Quality Framework Policies
Mayo Clinic Laboratories

PURPOSE

Mayo Clinic Laboratories is a reference laboratory operating within Mayo Clinic's Department of Laboratory Medicine and Pathology (DLMP). Mayo Clinic Laboratories specializes in providing esoteric laboratory testing services to customers across the United States and around the world. This document provides policy guidance on an expanse of topics for internal and external customers.

POLICY STATEMENTS

Animal Specimens

Mayo Clinic Laboratories does not accept animal specimens for laboratory testing.

Business Continuity and Contingency Planning

In the event of a local, regional, or national disaster, Mayo Clinic and Mayo Clinic Laboratories performing sites have comprehensive contingency plans in place in each location to ensure that the impact on laboratory practice is proactively addressed. With test standardization between our performing sites and medical practice locations throughout the country, we have worked to ensure that patient care will not be compromised.

Cancellation of Tests

Cancellations received prior to test setup will be honored at no charge. Requests received following test setup cannot be honored. A report will be issued automatically and charged appropriately.

Chain-of-Custody

Chain-of-custody, a record of disposition of a specimen to document the individuals who collected it, handled it, and performed the analysis, is necessary when results are to be used in a court of law. Mayo Clinic Laboratories has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody. This service is only offered for drug testing.

Compliance Policies

Mayo Clinic Laboratories is committed to compliance with applicable laws and regulations such as the Clinical Laboratory Improvement Amendments (CLIA). Regulatory agencies that oversee our compliance include, but are not limited to, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Department of Transportation (DOT). Mayo Clinic Laboratories develops, implements, and maintains policies, processes, and procedures throughout our organization which are designed to meet relevant requirements. We expect clients utilizing our services will ensure their compliance with patient confidentiality, diagnosis coding, anti-kick back statutes, professional courtesy, CPT-4 coding, CLIA-approved proficiency testing, and other similar regulatory requirements. Also see “Accreditation and Licensure,” “HIPAA Compliance,” and “Reportable Disease.”

Confidentiality of Results

Mayo Clinic Laboratories is committed to maintaining confidentiality of patient information. To ensure Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the College of American Pathologists (CAP) compliance for appropriate release of patient results, Mayo Clinic Laboratories has adopted the following policies:

Phone Inquiry Policy-One of the following unique identifiers will be required:

- Mayo Clinic Laboratories order ID number for specimen; **or**
- Client account number (assigned by Mayo Clinic Laboratories) along with patient name; **or**
- Client accession ID number interfaced to Mayo Clinic Laboratories; **or**
- Identification by individual that he or she is, in fact, "referring physician" identified on requisition form by Mayo Clinic Laboratories client.

Mayo Clinic Laboratories is authorized to release results to ordering physicians or other health care professionals responsible for the individual patient's care. Patients or a patients' personal representative requesting results can do so via the following link: Contact Us - Mayo Clinic Laboratories.

Critical Values / Critical Results

The "Mayo Clinic Laboratories Critical Results / Critical Values Policy" of the Department of Laboratory Medicine and Pathology (DLMP), Mayo Clinic, Rochester, Minnesota is described below. These values apply to Mayo Clinic patients as well as external clients of Mayo Clinic Laboratories. Clients should provide "critical value / critical results" contact information to Mayo Laboratory Inquiry (MLI) to facilitate call-backs. To standardize this process, a customized form is available at mayocliniclabs.com.

Definition of Critical Value / Critical Results-A critical value / critical result is defined as a value that represents a pathophysiological state at such variance with normal (expected values) as to be life-threatening unless something is done promptly and for which some corrective action could be taken.

Abnormals are Not Considered Critical Values / Critical Results-Most laboratory tests have established reference ranges, which represent results that are typically seen in a group of healthy individuals. While results outside these reference ranges may be considered abnormal, "abnormal" results and "critical values" are not synonymous. Analytes on the Mayo Clinic Laboratories Critical Results / Critical Values List represent a subgroup of tests that meet the above definition.

