

Framework for Quality

Updated: 3/10/2017

Mayo Medical Laboratories measures quality not simply by accreditation and licensure, but also by how efficiently esoteric laboratory results are interpreted and applied to a patient's clinical situation.

Our quality and standardization programs exceed the high level of testing proficiency and standardization that auditors require.

We are continuously improving all processes and services supporting patient care. We combine the efficiency of automation and Lean principles to simplify and streamline processes.

Purpose of Document

Mayo Medical Laboratories has prepared this statement of qualifications to assist our customers in the referral laboratory qualification process to meet regulatory and accreditation compliance requirements.

Mayo Medical Laboratories

Mayo Medical Laboratories is a reference laboratory operating within Mayo Clinic's Department of Laboratory Medicine and Pathology (DLMP). We specialize in providing esoteric laboratory testing services to customers across the United States and around the world.

Mayo Medical Laboratories' Mission

To support the local delivery of laboratory services by providing exceptional reference testing and support services to facilitate and augment community integration efforts.

Laboratory Services

Mayo Medical Laboratories provides personalized customer service and comprehensive consultative services 24 hours a day, seven days a week by the physicians, scientists and clinicians who treat Mayo Clinic patients. Mayo Clinic and Mayo Medical Laboratories' specimens follow the same stringent testing process. More than 20 million tests were processed by Mayo Clinic laboratories last year. We continue to expand our facilities to meet clinical needs and have a five-year plan that supports additional growth capacity.

Mayo Clinic has more than 51,000 employees, including more than 3,800 physicians, scientists and researchers, at its campuses in Phoenix/Scottsdale, Ariz., Jacksonville, Fla., and Rochester, Minn. The Department of Laboratory Medicine and Pathology (DLMP) is comprised of more than 3,200 employees, with supervisors and pathologists available around the clock. Mayo Medical Laboratories provides medical and scientific expertise in our specialized laboratories, which are equipped with state-of-the-art diagnostic instrumentation and are staffed by professionals committed to quality diagnostic testing.

Mayo Medical Laboratories Contact Information

Rochester	Jacksonville
3050 Superior Drive	4500 San Pablo Road
Rochester, MN 55901	Jacksonville, FL 32224
(800) 533-1710 phone	(800) 533-1710 phone
(507) 284-1759 fax	(507) 284-1759 fax

Certifications and Licensure

All of our laboratories hold College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvement Amendments (CLIA) licensure for each testing facility.

For more information, refer to our [complete list of certifications and licensures](#).

Laboratory	CAP	CLIA
Mayo Clinic Department of Laboratory Medicine and Pathology Hilton Laboratories	1808201 AU-ID: 1183832	24D0404292
Mayo Clinic Department of Laboratory Medicine and Pathology Superior Drive Support Center Laboratories	07193341 AU-ID: 1437185	24D1040592
Mayo Clinic Jacksonville Laboratories	2988901 AU-ID: 1189494	10D0269502

Quality and Compliance

Mayo Medical Laboratories' core quality principle is the continuous improvement of all processes and services supporting the care of patients. To support this principle, we developed a comprehensive Quality Management System, outlined by our Framework for Quality that is based on the Clinical and Laboratory Standards Institute (CLSI) and GP26-A4 consensus standards and also on programs and measurements such as Lean and Six Sigma. The Quality Management System allows us to deliver consistent, cost-effective and superior service to our clients. The system is comprised of 12 Quality System Essentials (QSEs) and organized by structure, process and outcome essentials. The policies, processes and procedures associated with these QSEs are applied to all operations in the path of workflow (e.g., pre-analytic, analytic and post-analytic). Quality management focuses on continuous quality improvement as measured by customer satisfaction.

