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Quality Systems Manual		

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Quality Systems Manual

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1. Introduction

The goal of the Quality Management System (QMS), as described in this Quality Systems Manual (QSM), is to establish an organizational structure for the CLIA Laboratory that fosters quality laboratory services. The QMS addresses the principles, standards, goals and activities fundamental to the quality functions of the CLIA Laboratory at Theranos, Inc. Included in the QMS are specific core Quality System Essentials (QSE) as defined by Clinical and Laboratory Standards Institute (CLSI). The College of American Pathologists (CAP) and CLSI emphasize the importance of documenting and optimizing the laboratory path of workflow. This path of workflow begins outside the laboratory's boundaries, with a provider's request for a laboratory examination, and ends outside the laboratory's boundaries, when the laboratory result influences a provider's decision making. Development of a system that provides for the continuous monitoring and evaluation of this workflow, as it pertains to CLIA laboratory services, is essential to the operational aspects of how lab services are provided. The system was designed to maintain compliance with applicable federal, state and local laws and regulations, as well as, organizational policies and ethical standards.

In the CLIA Laboratory at Theranos, the patient comes first in everything we do. We constantly seek ways to improve, adding value for all our customers. Innovation, collaboration, leadership and integrity are the keys to our successes in continuous process improvement. The concepts contained within this document are a roadmap to achieve these goals. Within the structure of the QMS, to include the Quality Management Plan (QMP) we address both the human and system factors dealing with quality and safety. The QMP, a separate document, outlines specific responsibilities of quality for the CLIA Laboratory.

The CLIA Laboratory at Theranos maintains a strong commitment to quality and patient safety. Personnel are encouraged to discuss quality and safety concerns with their superior and or quality assurance representative. It is the responsibility of management and all laboratory personnel to always do the right thing for the patient. Patient safety is an essential and inseparable component of laboratory quality.

2. Organization

Purpose

The QMS provides a method of detection and process improvements which maximize the quality of laboratory testing to produce the accurate and timely results needed in support of quality patient care. Functions periodically reviewed include policies, procedures, staffing, and personnel. Each is evaluated to include Theranos goals. The system includes provisions for employee training and competency assessment, document control requirements, procedures for the monitoring of quality control, quality indicators, internal and external customer satisfaction, a process for a systematic approach to occurrence management, processes for data access security and transfer integrity of internal quality improvement activities. Because of the rapidly changing laboratory environment, goals and standards will be periodically reassessed.

The QSEs provide the framework for delivery of laboratory services, and are utilized as a reference guide. The QMS describes the underlying quality principles/essentials that promote continuous quality improvement and improved patient safety. Quality management is the continuing process whereby the laboratory ensures quality, maintains compliance with applicable laws, regulations and company policies, and pursues quality improvement activities.

Quality Essentials

The CLIA Laboratory monitors pre-analytic, analytic and post-analytic phases of laboratory testing within Theranos, Inc. QSEs defined within this policy include the following. (Those in parentheses are subsumed by the overall company policies and procedures).

Organization	Information Management
Personnel	Documents & Records
Equipment	(Purchasing & Inventory)
Process Control	Occurrence Management
Assessments – External & internal	Process Improvement
Customer service	Facilities & Safety

Theranos

Mission

Our mission is to make actionable health information accessible to people everywhere in the world at the time it matters, enabling early detection and intervention of disease, and empowering individuals with information to live the lives they want to live.

CLIA Laboratory

Our immediate goal is to become the standard for improving the risk/benefit and safety profile and the efficacy of every therapy.

Core Values

Integrity
Excellence
A team approach

Mission

To provide the highest quality of laboratory services for our customers and their patients.

Core Values

We as employees of the CLIA Laboratory at Theranos put the patient first and in support of that goal will promote the highest quality of laboratory services and adhere to our company's policies and procedures at all times. We adopt performance standards which will ensure the delivery of superior health care services.

Ethical Decision Making

The laboratory staff is committed to attaining the highest level of integrity, compliance and ethics. This is evidenced in our daily work and our decisions. Specific expectations relating to integrity, compliance and ethics include, but are not limited to:

Respect for the patient
Generating confidential patient reports
High quality performance of laboratory testing
Adherence to all company policies and procedures
Determining when it is appropriate to raise an ethical issue

Quality Management Structure

The Quality Management System defines the Theranos CLIA Laboratory operating structure for continuous quality improvement across the testing spectrum. The continuum of quality is represented by the Quality Management System, as embodied in the Quality Systems Manual, and the Quality Management Program, as represented by the Quality Plan.