Action Taken when a Result is Obtained that Exceeds the Limit Defined by the Mayo Clinic Laboratories Critical Values / Critical Results List-In addition to the normal results reporting (e.g., fax, interface), Mayo Clinic Laboratories' staff telephone the ordering physician or the client-provided contact number within 60 minutes following laboratory release of the critical test result(s). In the event that contact is not made within the 60-minute period, we continue to telephone until the designated party is reached and the result is conveyed in compliance and adherence to the CAP.

Semi-Urgent Results- A Semi-Urgent Result is defined by Mayo Clinic as a result or finding which can be unexpected or ambiguous, does not pose an immediate health threat but has near-term severe health consequences if not acknowledged and/or treated. While not included on the Mayo Clinic Laboratories Critical Values / Critical Results List, this information is deemed important to patient care in compliance and adherence to the CAP. See the Mayo Clinic Laboratories Semi-Urgent Results List for additional information.

To complement Mayo Clinic Laboratories normal reporting mechanisms (e.g., fax, interface), Mayo Clinic Laboratories' staff will telephone results identified as semi-urgent findings to the ordering facility within 2 hours following laboratory release of the result(s). In the event that contact is not made within the 2-hour period, we will continue to telephone until the responsible party is reached and the result is conveyed. In addition, in most instances, you will see the comment **SIGNIFICANT RESULT** appear on the final report.

For information regarding the Mayo Clinic Laboratories Critical Values / Critical Results List or the Mayo Clinic Laboratories Semi-Urgent Results List , contact Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700 or visit mayocliniclabs.com.

Disclosures of Results
Under federal regulations, we are authorized to release results only to ordering physicians or other health care professionals responsible for the individual patient's care. Third parties requesting results are directed to the ordering facility.

Mayo Clinic Laboratories is authorized to release results to ordering physicians or other health care professionals responsible for the individual patient's care. Patients or a patients' personal representative requesting results can do so via the following link: Contact Us - Mayo Clinic Laboratories.

Environmental Specimens
Mayo Clinic Laboratories does not accept environmental specimens for laboratory testing.

Extracted Specimens
Mayo Clinic Laboratories will accept extracted nucleic acid for clinical testing, provided it is an acceptable specimen source for the ordered test **only** as listed in the Test Catalog, and if the isolation was performed in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

Framework for Quality
"Framework for Quality" is the foundation for the development and implementation of the quality program for Mayo Clinic Laboratories. Our framework builds upon the concepts of quality control and quality assurance providing an opportunity to deliver consistent, high-quality and cost-effective service to our clients. In addition, our quality program enhances our ability to meet and exceed the requirements of regulatory/ accreditation agencies and provide quality service to our customers.

A core principle at Mayo Clinic Laboratories is the continuous improvement of all processes and services that support the care of patients. Our continuous improvement process focuses on meeting the needs of you, our client, to help you serve your patients.

The Mayo Clinic Department of Laboratory Medicine and Pathology Quality Management System (DLMP QMS) is composed of twelve (12) "Quality System Essentials", or QSEs. The policies, processes, and procedures associated with the QSEs can be applied to all operations in the path of workflow (e.g., pre-analytical, analytical, and post-analytical). Performance is measured through active monitoring of activities in the path of workflow and comparing performance through benchmarking internal and external quality indicators and proficiency testing. The DLMP QMS is the basis for all that we do and is integrated into our daily work processes.

Data generated by quality indicators drives process improvement initiatives to seek resolutions to system-wide problems. Mayo Clinic Laboratories utilizes Failure Modes and Effects Analysis (FMEA), Plan Do Study Act (PDSA), LEAN, Root Cause Analysis, and Six Sigma quality improvement tools to determine appropriate remedial, corrective, and preventive actions.

Quality Indicators-Mayo Clinic Laboratories produces hundreds of Key Performance Indicators (KPI) for our business and operational areas, and we review them regularly to ensure that we continue to maintain our high standards. A sampling of these metrics includes:

- Pre-analytic performance indicators
  - Incoming defects*
  - Lost specimens*
  - Specimen identification*
- Analytic performance indicators
  - Proficiency testing

    - Quality control
    - Turnaround (analytic) times
    - Quantity-not-sufficient (QNS) specimens*
- Post-analytic performance indicators
    - Revised reports*
    - Total Critical Results Notification Reports*
- Operational performance indicators
    - Incoming call resolution
    - Incoming call abandon rate
    - Call completion rate
    - Call in-queue monitoring
    - Customer complaints
    - Customer satisfaction surveys

*Measured using Six Sigma defects per million (dpm) method.