Quality System Essentials

Structure

Organization and Leadership

- Structure
- Mission, Vision, Value
- Leadership Review
- Resources

Facilities and Safety

- Structure and Utilities
- Environmental Conditions
- Communications
- Safety Programs
- Emergency Management

Personnel

- Staff Qualifications
- Job Description
- Orientation and Training
- Competency
- Continuing Education

Process

Purchasing and Inventory

- Critical Materials and Services
- Supplier Qualification
- Supplier/Customer Agreements
- Inventory Management
- Market Recall

Equipment

- Selection and Acquisition
- Equipment Qualification
- Operations and Calibration
- Maintenance and Repairs

Process Management

- Process Design and Development
- Validation
- Performance
- Quality Control
- Change Control

Documents and Records

- Document Creation
- Use and Maintenance
- Annual Review
- Document Control
- Record Quality and Review
- Retention, Storage and Retrieval

Information Management

- Training and Reference Guides
- Software Validation
- Interface Testing
- Report Validation

Outcome

Event Management

- Detection, Documentation and Investigation
- Categorization and Analysis
- External Notification
- Product/Result Recall/Correction

Monitoring and Assessment

- Quality Indicators
- Internal Audit Program
- External Inspections/Assessments
- Proficiency Testing
- Quality Reporting

Service and Satisfaction

- Needs Assessments
- Customer Comments
- Consultation
- Complaint Resolution

Continual Improvement

- Data Analysis
- Identification of Opportunities for Improvement
- Quality Management Tools
- Process Improvement

Operating within a Quality System allows us to meet and exceed the requirements of regulatory/accreditation agencies and facilitates service satisfaction for our customers. We have defined processes for planning and evaluating the effectiveness and efficiency of our Quality System through scheduled internal audits, quality performance monitoring, and leadership reviews.

Quality Indicators

Mayo Medical Laboratories produces hundreds of Key Performance Indicators 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*
- *MayoTrac*[™] Compliance
- On-time delivery
- Specimen identification*

Analytic performance indicators

- Proficiency testing
- Test reliability
- 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.

Quality Improvement Programs

Mayo Clinic encourages innovative thinking and promotes high performance in daily operations. Our values and mission guide our interactions with patients and customers. Mayo Medical Laboratories and Mayo Clinic's DLMP employ systems engineers who are Six Sigma Green Belts and Black Belts. They work to improve laboratory procedures and enhance overall operations performance.

Mayo Medical Laboratories strives for continuous improvement that constantly enhances value to the customer. This is achieved by defining value from our customers' perspective. Specifically, we rely on Six Sigma practices including project management, FMEA (failure modes and effects analysis), process mapping, statistical analysis, design of experiments, cause and effect matrix/diagrams, control charts, 5 "whys," capability analysis, and control plans.

Our best demonstration of quality and customer satisfaction is our extremely high client retention rate. Client satisfaction is also documented and monitored regularly. A priority at Mayo Medical Laboratories is efficiency in interpreting and applying esoteric laboratory results to the patient's clinical situation. Our clients' patients benefit from access to the comprehensive resources of Mayo Clinic, and physicians realize value in the collegial relationships developed with peers at Mayo Clinic.

Assessments/Proficiency Testing

We participate in both internal and external assessments. Performance is measured through the use of quality indicators and CAP Q-Tracks®. We also participate in a wide variety of proficiency testing to ensure the accuracy of test results. In addition, we participate in external assessments that include, but are not limited to, regulatory inspections and/or accreditation assessments. An internal audit program also monitors operations and the quality system. It is designed to assess the effectiveness of the quality system and assess the adequacy of standard operating procedures.

Our laboratories participate in interlaboratory proficiency testing which includes the following independent state, national and international programs:

- American Association of Bioanalysts (AAB)
- AABB (formerly American Association of Blood Banks)
- The Binding Site
- Centers for Disease Control and Prevention (CDC)
- College of American Pathologists (CAP) Surveys
- European Molecular Genetics Quality Network (EMQN) External Quality Assessment (EQA) Scheme
- European Research Network of Inherited Disorders of Metabolism (ERNIM)
- Heathcontrol (TDM LGC)
- Le Centre de Toxicologie du Quebec, Quality Assessment Scheme (QMEQAS)
- Le Centre de Toxicologie du Quebec, Comparison Program (PCI)
- New York State Department of Health
- NordiQC
- Pennsylvania State Department of Health
- Vitamin D External Quality Assessment Scheme (DEQAS)
- Wisconsin State Laboratory of Hygiene

Additionally, we conduct alternate assessments of performance to ensure the accuracy and reliability of patient testing when interlaboratory comparison is not available — or additional quality monitoring is desired. We comply with the regulations set forth in Clinical Laboratory Improvement Amendments (CLIA-88).