Quality Initiatives

Each year, Quality Indicators of the CLIA Laboratory Quality Plan are established and approved following the Laboratory Director's, Quality Manager's or designee's review of quality measures and annual safety goals. The quality initiatives are approved by the Laboratory Director and communicated each year at the appropriate staff meeting(s).

The SOP will include all approved/applicable QA indicators. For example,

- The patient and sample identification process
- Verification and communication of life threatening/altering information.
- Identification, communication and correction of errors
- Coordination of the laboratory patient safety role

Laboratory Leadership

The Laboratory Director, with the assistance of the QA/QC Manager, Technical and/or General Supervisors and Safety Manager, oversee the management of quality and safety within the CLIA Laboratory.

Responsibility

While it is the responsibility of every employee to practice and implement quality related processes, specific duties are as follows:

Staff	Responsibility
Laboratory Director	Content and administration of Quality Management System and Program Compliance with system and program requirements Support of the Quality Plans Annual appraisal of effectiveness of Quality Management System and Quality Plan
Quality Assurance / Quality Control Manager or designee Safety Manager	Support the work of the Quality Plan
Laboratory Technical and General Supervisors(s)	Ensure effectiveness of quality plans Ensure the effectiveness of implemented improvements Ensure quality compliance

Regulatory Terms of Accreditation

The CLIA Laboratory at Theranos complies with federal regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The CLIA Laboratory is under the direction of a qualified Laboratory Director as required by CLIA and other applicable regulatory authorities/ agencies.

A certificate of accreditation (one means of satisfying the regulatory

requirement) will be sought from a Centers for Medicare & Medicaid Services (CMS) approved agency.

As required, the CLIA laboratory will maintain state licensure and local permits.

Regulatory Agency Inspections

CMS or a CMS approved agency may conduct announced or unannounced inspections ("surveys") in a laboratory holding any type of CLIA certificate. The reasons for and frequency of inspections varies by certificate type.

State and local authorities may also conduct inspections.

Laboratories cooperate with all regulatory agencies and comply with applicable policy.

Test results are released to government agencies as defined by state and local regulations.

Referral Testing

Referral laboratories must hold a valid Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate appropriate to the complexity of the specialties and subspecialties of testing and any applicable State license or permit before being referred.

The Laboratory Director, in conjunction with the QA / QC Manager or designee, annually reviews and approves the list of any referral laboratories.

3. Process Improvement

Purpose

The goal of the Theranos CLIA Laboratory Quality Management System is to establish and outline the structure that fosters quality laboratory services. The quality improvement plan involves all areas of operations (pre- analytic, analytic, and post-analytic) in each area of the laboratory. The laboratory division participates in continuous quality improvement activities, which are integrated into the overall quality management structure.

Quality Improvement (QI) is the continuous study and adaptation of an organization's function, and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals and other users of services. The CLIA Laboratory quality program/plan that collectively support the systems, personnel, processes and procedures that assure the quality of test results and service commensurate with company's mission and values. The laboratory incorporates quality assurance and quality improvement measures into its quality plan. The plan identifies and gives direction for pursuing opportunities to improve customer service and patient safety.

Definitions

Quality Assurance (QA) is a system of quality control activities that promote the quality of higher-level processes and functions. These higher-level processes are typically composed of multiple steps, each of which may fail and each of which are individually subject to quality control. QA is best applied to all steps in the laboratory test cycle, including integrity of the test ordering process and collection process, analyses, and the reporting of results, as well as to other important variables that impact quality, such as the training of laboratory personnel (CAP 2005).

Quality Improvement (QI) is a separate activity that supplements Quality Assurance. QI is the effort to improve the quality of product/process beyond its current state. It is more a proactive than monitoring/reactive process. Quality may also be improved by redesigning a process-eliminating unnecessary steps or reworking operations that have a high risk of failure (CAP 2005). The focus of QI is enhancing the quality of services provided and customer satisfaction.

Responsibility

Continuous quality improvement is a shared responsibility of the company and its employees. Everyone is a stakeholder in the effort to improve patient safety within the organization.

Quality Plans

The CLIA Laboratory quality initiative identifies opportunities to improve systems and processes that relate to the patient safety, quality and service goals that support high quality laboratory services.