The system provides a planned, systematic program for defining, implementing, monitoring, and evaluating our services.

HIPAA Compliance
Mayo Clinic Laboratories is fully committed to compliance with all privacy, security, and electronic transaction code requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All services provided by Mayo Clinic Laboratories that involve joint efforts will be done in a manner which enables our clients to be HIPAA and the College of American Pathologists (CAP) compliant.

Informed Consent Certification
Submission of an order for any tests contained in the Test Catalog constitutes certification to Mayo Clinic Laboratories by ordering physician that: (1) ordering physician has obtained "Informed Consent" of subject patient as required by any applicable state or federal laws with respect to each test ordered; and (2) ordering physician has obtained from subject patient authorization permitting Mayo Clinic Laboratories to report results of each test ordered directly to ordering physician.

On occasion, we forward a specimen to an outside reference laboratory. The laws of the state where the reference laboratory is located may require written informed consent for certain tests. Mayo Clinic Laboratories will request that ordering physician pursue and provide such consent. Test results may be delayed or denied if consent is not provided.

Non-Biologic Specimens
Due to the inherent exposure risk of non-biologic specimens, their containers, and the implied relationship to criminal, forensic, and medico-legal cases, Mayo Clinic Laboratories does not accept nor refer non-biologic specimen types. Example specimens include unknown solids and liquids in the forms of pills, powder, intravenous fluids, or syringe contents.

Patient Safety Goals
The Joint Commission National Patient Safety Goal #1 is to improve the accuracy of patient identification by using at least two (2) patient identifiers when providing care, treatment, or services.

Mayo Clinic Laboratories uses multiple patient identifiers to verify the correct patient is matched with the correct specimen and the correct order for the testing services. As a specimen is received at Mayo Clinic Laboratories, the client accession number, patient first and last name, and patient age and date of birth are verified by comparing the labels on the specimen tube or container with the electronic order and any paperwork (batch sheet or form) that may accompany the specimen to be tested. When discrepancies are identified, Mayo Laboratory Inquiry will notify the client to verify discrepant information to assure Mayo Clinic Laboratories is performing the correct testing for the correct patient. When insufficient or inconsistent identification is submitted, Mayo Clinic Laboratories will recommend that a new specimen be obtained, if feasible. In cases where an irreplaceable specimen is mislabeled, additional conditions must be met prior to testing.

In addition, Anatomic Pathology consultation services require the Client Pathology Report. The pathology report is used to match the patient name, patient age and/or date of birth, and pathology case number. Since tissue blocks and slides have insufficient space to print the patient name on the block, the pathology report provides Mayo Clinic Laboratories another mechanism to confirm the patient identification with the client order and labels on tissue blocks and slides.

Comparison/Validation Testing
Parallel testing may be appropriate in some cases to re-establish patient baseline results when converting to a new methodology at Mayo Clinic Laboratories. Contact your Hospital Account Executive at 800-533-1710 or 507-266-5700 for further information. Specific planning is required prior to implementation.

Proficiency Testing
Mayo Clinic Laboratories are College of American Pathologists (CAP)-accredited, CLIA-licensed laboratories that voluntarily participate in many diverse external and internal proficiency testing programs. It is Mayo Clinic Laboratories' expectation that clients utilizing our services will adhere to CLIA requirements for proficiency testing (42 CFR 493.801). This includes a prohibition of discussion about proficiency testing samples or results and sending of proficiency testing materials to Mayo Clinic Laboratories during the active survey period.

Mayo Clinic Laboratories' proficiency testing includes participation in CMS-approved programs. Mayo Clinic Laboratories also performs alternative assessment using independent state, national, and international programs when proficiency testing is not available. Mayo Clinic Laboratories also conducts comparability studies to ensure the accuracy and reliability of patient testing, when necessary. We comply with the regulations set forth in Clinical Laboratory Improvement Amendments (CLIA-88), the Occupational Safety and Health Administration (OSHA), or the Centers for Medicare & Medicaid Services (CMS).

