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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 empower individuals to monitor and treat any condition effortlessly and in real-time.

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

CLIA Laboratory

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 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 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 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 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.

5. Occurrence Management

Purpose

The Laboratory is actively involved in capturing and analyzing information from nonconforming events to identify systematic laboratory problems, both internal and external. Errors are detected by random review of internal processes, and those reported by a health care provider, or other customer/individual outside the laboratory. A summary of laboratory occurrences (including trends) is reviewed monthly by the QA Manager or designee, and presented as warranted to the Laboratory Director. The management of occurrences is used to improve laboratory performance and patient safety.

Responsibility for the management of the complaints is delegated to Theranos Customer Solutions, the Clinical Consultant, or designee. All complaints/grievances received by personnel should be forwarded to the QA Manager or designee for tracking and trending.

As always, all staff are to actively work to resolve issues and concerns. Procedures are to be followed to protect the privacy and confidentiality of patients when issues/complaints and grievances are expressed.

Quality Issues The Quality Manager or designee coordinates the corrective action process and evaluates the occurrence of the issue for patterns requiring preventive and or proactive action.

Recalls The Quality Manager or designee is notified in the event of a quality issue, including but not limited to major product issues involving testing, materials/customer supplies or major information management issues where there is a known or potential effect on testing results/interpretation. Legal may be notified of the quality issue as warranted.

FDA notification Medical Device failure

When information reasonably suggests that any laboratory instrument, reagent or other device has or may have caused or contributed to a patient death or serious patient injury, the event is reported by the Laboratory Director, the Quality Manager or designee after review by Legal to the FDA as required. Reports must be submitted on FDA Form 3500A (or an electronic equivalent) as soon as possible, but no later than 10 days from the time medical personnel become aware of the event.

6. Audits – External & Internal

Purpose

The laboratory will undergo internal and external assessments to determine the effectiveness of the laboratory's quality management system to include interim self-assessment. The CLIA laboratory participates in internal and external assessments as required by federal and, as applicable, state law. Assessments such as these take many forms and are an integral part of the management of quality in the healthcare industry.

External & Internal Assessments

The CLIA laboratory will communicate and document externally and internally identified problems.

Forms specified in individual SOPs are used for reporting of internal quality and patient safety concerns.

Annual internal inspections are coordinated by the QA Manager or designee to help ensure compliance with regulatory requirements.

Proficiency Testing or Alternative Testing is also performed and results monitored.

Regulatory Agency Inspections

CMS or its designee may conduct announced or unannounced inspections/surveys in laboratories holding any type of CLIA certificate. The reasons for and frequency of inspections varies by certification.

State and local authorities may also conduct inspections.

Customer Complaints and Problems

Complaints and problems reported to the laboratory via Theranos Customer Solutions, the Clinical Consultant or other sources are documented and investigated. Issues are researched and, as appropriate, corrective actions are taken. Opportunities that arise are folded into the PDSA model for potential process improvement.

The CLIA laboratory will document any problems that occur as a result of communications breakdowns with customers. Corrective actions are to be documented and monitored. The particular procedures are delineated in specific SOPs.

7. Documents

Purpose

Document control ensures that information used by staff is available, current, and authentic. The CLIA Laboratory follows specific document elements and types specified and defined in its own SOPs that follow CLSI guidelines.

Responsibility

Managers and or supervisors are responsible for:

Ensuring that personnel have current copies of the documents they need to perform their work

Promptly removing outdated documents from the workplace

Submitting SOPs for re-approval if there is a change in directorship.

Retention

Technical SOPs contain all the appropriate regulatory elements. Document types are generated, reviewed, and retained in accordance with applicable regulatory and accreditation requirements.

Document Elements

Elements (Q-Probe 2008)	Description
Authorized	A document has been authorized if there is evidence that someone who has the authority to approve the document approved it. A signature is evidence.
Available	A document is available if it is reasonably accessible by all individuals who are likely to need access to the document.
Archived	A document is considered to be archived if the document in its current form has been in force for fewer than 2 years (5 years for TM documents), AND other versions of the document are retrievable from a file or some other source.
Current	A document is current if it is in use and there is no more recent, authorized version of the document. A document should still be considered current if a newer version is in development, but has not yet been authorized and made available to staff.
Management Review	A document has undergone review if there is evidence that management approved of the document within the past 12 months.
Staff Review	A document has been reviewed by staff if there is evidence that staff reviewed it within 45 days of the time it was placed in service or most recently updated (whichever comes later).

