

Quality Management System

Barbara Parsons, MA MT (ASCP)
Patricia Wachter, MA CT/HT(ASCP)
Quality Assurance Workgroup

Chief of Service, Laboratory Director, Department Chair: Dr. J. Brooks Jackson

Deputy Director of Clinical Affairs: Dr. Michael Borowitz

Physician Advisor: Dr. Thomas Kickler

Assistant Director of Quality Improvement: Barbara Parsons MA, MT (ASCP)

(All signatures on file)

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Introduction

The goal of the Quality Management System (QMS) is to establish an organizational structure that fosters quality laboratory services. Our QMS addresses the principles, standards, goals and activities fundamental to the quality functions of Johns Hopkins Department of Pathology and Johns Hopkins Healthcare System. Included in our 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 clinical laboratory services, is essential to the operational aspects of how lab services are provided. The system was designed to maintain compliance with federal, state and local laws and regulations, as well as, organizational policies and ethical standards.

At Johns Hopkins Hospital the patient comes first in everything we do. We constantly seek ways to improve the patient experience, adding value for all our customers. Innovation, collaboration, leadership and integrity are the keys to our successes in the journey of continuous process improvement. The concepts contained within this document are a roadmap to achieve these goals. Faculty and staff at Johns Hopkins Hospital are aware of the human factors and the system factors that threaten the quality of patient care. Within the structure of the QMS, to include the Quality Management Program (QMP) and division Quality Plans we address both the human and system factors dealing with patient safety. The QMP, a separate document, outlines departmental and individual responsibilities of quality across the continuum of care at Johns Hopkins Hospital as it relates to The Department of Pathology.

The Department of Pathology maintains a strong commitment to quality and patient safety. Faculty and staff are encouraged to discuss quality and safety concerns with their superior and or quality assurance specialist. 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.

1. 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 qualifications. Each is evaluated to include hospital and departmental 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 must be continuously reassessed.

The QSEs provide the framework for delivery of different types of lab 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 institutional policies, and pursues quality improvement activities.

Quality Essentials

The department monitors pre-analytic, analytic and post-analytic phases of laboratory testing within Johns Hopkins Hospital Department of Pathology. QSEs defined within this policy are as follows:

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

**Johns Hopkins
Medicine**

Mission

The mission of Johns Hopkins Medicine is to improve the health of the community and the world by setting the standard of excellence in medical education, research and clinical care. Diverse and inclusive, Johns Hopkins Medicine educates medical students, scientists, health care professionals and the public; conducts biomedical research; and provides patient-centered medicine to prevent, diagnose and treat human illness.

Vision

Johns Hopkins Medicine provides a diverse and inclusive environment that fosters intellectual discovery, creates and transmits innovative knowledge, improves human health, and provides medical leadership to the world.

Core Values

Respect & Collegiality
Excellence & Discovery

Diversity & Inclusion
Leadership & Integrity

**Department of
Pathology**

Mission

To engage in the discovery, application and dissemination of knowledge in the study of disease in order to advance human health and to provide the highest quality of patient care for Johns Hopkins Medicine.

Vision

To be the leading academic pathology department nationally in patient safety and clinical innovation, medical discovery, and training the most promising students as clinical and scientists.

Core Values

We as employees of the Department of Pathology at Johns Hopkins Medical Institutions will promote the highest quality of care and adhere to our organizations policies and procedures at all times. We adhere to performance standards which 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 and using confidential patient reports
- High quality performance of laboratory testing
- Adherence to all hospital and laboratory policies and procedures
- Determining when it is appropriate to raise an ethical issue

Quality Management Structure

The Quality Management System defines the Department of Pathology's operating structure for continuous quality improvement across the testing spectrum. Johns Hopkins Department of Pathology continuum of quality is represented by the Quality Management System, the Quality Management Program, administered by the office of Continuous Quality Improvement (CQI) and the Quality Plans, designed and administered by each division and the CQI office.

Quality Initiatives

Each year, Quality Indicators of the division/area Quality Plans are developed in alignment with the Quality Improvement Council's review of quality measures and annual patient safety goals as developed by College of American Pathologists (CAP) and The Joint Commission (TJC). The quality initiatives are approved by the Physician Advisor and communicated each year to the appropriate committee and or at department/division staff meetings.

The Quality Indicators include, but are not limited to, improving the following:

- 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 within Johns Hopkins Medicine

Laboratory Leadership

The Laboratory Director in Chief, Deputy Directors and Administrators oversee the management of quality and patient safety within the Department of Pathology. The clinical laboratories are organized into 7 administrative groups, each managed by an Administrator or Manager who reports to his/her Lab Directors and Administrators.