It is Mayo Clinic Laboratories' expectation that clients utilizing our services will adhere to CLIA requirements for proficiency testing including a prohibition on discussion about samples or results and sharing of proficiency testing materials with Mayo Clinic Laboratories during the active survey period.

Radioactive Specimens
Specimens from patients receiving radioactive tracers or material should be labeled as such. All incoming shipments arriving at Mayo Clinic Laboratories are routed through a detection process in receiving to determine if the samples have any levels of radioactivity. If radioactive levels are detected, the samples are handled via an internal process that assures we do not impact patient care and the safety of our staff. This radioactivity may invalidate the results of radioimmunoassay (RIA).

Record Retention
Mayo Clinic Laboratories retains all test requisitions and patient test results at a minimum for the retention period required to comply with and adhere to the CAP, CLIA and New York State (NYS) requirements. A copy of the original report can be reconstructed including reference ranges, interpretive comments, flags, and footnotes with the source system as the Department of Laboratory Medicine's laboratory information system.

Referral of Tests to Another Laboratory
Mayo Clinic Laboratories forwards tests to other laboratories as a service to its clients. This service should in no way represent an endorsement of such test or referral laboratory or warrant any specific performance for such test.

We have established collaborative relationships with more than 200 laboratories within the United States. Outside vendors are selected on the basis of certifications, service, turnaround time, methodology, reference range and price. Laboratory qualifications are reviewed by our internal operations and quality teams. A recommendation is forwarded to our medical director for final consideration as to compliance with and adherence to College of American Pathologists (CAP) Laboratory General Checklist (GEN.41350). Once selected, each laboratory is monitored to ensure that turnaround time is prompt and certain customer service criteria are met. The referral laboratories must requalify every two years, or as their test offerings change.

Reflex Testing
Mayo Clinic Laboratories identifies tests that reflex when medically appropriate. In many cases, Mayo Clinic Laboratories offers components of reflex tests individually as well as together. Clients should familiarize themselves with the test offerings and make a decision whether to order a reflex test or an individual component and only order test offerings based on medical necessity. Clients, who order a reflex test, can request to receive an "Additional Testing Notification Report," which indicates the additional testing that has been performed. This report will be faxed to the client. Clients who wish to receive the "Additional Testing Notification Report" should contact their Hospital Account Executive or Regional Service Representative. Do not send reflex testing on proficiency testing samples to Mayo Clinic Laboratories before the Proficiency Testing submission deadline.

Reportable Disease
Mayo Clinic Laboratories, in compliance with and adherence to the College of American Pathologists (CAP Laboratory General Checklist (GEN. 41316) strives to comply with laboratory reporting requirements for each state health department regarding reportable disease conditions. We report by mail, fax, and/or electronically, depending upon the specific state health department regulations. Clients shall be responsible for compliance with any state specific statutes concerning reportable conditions, including, but not limited to, birth defects registries or chromosomal abnormality registries. This may also include providing patient address/demographic information. Mayo Clinic Laboratories' reporting does not replace the client or physician responsibility to report as per specific state statues.

Request for Physician Name and Number
Mayo Clinic Laboratories endeavors to provide high quality, timely results so patients are able to receive appropriate care as quickly as possible. While providing esoteric reference testing, there are times when we need to contact the ordering physician directly. The following are 2 examples:

- When necessary to the performance of a test, the ordering physician's name and phone number are requested as part of "Specimen Required." This information is needed to allow our physicians to make timely consultations or seek clarification of requested services. If this information is not provided at the time of specimen receipt, we will call you to obtain the information. By providing this information up front, delays in patient care are avoided.
- In some situations, additional information from ordering physician is necessary to clarify or interpret a test result. At that time, Mayo Clinic Laboratories will request physician's name and phone number so that one of our staff can consult with the physician.

We appreciate your rapid assistance in supplying us with the ordering physician's name and phone number when we are required to call. Working together, we can provide your patients with the highest quality testing services in the shortest possible time.