Document Types

Four types of documents are used in the clinical laboratory:

Type (Q-Probe 2008)	Description
Forms	A document that is used to record information related to laboratory activities. A form typically consists of paper used to record an observation (e.g., results of QC testing). A form must contain some information itself, above and beyond the information that is to be recorded. A lined sheet used to record daily refrigerator temp should not be considered a form unless it contains some additional information.
Policy	A document that indicates an organization's intentions or commitments, for example, a written statement that critical laboratory results should be called to the provider.
Procedure (SOP)	A document that provides instructions for an individual to follow in order to correctly perform an activity or step in a larger process, for example, step-by-step instructions for performing a particular chemistry assay.
Work Aids	A summary of part of a procedure that is immediately available in close proximity to where the procedure is to be performed. A chart at a laboratory bench showing media set up for different microbiology specimens would be considered a work aid if the chart summarized parts of one or more procedures.

Results Verification and Release

The CLIA Laboratory has written procedures describing the steps involved in results verification and release. These procedures support the timely detection of:

Clerical errors
Analytical errors
Unexpected test results

They are monitored according to the QA Protocol.

8. Personnel

Purpose

The Theranos CLIA Laboratory has established and maintains personnel policies so that employees have the necessary qualifications and training required to appropriately perform their duties. The CLIA Laboraory complies with federal regulations as set forth under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The laboratory is under the direction of a qualified Laboratory Director as required by CLIA.

Laboratory Director Responsibilities

The Laboratory Director specifies, in writing, the duties and responsibilities of each qualified consultant and supervisor and indicates which Laboratory Director duties have been delegated. Documentation is also available for the authorization of duties for each employee engaged in the pre-analytic, analytic and/or post-analytic phases of testing.

Personnel Qualifications

Theranos requires all personnel in the CLIA Laboratory engaged in the pre - analytic, analytic and post-analytic phases of testing to meet applicable federal, state and local regulatory requirements.

The laboratory collaborates with Human Resources at Theranos to hire qualified personnel and ensure that they have and can demonstrate the knowledge and skills necessary to perform their duties.

Visual Color Discrimination

Technical employees are tested for color discrimination if required for their job assignments and responsibilities are assigned accordingly.

Job Descriptions

All personnel involved in the pre-analytic, analytic and post-analytic phases of testing have written job descriptions.

Orientation	Upon hire each employee attends company- and laboratory-specific orientations.
Training	Before employees handle or test patient specimens, they are required to have education, experience and documented training appropriate for the type and complexity of work performed.
Competency	Competency is assessed and documented at least semi-annually during the first year of employment and annually thereafter.
Performance and Development Review	Theranos follows a defined process for annual performance appraisals.
Continuing Education	The company seeks to provide employees and workgroups with the knowledge and skills necessary to meet the requirements of their jobs while providing access to continuing education programs that assist in satisfying certification renewal requirements.
Personnel Records	Personnel records are maintained by Human Resources in accordance with company policy.

9. Customer Service

Purpose	The laboratory has identified internal and external customers and their needs and expectations. Using this information as a spring board, the laboratory develops/changes processes in order to meet these needs. The laboratory's quality management activities are focused on the voice of the customer as it relates to patient safety and process improvement..

Service Quality Measures

The laboratory tracks key service quality measures that:
- Reflect issues important to the quality of patient care
- Are objectively measured
- Are systematically evaluated to identify improvement opportunities
- Document the impact of specific actions taken to effect improvement
- Track progress toward QI goals and objectives

Service Solutions

The laboratory has a process for responding to customer complaints and detecting errors that may affect the quality of service. Data is examined and trended to identify opportunities for improvements.

Notification of Changes in Testing

The Laboratory Director, Quality Manager, or designee notifies the appropriate federal, state and/or accrediting agency, as required, of certain types of changes in its test menu.

Analytical Methodology Changes

Changes in analytical methodology that significantly affect test results or their interpretation are explained to the clients in a comment in the final test report.

Delay in Reporting

In the event testing results will be significantly outside the predetermined TAT, the requester will be notified of the delay. If the requester is not available the appropriate health care personnel will be notified.

Critical Values

The laboratory follows written procedures for reporting critical (panic) values.

Patient Reports

The patient report is confidential and sent only to a licensed physician or other authorized individual(s). The report includes, at a minimum the qualifications listed in the CAP Laboratory General Checklist. Patient reports also include qualifications listed in the States of California and New York, as appropriate.