The laboratory has a quality plan that fosters objective and systematic monitoring of the quality and appropriateness of the services provided through an operational plan.

The PDSA cycle is a method of quality improvement, which involves the design of a change to improve a process ("Plan"), implementation of the change on a test basis ("Do"), evaluation of the impact of the change on process variation and bias ("Study"), and if the change is successful, implementation on an ongoing basis ("Act"). Once the laboratory is certified, PDSA projects will be part of the quality plan.

Quality Measures

The CLIA laboratory tracks key service quality measures that:

Reflect issues important to the quality of patient care
Affect a significant segment of the laboratory's patients/ clients
Are objectively measured
Are systematically evaluated to identify improvement opportunities
Document the impact of specific actions taken to effect improvement
Track progress toward quality goals and objectives

Quality Plan Review

The CLIA Laboratory quality plan is to be evaluated annually for effectiveness by the Laboratory Director.
Quality plan review is documented and offers objective evidence when improvement has occurred.
Quality records are retained in accordance with the Record Retention Protocol.

4. Process Control

Purpose

The laboratory documents and validates the processes in the pre-analytic, analytic, and post-analytic activities path of workflow. This policy outlines the direction for the processes and procedures necessary to ensure that testing procedures are correctly performed, testing methods work as expected to yield reliable results, and governmental and other regulations are met. It also provides direction to effectively manage the laboratory's processes such that all impacts of the changes on customers and other processes are considered and dealt with accordingly. The laboratory documents and validates all processes in the path of workflow prior to implementation.

Specimen handling and testing processes and procedures are designed and tested to ensure they work as intended. Specimens are received and processed under conditions that allow for positive specimen identification and maintenance of specimen integrity throughout the testing process.

Quality control (QC), sometimes called Process Control, is an integral component of quality assurance that occurs during the analytical phase of testing (i.e. before patient results are reported). QC is comprised of the activities that ensure that specific processes and basic functions meet acceptable parameters. Intrinsic to QC is the development of standards of acceptable performance, a system for measuring performance, and rejection (or remediation) if acceptable standards are not met. The management of quality control occurs on a real-time basis and as a continuous tool in evaluating the reliability of test data.

Control materials, with known target values, are processed/tested in parallel with patient specimens on every analytical run. Before patient results are reported, the control results must meet the stated acceptability criteria. Laboratory staff establishes and follows written procedures for monitoring and evaluating the results of QC testing. Control results must meet stated acceptability criteria prior to the reporting of test results.

All pre-analytic, analytic, and post-analytic activities utilize methods that have been verified or validated and have established and verified reportable ranges and reference intervals. Before a new test method or significant test modification is placed into service and test results are reported, test performance is evaluated and validated under routine laboratory conditions.

Specimen Processing

The area in which specimens are received and/ or processed has written procedures that cover:

- Specimen receipt, labeling and preservation
- Registration/order entry
- Specimen rejection and suboptimal specimens
- Acceptance from authorized source

Availability of Instructions

Written instructions for specimen labeling, preservation and conditions for specimen transport are made available to customers.

Proficiency Testing

The CLIA laboratory participates in a PT program either through CAP, other CMS/CAP approved vendors or an alternative testing program for each reportable analyte. Written procedures describe the appropriate handling of PT samples.

Quality Control Procedures

Each technical procedure includes instructions for the use of QC material, including, but not limited to:

- Specific control material to be used
- Instructions for the preparation and handling of control material
- Frequency at which controls are to be analyzed
- Criteria for accepting/rejecting a run
- Actions to be taken when QC results do not meet stated acceptability
- Proper storage and stability
- Changing an established target QC limit

Method Performance Specifications

Procedures defining the validation and calibration processes address:

- Validation
- Calibration
- Calibration Verification

Authorization

The Laboratory Director approves the Laboratory Validation for all new tests/methods and significant changes to existing tests/methods.

Method and Instrument Comparison

The CLIA laboratory has defined procedures to evaluate and define the relationship of test results when testing is performed on multiple instruments, or using different methodologies.

Water Quality

The laboratory determines the CLSI grade of water (Clinical Laboratory Reagent Water, CLRW) necessary for each procedure and has a system for delivering adequate volumes of the required grade of water.

If not commercially purchased, Theranos has a procedure and schedule for routine water production, equipment maintenance and water quality testing.