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 in Chief Deputy Director Clinical Affairs Physician Advisor Division Laboratory Directors	<ul style="list-style-type: none"> • Content and administration of Quality Management System and Program • Compliance with system and program requirements • Support of the Quality Improvement plans of the divisions • Annual appraisal of effectiveness of Quality Management System and division plans
CQI Assistant Director QA Specialist QA Technologists	<ul style="list-style-type: none"> • Ensure QMS compliance • Local application of QI plans • Support the work of QI plans
Administrators Division/area Managers Division/area Supervisors Division/area QA Personnel	<ul style="list-style-type: none"> • Ensure effectiveness of quality plans • Ensure the effectiveness of implemented improvements • Monitor regulatory compliance within the division/area

Regulatory Terms of Accreditation

- Laboratories within the Department of Pathology at Johns Hopkins Hospital comply with federal regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and hold the required certification from the Centers for Medicare and Medicaid Services (CMS).
- All laboratories are under the direction of a qualified Laboratory Director as required by CLIA.
- A certificate of accreditation (one means of satisfying the regulatory requirement) is granted by CMS approved agencies, the foremost of which is the College of American Pathologists (CAP).
- Where required, each laboratory division maintains state and local certification, licensure or permit.

**Regulatory
Agency
Inspections**

- CMS or CAP may conduct announced or unannounced inspections (“surveys”) in laboratories 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 a Maryland Permit before being referred.
- The Laboratory Director in Chief and the Deputy Director of Clinical Affairs, in conjunction with clinical representatives in attendance at the Laboratory Advisory Committee (LAC) annually reviews and approves the list of referral laboratories.

2. Process Improvement

Purpose

The goal of the Department of Pathology Quality Management System is to establish and outline the structure that fosters quality laboratory services. Division quality improvement plans involve all areas of operations (pre-analytic, analytic and post-analytic) in each area of the laboratory. Each laboratory division participates in continuous quality improvement activities, which are integrated into the overall Department of Pathology quality management structure.

Quality Improvement (QI) is the continuous study and adaptation of a health care 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. Johns Hopkins Hospital Department of Pathology has department and division quality programs/plans that collectively support the systems, personnel, processes and procedures that assure the quality of test results and service commensurate with department’s mission and values. Each laboratory division incorporates quality assurance and quality improvement measures into their individual quality plans. The plans identify and give 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 hospital and its employees. Everyone is a stakeholder in the effort to improve patient safety within the organization.

Quality Plans

- The Department of Pathology quality initiative identifies opportunities to improve systems and processes that relate to the current patient safety, quality and service goals that support high quality laboratory services.
- Each division has a quality plan that fosters objective and systematic monitoring of the quality and appropriateness of the services provided by the area through an operational plan.
- The PDSA cycle is a simple 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”). PDSA projects are part of each local QI plan.

Quality Measures

Each laboratory/division tracks key service quality measures that:

- Reflect issues important to the quality of patient care
- Affect a significant segment of the laboratory's patients
- 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

Quality Plan Review

- The Department of Pathology and division quality plans are evaluated annually for effectiveness by the Laboratory Director in Chief and the division Laboratory Director or designee, respectively.
- Quality plan review is documented and offers objective evidence when improvement has occurred.
- Quality records are retained in accordance with the *Retention Times for Records, Reports and Specimens* policy.

3. Process Control

Purpose

The laboratory documents and validates all 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, policies and procedures are designed and validated to ensure they work as intended. Specimens are collected, transported 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) of product that does not meet acceptable standards. 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

Each area in which specimens are collected and or processed has written procedures for:

- Specimen collection, labeling and preservation
- Ensuring patient identification at the time of specimen collection
- Specimen packaging and transport
- Registration/order entry
- Specimen rejection and suboptimal specimens
- Acceptance from authorized source

Availability of Instructions

Written instructions for patient preparation, specimen collection, labeling, preservation and conditions for specimen transport are made available to customers. Laboratory Services Directory, residing in Pathology Data System (PDS), is a specimen collection manual made available electronically within Johns Hopkins Hospital and to clients outside the hospital. The directory is reviewed annually for accuracy.

Proficiency Testing	All laboratories participate in a PT program either through CAP or other CMS/CAP approved vendors. 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: <ul style="list-style-type: none">• 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 exist in each division and address: <ul style="list-style-type: none">• Validation• Calibration• Calibration Verification
Authorization	At the divisional level, the specific Laboratory Director approves the Laboratory Validation for all new tests/methods and significant changes to existing tests/methods.
Method and Instrument Comparison	Each laboratory area has defined procedures to evaluate and define the relationship of test results when testing is performed on multiple instruments, using different methodologies or at multiple testing areas.
Water Quality	<ul style="list-style-type: none">• Each 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.• Each laboratory that produces CLRW has a procedure and schedule for routine water production, equipment maintenance and water quality testing.

4. 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 physician, nurse, or other customer/individual outside the laboratory. A summary of laboratory occurrences (including trends) is reviewed monthly by the QA Workgroup, Process Improvement Committee (PIC) and presented as warranted at the Laboratory Advisory Committee (LAC). The management of occurrences is used to improve laboratory performance and patient safety.

Responsibility for the management of the patient complaints is delegated to the Patient Relations Department for the hospital and appropriate department liaison. The Pathology Administrator is the liaison for the Department of Pathology. All complaints/grievances received by the hospital staff should be forwarded to the Patient Relations Department for tracking and trending.