Meeting Your Accreditation and Regulatory Standards

Compliance Policies

We comply 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 & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the U.S. Department of Transportation (DOT). Mayo Medical Laboratories develops, implements, and maintains policies, processes, and procedures throughout the organization that are designed to meet relevant requirements. We expect that clients utilizing our services will comply with patient confidentiality, diagnosis coding, anti-kickback statutes, professional courtesy, CPT-4 coding, CLIA proficiency testing, and other similar regulatory requirements.

Confidentiality of Results

Maintaining confidentiality of patient information is one of Mayo Clinic's core values. To ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the College of American Pathologists (CAP) Laboratory General Checklist (**CAP GEN. 41304**) for appropriate release of patient results, Mayo Medical Laboratories has adopted the following policies:

Phone Inquiry Policy

One of the following unique identifiers will be required:

- Mayo Medical Laboratories' accession ID number for specimen; **or**

- Client account number from Mayo Medical Laboratories along with patient name; **or**
- Client accession ID number interfaced to Mayo Medical Laboratories; **or**
- Identification by individual that he or she is, in fact, "referring physician" identified on requisition form by Mayo Medical Laboratories' client.

Health Information Portability and Accountability Act (HIPAA) Compliance

Mayo Clinic 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 Medical Laboratories that involve joint efforts will be done in a manner which enables our clients to comply with HIPAA and the College of American Pathologists (CAP) Laboratory General Checklist (**CAP GEN. 41303**).

Disclosure of Results

Under federal regulations, we are only authorized to release results to ordering physicians or other health care providers responsible for the individual patient's care. Third parties requesting results, including requests directly from the patient, are directed to the ordering facility.

Informed Consent Certification

Submission of an order for any tests contained in our test menu constitutes certification to Mayo Medical Laboratories by the 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 Medical 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 that reference laboratory is located may require written informed consent for certain tests. Mayo Medical Laboratories will request that the ordering physician pursue and provide such consent. Test results may be delayed or denied if consent is not provided.

Critical Values / Critical Results

Mayo Clinic's Department of Laboratory Medicine and Pathology Clinical Practice Committee, a team of laboratory directors and Mayo Clinic physicians, determines the critical values for analytical tests. These decision limits are built into our Laboratory Information System (LIS). Our call center is notified of possible critical values 24 hours a day, seven days a week by representatives in our performing laboratories in compliance with and adherence to the College of American Pathologists (CAP) Laboratory All Common Checklist (**CAP COM.30000**). These values apply to Mayo Clinic patients as well as the extramural practice administered through Mayo Medical Laboratories. Clients will be required to provide contact information to us to facilitate accurate and timely notification of critical values/critical results.

For up-to-date policies and lists, see [Critical Values / Critical Results](#).

Patient Safety Goals

The Joint Commission and the College of American Pathologists patient safety goals for improving patient safety through accurate patient identification requires the use of two patient identifiers when providing laboratory services. As such, we have developed the following specimen identification policy.

Specimen Identification Policy

Mayo Medical 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 Medical 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 telephone the client to verify discrepant information to assure Mayo Medical 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 Medical Laboratories will recommend that a new specimen be obtained. 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 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 Medical Laboratories another mechanism to confirm the patient identification with the client order and labels on tissue blocks and slides.

Test Development Process

Mayo Medical 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 positively streamlines all development operations and activities and aligns with FDA test development definitions. Assays utilized at Mayo Clinic, whether laboratory developed or FDA cleared, undergo a verification, validation and performance documentation period before the test becomes available for clinical use, including:

- 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

*Reference values provided by Mayo Medical 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 Classifications

Analytical tests offered by Mayo Medical Laboratories are classified according to the FDA status of the test kit or reagent and to their usage. A test is classified as either FDA cleared, approved or exempt, or as a laboratory developed test (LDT). Where appropriate, analytical test listings contain a statement regarding the test classification, test development and performance characteristics of the test.