Special Handling
Mayo Clinic Laboratories serves as a reference laboratory for clients around the country and world. Our test information, including days and time assays are performed as well as analytic turnaround time, is included under each test listing in the Test Catalog on mayocliniclabs.com. Unique circumstances may arise with a patient resulting in a physician request that the specimen or results receive special handling. There are several options available. These options can only be initiated by contacting Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700 and providing patient demographic information.

There is a nominal charge associated with any special handling.

- **Hold:** If you would like to send us a specimen and hold that specimen for testing pending initial test results performed at your facility, please call Mayo Laboratory Inquiry. We will initiate a hold and stabilize the specimen until we hear from you.
- **Expedite:** If you would like us to expedite the specimen to the performing laboratory, you can call Mayo Laboratory Inquiry and request that your specimen be expedited. Once the shipment is received in our receiving area, we will deliver the specimen to the performing laboratory for the next scheduled analytic run. We will not set up a special run to accommodate an expedite request.
- **STAT:** In rare circumstances, STAT testing from the reference laboratory may be required for patients who need immediate treatment. These cases typically necessitate a special analytic run to turn results around as quickly as possible. To arrange STAT testing, please have your pathologist, physician, or laboratory director call Mayo Laboratory Inquiry. They will be connected with one of our medical directors to consult about the patient's case. Once mutually agreed upon that there is a need for a STAT, arrangements will be made to assign resources to run the testing on a STAT basis when the specimen is received.

Specimen Identification Policy
Mayo Clinic Laboratories uses a minimum of two patient-specific identifiers to verify the correct patient is matched with the correct specimen and the correct order for testing services. As a specimen is received at Mayo Clinic Laboratories, the patient's first and last name, date of birth, medical record number, and client accession number are verified by comparing the labels on the specimen tube or container with the electronic order and any paperwork (batch sheet or form) that may accompany the specimen to be tested. When discrepancies are identified, the Mayo Laboratory Inquiry Call Center will notify the client to verify discrepant information to assure Mayo Clinic Laboratories is performing the correct testing for the correct patient. Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and information accompanying the specimen (e.g. computer system, requisition form, additional paperwork). When insufficient or inconsistent identification is submitted, Mayo Clinic Laboratories will recommend that a new specimen be obtained.

In addition, Anatomic Pathology consultation services require the client pathology report. The pathology report is used to match patient name, patient age and/or date of birth and pathology case number. Since tissue blocks and slides have insufficient space to print the patient name on the block, the pathology report provides Mayo Clinic Laboratories another mechanism to confirm the patient identification with the client order and labels on tissue blocks and slides.

Specimen Rejection
All tests are unique in their testing requirements. To avoid specimen rejection or delayed turnaround times, check the "Specimen Required" field within each test. You will be notified of rejected or problem specimens upon receipt.

Please review the following conditions prior to submitting a specimen to Mayo Clinic Laboratories:

- Full 24 hours for timed urine collection
- pH of urine
- Lack of hemolysis/lipemia

- Specimen type (plasma, serum, whole blood, etc.)
- Specimen volume
- Patient information requested
- Proper identification of patient/specimen
- Specimen container (metal-free, separation gel, appropriate preservative, etc.)
- Transport medium
- Temperature (ambient, frozen, refrigerated)

Specimen Volume
The "Specimen Required" section of each test includes the preferred volume, but the "Specimen Minimum Volume" is also provided. Preferred volume has been established to optimize testing and allows the laboratory to quickly process specimen containers, present containers to instruments, perform test, and repeat test, if necessary. Many of our testing processes are fully automated; and as a result, this volume allows hands-free testing and our quickest turnaround time (TAT). Since patient values are frequently abnormal, repeat testing, dilutions, or other specimen manipulations often are required to obtain a reliable, reportable result. Our preferred specimen requirements allow expeditious testing and reporting.

When venipuncture is technically difficult or the patient is at risk of complications from blood loss (e.g., pediatric or intensive care patients), smaller volumes may be necessary. Specimen minimum volume is the amount of sample necessary to provide a clinically relevant result as determined by the Testing Laboratory.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit preferred volume to facilitate rapid, cost-effective, reliable test results. Submitting less than preferred volume may negatively impact quality of care by slowing TAT, increasing the hands-on personnel time (and therefore cost) required to perform test.