10. Information Management

Purpose

Information is maintained so that patient/testing data are secure, accurate and reliable. The laboratory controls how patient and laboratory information is received, accessed, transmitted, and stored in either paper-based and, in the future, electronic information systems. Direction is provided for the processes and procedures to effectively manage laboratory-generated information. Processes are designed to ensure that patient information is kept private and confidential. Data is retrievable only to authorized personnel. The confidentially of all patient related information is maintained in accordance with Health Insurance Portability and Accountability Act (HIPAA) guidelines.

Environment

If adopted, a Laboratory Information System (LIS) will be maintained in a secure, clean and adequately ventilated environment with protection against electrical power fluctuations.

LIS Procedure Manuals

If an LIS is implemented, written procedures will be maintained for the:

- Operation of computer equipment
- Preservation of data and equipment
- System Security
- Data retrieval and storage
- Hardware and Software Documentation
- System Maintenance
- Verification for Results Transmission

Functionality and Reliability of Computer System

The Laboratory Director and Information Technology will assess the adequacy of any computer system (hardware and software) adopted to meet the needs of laboratory service and ultimately patient care. In the event new hardware or software is being considered the Laboratory Director or designee, in conjunction with Information Technology, is involved in the system and or software choice.

Reporting Systems

The laboratory will have adequate systems in place to report results in a timely, accurate and reliable manner.

Report Format Review

The laboratory has a process for the annual review/approval by the Laboratory Director or designee of all types (paper and, if adopted, electronic) of patient reports, to include content and format.

Report Accuracy

There are systems in place which aid in detecting clerical errors, analytical errors and unusual test results.

These systems allow for the timely correction of errors.

Manual, and if implemented, automated result entries are verified before final acceptance and reporting.

Should the laboratory employ auto-verification procedures for test results, there will be documentation of validation of the process and Laboratory Director approval.

Result Modification

Any results changed or modified are documented to show both the original and modified results, reason for change, and date of newly revised final report.

Verification of Computer Calculations

Should an LIS be adopted, calculation routines will be verified annually and after any changes to the LIS that may affect the calculations.

11. Equipment

Purpose

The laboratory maintains equipment in a manner appropriate to the proper collection, handling, preparation, testing and storage of specimens and generation of test results and patient reports. The laboratory maintains an inventory of equipment used in the path of workflow. The Laboratory Director or designee is involved in the selection of new equipment.

Installation

Equipment is installed according to manufacturer's specifications. Equipment function is validated after installation and if the equipment is moved to another location.

Function Checks

Function checks are performed to evaluate critical operating characteristics. For each type of equipment, written procedures specify the performance of function checks, at specified intervals, tolerance limits, trending and corrective action as needed.

Preventive Maintenance Procedures

The laboratory has written procedures for the PM of each instrument, device or test system, which meets or exceeds the manufacturer's specifications.

When a service contract for PM from an outside vendor is used, there is a written description of the service to be performed and the frequency of service or each instrument. Additional repair work is performed as needed.

PM/Function Check Review

PM records and function check documentation are reviewed monthly by a supervisor or supervisor designee.

Temperature Dependent Equipment

Temperature-dependent equipment is monitored and temperatures are recorded each day of use. Temperatures are recorded manually or by a temperature chart recorder as applicable.

Equipment Checks and PM

The laboratory is responsible for documentation of preventive maintenance, periodic inspections, and performance testing as determined by manufacturer guidelines. The equipment is evaluated with respect to all operating characteristics. Supervisory personnel review the documentation of calibration records, maintenance logs, temperature charts and quality control records monthly and sign-off on the forms.

The equipment monitored includes but is not limited to:

- Analytical instruments
- Thermometers (checked against an NIST-certified thermometer)
- Balances
- Timers
- pH meters
- Centrifuges
- Pipettes/Dilutors
- Autoclaves

Glassware

The laboratory has procedures for glassware handling and washing, including methods of testing for detergent removal.

Room Temperature and Humidity

The laboratory has an established system for monitoring room temperature and humidity where applicable and corrective action as needed.

12. Facilities & Safety

Purpose

The laboratory facilities are designed, renovated, used, and maintained to meet all applicable requirements for safety, efficiency, and ergonomics. Laboratory practices ensure the safety of all employees and visitors. The Laboratory Director is responsible for collaborating with facilities and the Safety Manager to obtain optimal facilities for laboratory safety. Laboratory Manager/Supervisors are responsible for communicating the needs of the laboratory through workflow analysis and for providing a safe workplace for all laboratory personnel.

Laboratory work areas are designed such that testing can be performed without compromising the quality of work or the safety of personnel or patients. The laboratory provides a safe working environment and opportunities for each employee to comply with safety requirements by providing training and appropriate personal protective and other safety equipment. The facility is routinely inspected to maintain a safe and comfortable workspace. Hazardous chemicals are stored according to standards in compliance with federal, state and local regulations.