Test Standardization

The Mayo Laboratory Standardization Group (MLSG) is a department-wide, multisite initiative focusing on standardizing platforms, assays, procedures and controls across all testing sites. The goal of these activities is to assure the same results are obtained at all testing sites. The group actively identifies the best method for each test and standardizes processes across testing sites to ensure high-quality and consistent results, regardless of testing location.

Turnaround Time (TAT)

Mayo Medical Laboratories' extensive test menu reflects the needs of our health care practice. We are committed to providing the most expedient turnaround time possible to improve diagnosis and treatment. We consider that laboratory services are part of the patient care continuum and the needs of the patient are paramount. Our history of service and quality metrics document our ability to deliver on all areas of service including turnaround time. Mayo Medical Laboratories defines turnaround time as the analytic test time (the time from which a specimen is received at the testing location to the time of result). Turnaround time is monitored continuously by each performing site.

Record Retention

Mayo Medical Laboratories, in compliance and adherence to the College of American Pathologists (CAP) Laboratory General Checklist (**CAP GEN. 43900**), retains all test requisitions and patient test results at a minimum for the retention period required.

Reportable Disease Notification

Mayo Medical Laboratories, in compliance with and adherence to the College of American Pathologists (CAP) Laboratory General Checklist (**CAP GEN. 20374**), strives to abide by laboratory reporting requirements for each state health department regarding reportable disease conditions. We report by fax, mail 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 Medical Laboratories reporting does not replace the client/physician responsibility to report as per specific state statutes.

Referral of Tests to Another Laboratory

We have established collaborative relationships with more than 140 laboratories within the United States. Mayo Medical Laboratories selects outside vendors 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 (**CAP 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.

Results Reporting

Clients of Mayo Medical Laboratories receiving Mayo final reports have the responsibility in compliance with and adherence to the CAP Laboratory General Checklist (**CAP GEN.48500**) to validate and verify that the contents of their patient reports transmitted to their ordering physician or patient electronic medical record compares to the MayoAccess Report. The client is responsible for the transmission of patient results through the interface activities within their own system (LIS and HIS).

Paper or electronic reports of a patient's results include all required elements and information in compliance with and adherence to the College of American Pathologists (CAP) Laboratory General Checklist (**CAP GEN. 41096**), with the address of the reporting laboratory on the report.

If Mayo Medical Laboratories changes a result or adds an additional comment, "revised report" will appear on the printed or electronic report under the test name. All revised reports will also be telephoned to the client. The report will show both the previous reported results and the revised or corrected results in compliance with and adherence to the CAP Laboratory General Checklist (**CAP GEN. 41310**).

Transportation and Handling

Mayo Medical Laboratories warrants that all in-house and contracted couriers are appropriately licensed and have received training required by OSHA regarding bloodborne pathogens. We also require training specified by the U.S. Department of Transportation regulations as detailed in 49 CFR, Parts 100-185. Personnel are trained in appropriate safety and packaging

procedures suitable to specimen types and distance transported, and certified training is documented in compliance with and adherence to the College of American Pathologists (CAP) General Checklist (**CAP GEN. 40515**). Our couriers are also trained to adhere to any federal, state and local guidelines related to transportation of laboratory samples.

Infectious Material

The Centers for Disease Control and Prevention (CDC), in its regulations of July 21, 1980, has listed organisms/diseases for which special packaging and labeling must be applied. Required special containers and packaging instructions can be obtained from our [Supply Catalog](#) and by using the [Request for Supplies](#) form.

Shipping regulations require that infectious substances affecting humans be shipped in a special manner. A copy of the regulations can be requested from the International Air Transport Association (IATA) by phone at 514-390-6726 or fax at 514-874-9659 or by e-mail at custserv@IATA.org.

Business Continuity and Contingency Planning

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

Personnel

Mayo Medical Laboratories is unique in the reference laboratory industry, because we are part of a large, practicing health care system. We do not rely on a single medical director to consult with clients. Rather, we offer clients access to the more than 160 physicians and scientists practicing in Mayo Clinic's Department of Laboratory Medicine and Pathology. These professionals are available for consultation regarding test selection, order clarification, collection and processing procedures, and result interpretation.