Mayo Clinic Laboratories makes every possible effort to successfully test your patient's specimen. If you have concerns about submitting a specimen for testing, please call Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700. Our staff will discuss the test and specimen you have available. While in some cases specimens are inadequate for desired test, in other cases, testing can be performed using alternative techniques.

Supplies
Shipping boxes, specimen vials, special specimen collection containers, and request forms are supplied without charge. Supplies can be requested using one of the following methods: use the online ordering functionality available at mayocliniclabs.com/supplies or call Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700.

Test Classifications
Analytical tests offered by Mayo Clinic Laboratories are classified according to the FDA labeling of the test kit or reagents and their usage. Where appropriate, analytical test listings contain a statement regarding these classifications, test development, and performance characteristics.

Test Development Process
Mayo Clinic Laboratories is dedicated to providing clinically useful, cost-effective testing strategies for patient care. Development, validation and implementation of new and improved laboratory methods are major components of that commitment. We have launched a standardized test life cycle process (TLCP), which includes seven specific phases of the test life cycle process (test design, development, verification, validation, launch, maintenance and test retirement). This process streamlines all development operations and activities and aligns with FDA test development definitions. Assays utilized at Mayo Clinic, whether laboratory developed or FDA cleared/approved/exempt, undergo verification and validation before the test becomes available for clinical use, including (as applicable):

- Accuracy
- Precision
- Sensitivity
- Specificity and interferences
- Reportable range
- Linearity
- Specimen stability
- Specimen type comparisons
- Urine preservative stability studies
- Comparative evaluation
- Reference values*
- Workload recording
- Limitations of the assay
- Clinical utility and interpretation (written by Mayo Clinic medical experts, available electronically - MayoAccess™)

*Reference values provided by Mayo Clinic Laboratories are derived from studies performed in our laboratories. If reference values are obtained from other sources, the source is indicated in the "Reference Values" field.

Test Result Call-Backs
Results will be phoned to a client when requested from the client (either on Mayo Clinic Laboratories request form or from a phone call to Mayo Clinic Laboratories from the client). See also Critical Values.

Time-Sensitive Specimens
Please contact Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700 prior to sending a specimen for testing of a time-sensitive nature. Relay the following information: facility name, account number, patient name and/or Mayo Clinic Laboratories accession number, shipping information (i.e., courier service, FedEx®, etc.), date to be sent, and test to be performed. Place specimen in a separate Mayo Clinic Laboratories temperature appropriate bag. Please write “Expedite” in large print on outside of bag.

Turnaround Time (TAT)
Mayo Clinic Laboratories extensive test menu reflects the needs of our own health care practice. We are committed to providing the most expedient TAT possible to improve diagnosis and treatment. We consider laboratory services as part of the patient care continuum wherein the needs of the patient are paramount. In that context, we strive to fulfill our service obligations. Our history of service and our quality metrics will document our ability to deliver on all areas of service including TAT.

Mayo Clinic Laboratories defines TAT as the analytical test time (the time from which a specimen is received at a Mayo Clinic Laboratories’ location to time of result) required and is listed for each test as “Report Available”. TAT is monitored continuously by each performing laboratory site within the Mayo Clinic Department of Laboratory Medicine and Pathology. For the most up-to-date information on TAT for individual tests, please visit us at mayocliniclabs.com or contact Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700.

Unlisted Tests
Mayo Clinic Laboratories does not list all available test offerings in the catalog. New procedures are developed throughout the year; therefore, some tests are not listed in this catalog. Although we do not usually accept referred tests of a more routine type, special arrangements may be made to provide your laboratory with temporary support during times of special need such as sustained instrumentation failure. For information about unlisted tests, please call Mayo Laboratory Inquiry at 800-533-1710 or 507-266-5700.

POLICY NOTE

Review MCL Framework for Quality document simultaneously with this policy: https://www.mayocliniclabs.com/it-mmfiles/quality-compliance.pdf.