Quality of the Workplace

Facilities Engineering is responsible for the general maintenance of the facility. The Laboratory Safety Officer is responsible for providing guidance to laboratory management and staff regarding safety issues and responsibilities. The company is committed to maintaining a safe and secure workplace. Company policies and procedures address (at a minimum):

Blood borne Pathogens, Fire Safety and other Occupational Safety and Health Administration (OSHA) standards
Chemical hygiene standards
Department of Transportation (DOT) standards

A documented Chemical Hygiene Plan (CHP) and MSDS are available to laboratory personnel at all times. These are reviewed annually. All safety related records (including employee injury records, personnel training records, employee reports of hazards, hazardous waste disposal records) are maintained and reviewed. A documented plan for storage and disposal of hazardous waste materials is maintained and administered by the Safety Manager.

13. Purchasing & Inventory

Purpose

All reagents, calibrators, standards, controls, solutions, culture media, stains and other testing supplies are required to be labeled, stored and handled according to defined procedures, including being checked for acceptability prior to or concurrent with being placed into service. Processes and procedures are in place for receiving, inspecting, storing and managing the inventory of supplies and reagents used in the path of workflow. An inventory of equipment, supplies, and reagents used in the path of the workflow is maintained by each division. The laboratory works through Point Purchasing™, the brand name of the software package implemented by the company for purchasing of supplies and reagents. Purchased chemicals used to prepare reagents are of American Chemical Society (ACS) -grade quality, or higher quality if required, as applicable.

Reagent Specifications

As necessary, procedures contain specifications such as supplier and catalog number, storage and handling instructions (e.g., temperature and humidity requirements), precautions and information necessary for preparing reagents.

Periods of Use	Outdated reagents are not used. Stability may only be extended by the manufacturer via written documentation. Contaminated or deteriorated reagents or other testing supplies are discarded regardless of expiration date.
Reagent Kit Components	Components of a reagent kit are not interchanged with like components from kits with different lot numbers, unless specified by the manufacturer.
Reagent Verification	Written procedures specify the verification of each new batch, lot or shipment of reagent.
Package Inserts	All versions and updates of manufacturer package inserts are reviewed for changes by testing personnel before test performance. Current versions of package inserts for reagents/testing materials are available in the laboratory.

14. Related Documents

Quality Plan for the CLIA Laboratory

15. References

a) Berte, LM. Laboratory quality management: a roadmap. Clin Lab Med 2007;27:771-790.
b) California Code of Regulations, Volume 22, Title 17, Division1, Chapter 2, Laboratories.
c) CLSI. *A Quality Management System Model for Health Care; Approved guideline – Second Edition.* CLSI document HS1-A2 (ISBN 1-56238-554-2). Clinical Laboratory and Standards Institute, 940 West Valley Rd, Suite 1400, Wayne, PA 19087 USA, 2004.
d) CLSI. *Application of a Quality Management System Model for Laboratory Services; Approved guideline – Third Edition.* CLSI document GP26-A3 (ISBN 1-56238-553-4). Clinical Laboratory and Standards Institute, 940 West Valley Rd, Suite 1400, Wayne, PA 19087 USA, 2004.
e) Federal Code of Regulations, Title 42, Part 493. Laboratory Requirements.
f) Theranos. Bloodborne Pathogens Safety Plan 2010.
g) Theranos. Chemical Safety Plan 2010.

h) Theranos. Competence Awareness and Training, QOP-62-00001, Revision A, 02/23/10.
i) Theranos. Control of Documents, QOP-42-000001, Revision B, 03/24/10.
j) Theranos. Employee Safety and Health Plan 2010.
k) Theranos. Fire Safety and Evacuation Plan 2010.
l) Theranos. Hazardous Waste Safety Plan 2010.
m) Theranos. Personal Protective Equipment Safety Plan 2010.
n) Theranos. Quality Systems Manual, QM-00001, Revision C, 03/24/10.
o) United States Public Law 104-191. Health Insurance Portability and Accountability Act of 1996, Aug. 21, 1996.
p) Valenstein, Paul, MD (Editor); Quality Management in Clinical Laboratories, *Promoting Patient Safety Through Risk Reduction and Continuous Improvement.* Northfield, Illinois: College of American Pathologists; 2005.

16. Revision History

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	06/09/2011	Arnold Gelb	CL ECO-00001
Section Number	**Description and Justification of Changes**		
ALL	Initial Release		