Curriculum vitae for our physicians and scientists are available upon request.

Glossary

5S — (Sort, Shine, Set in Order, Standardize, and Sustain) A method of creating a clean and orderly workplace that exposes waste and errors.

ASR — **Analyte Specific Reagents** — “Antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.” 21 CFR 864.4020(a).

Assessment — A systematic, independent examination that is performed at defined intervals and at sufficient frequency to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments usually include comparison of actual results to expected results. Types of assessments include external, internal and quality assessments, self-assessments, and peer review.

CLIA — **Clinical Laboratory Improvement Amendments** of 1988 (42 CFR Part 493).

CLSI — **Clinical Laboratory Standards Institute** — Formerly known as the National Committee for Clinical Laboratory Standards (NCCLS).

CAP — **College of American Pathologists**.

Critical Value — 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 (Clinical Pathology Working Group, April 2000).

Defect — A part, product, or service that does not conform to specification or customer expectations.

DPM — *Defects Per Million*.

DLMP — *Department of Laboratory Medicine and Pathology*.

FMEA — *Failure Modes and Effects Analysis* — A fault tree method (first developed for systems engineering) that examines potential failures in products or processes. It may be used to evaluate risk management priorities for mitigating known threat-vulnerabilities.

IUO — *Investigational Use Only* — Investigational use only reagents or test kits.

IVD — *In vitro Diagnostic* — "In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." 21 CFR 809.

Joint Commission, The — Formerly known as Joint Commission on Accreditation of Healthcare Organizations.

KPI — *Key Performance Indicators* — Measurements that represent the status of an operational area and progress made to reach operational objectives.

Laboratory — A facility for the biochemical, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the impairment of or the assessment of the health of human beings (42CFR 493.2). A laboratory is a facility designed for collection, processing and/or testing of specimens or procedures (DLMP Enterprise Information Model).

Lean Manufacturing — A management philosophy focusing on reduction of the seven wastes (over-production, waiting time, transportation, processing, inventory, motion and scrap) in manufactured products. By eliminating waste, quality is improved, and production time and cost are reduced. Lean "tools" include constant process analysis, "pull" production, and mistake-proofing.

Proficiency Testing — A program in which multiple specimens are periodically sent to a group of laboratories for analysis and/or identification; in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value and reported to the participating laboratory and others (CLSI GP27-A2). Proficiency testing is an evaluation of the ability of a laboratory to achieve a correct test result when compared with other laboratories using the same methodology. This is accomplished using the laboratory's materials, personnel, equipment, environmental conditions, and procedures through the analysis of unknown specimens distributed at periodic intervals by an external source.

Quality Indicator — A specific measurement of the performance of functions and processes used to make informed decisions regarding whether a process is in control or to identify opportunities for improvement.

Quality Management — All activities of the overall management function that determine quality policy, objectives and responsibilities, and implementation by means such as quality planning, quality control, quality assurance, and quality improvement within the quality system (CLSI GP26-A3).

Quality Program — The comprehensive planned, written, and managed system for significantly decreasing errors, lending credibility to test results, and improving product and service safety and quality.

RUO — *Research Use Only* — The FDA considers RUO products to be those in the laboratory research phase of development; that is, either basic research or the initial search for potential clinical utility.

Six Sigma — A statistical concept that represents the amount of variation present relative to customer requirements or specifications.

- 6σ = 3.4 defects per million opportunities
- 5σ = 233 defects per million opportunities
- 4σ = 6,210 defects per million opportunities
- 3σ = 66,807 defects per million opportunities
- 2σ = 308,537 defects per million opportunities
- 1σ = 691,462 defects per million opportunities

TLCP - Define, document, and implement a standardized test life cycle process (TLCP) that improves DLMP operations and prepares all Mayo Clinic CLIA laboratories for increased FDA and other regulatory oversight of lab tests, especially Laboratory Developed Tests (LDTs).

Total Test Count — Total count of orderable tests. Count occurs at time of result.