyairl.lab@amerimmune.com
      vi. Providers Signature (sign with Mouse)
      vii. Date of Signature (order date)
   e. Attachments
      i. You can upload any relevant information you deem necessary for the test if required
   f. Do you need to view Blood Collection Options and Procedures (Select Yes or No)
   g. Then Click on Next
   h. Review Form
      i. This is where you can check patients name and demographics are all correct.
      ii. Name is not in All Caps
      iii. All Names should be Capitalized in English.
      iv. Names and Date of Births should match what's on the Specimen Label.

Specimen Labeling

1. All specimens are labeled at time of draw with:
    a. Last Name, First Name.
    b. Date of Birth.
    c. Dated Collected and Time
2. In the event a sample is received with a label that is incorrect, the following actions must be applied:
    d. Investigate.
    e. Document in the error and deviation log.
    f. Contact Ordering Practitioners Office.
    g. Correct and update the error and deviation log.
    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 30 hours (EDTA Tube) or 48 hours (Heparin).
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. An error 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 must be delivered to the NYAIRL room.
2. Specimens may be hand delivered by staff where available AND approved by the laboratory.
3. All samples must be transported in the biohazard labeled specimen bag pouches.
4. All samples are considered infectious and should be treated as such.
5. 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.
6. 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-000
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.

Chain-of-Custody Procedures

1. When samples that require a Chain-of-Custody are referred to another laboratory for testing, the referral laboratory will follow the Chain-of Custody instructions setup by the referring laboratory.

Chain-of-Custody Records

1. The external and internal Chain-of-Custody records, (as applicable), for specimen collection, receiving, accessioning, and handling, are complete and include the following:
    a. Type of specimen collected.
    b. Verification of patient and/or specimen identity.
    c. Identification of laboratory-generated aliquots.
    d. Verification of the integrity, (tamper-evident), of the specimen container.
    e. Identity of individuals handling the specimens.
    f. Storage location when not in the possession of an authorized individual, including aliquots.
    g. Reason for the transfer of custody and date of transfer.