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

Quality Issues

CQI coordinates the corrective action process with the affected division and evaluates the occurrence of the issue for patterns requiring preventive and or proactive action on a hospital/department wide basis.

Patient Safety Net

- Patient Safety Net (PSN), through University Health System Consortium (UHC), is the web based tool for employees to utilize in the event of a quality and or patient safety issue.
- PSN events are trended and issues resulting from this information are discussed at the monthly QA Workgroup, PIC meeting and, as warranted, at the monthly CAC meeting, within Pathology, and or the LAC.

Recalls

- Risk and Safety Management Alert System (RASMAS) 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.
- According to the policy in the Interdisciplinary Clinical Practice Manual (ICPM) RASMAS notifies the JHH Risk Management Office and Risk Management notifies Legal of the quality issue.

**FDA notification
Medical Device
failure** When information reasonably suggests that any laboratory instrument, reagent or other device (including all instruments in the core laboratory, other laboratories, point-of-care testing programs, and accessory devices used for phlebotomy or specimen collection) has or may have caused or contributed to a patient death or serious patient injury, the event is reported by Risk Management 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. (See Department of Pathology, Equipment Management Policy).

5. Assessment – 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. Each laboratory division and outreach 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** Each laboratory division has a system to communicate and document externally and internally identified problems.

- PSN is the chosen system for reporting of internal quality and patient safety concerns.
- Patient and physician surveys are utilized through Press Ganey and Survey Monkey and other internal survey tools.
- Periodic internal inspections are coordinated by the CQI office to help ensure compliance with regulatory requirements.
- Proficiency 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 PSN and other sources are documented and investigated. Issues are researched and, as appropriate, corrective actions are taken.
 - Opportunities that arise from customer surveys are folded into the PDSA model for potential process improvement.
 - Each laboratory has a system in place to document problems that occur as a result of communications breakdowns with customers.
 - Corrective actions are documented and monitored.

6. Documents

Purpose Document control ensures that information used by staff is available, current, and authentic. Johns Hopkins Department of Pathology and other laboratories follow the six specified elements and four specified types as defined by CAP for document control.

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 whenever 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 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 if 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 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 most commonly consists of paper used to record some observation (eg, 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 within 60 minutes.
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 ABO identification in the transfusion service or quality control of media in the microbiology section of the laboratory.
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 Each division 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

7. Personnel

Purpose Johns Hopkins Department of Pathology has established and maintains personnel policies so that employees have the necessary qualifications and training required to appropriately perform their duties. The Department of Pathology complies with federal regulations as set forth under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). All laboratories/divisions are 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

- Johns Hopkins Department of Pathology requires all personnel 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 the Human Resources Department 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 screened for color discrimination at the time of their pre-employment physical. 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 hospital and department specific orientation.

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 Johns Hopkins Department of Pathology follows a defined process for annual performance appraisals.

Continuing Education The Hospital seeks to provide employees and workgroups with the knowledge and skills necessary to meet the requirements of the institution, current and future jobs while providing access to continuing education programs that assist in satisfying certification renewal requirements.

Personnel Records Personnel records are housed in the Human Resources department, the work area, or both, and are maintained in accordance with the requirements of the Hospital System.

8. Customer Service

Purpose The laboratory has identified internal and external customers and their needs and expectations. Using this information as a spring board Johns Hopkins Department of Pathology develops/changes processes in order to meet these needs. The Department of Pathology encourages interactive exchange between customer and supplier. Our department's quality management activities are focused on the voice of the customer as it relates to patient safety and process improvement.

Service Quality Measures	<p>Each laboratory tracks key service quality measures that:</p> <ul style="list-style-type: none">• 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	<p>Johns Hopkins Medical Institution has defined 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.</p>
Directory of Services	<p>The Johns Hopkins Department of Pathology <i>Laboratory Services</i> is available on the department website (intranet and internet) and provides the basic information needed by customers ordering tests.</p>
Notification of Changes in Testing	<p>The CQI office notifies the appropriate federal, state and/or accrediting agency, as required, of certain types of changes in their test menu.</p>
Analytical Methodology Changes	<p>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.</p>
Delay in Reporting	<p>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 patient care personnel will be notified.</p>
Critical Values	<p>Johns Hopkins Department of Pathology has developed and follows written procedures for reporting Critical Values.</p>
Patient Reports	<p>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 State of Maryland COMAR.</p>

9. Information Management

Purpose	The Laboratory Information System (LIS) are established and 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 both paper-based and 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. Electronic data is retrievable only to authorized personnel. The confidentiality of all patient related information is maintained in accordance with Health Insurance Portability and Accountability Act (HIPAA) guidelines.
Environment	The LIS is maintained in a secure, clean and adequately ventilated environment with protection against electrical power fluctuations.
PDS/LIS Procedure Manuals	Written procedures are maintained for the: <ul style="list-style-type: none">• 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 assesses the adequacy of the Department of Pathology computer system (hardware and software) to meet the needs of patient care. In the event new hardware or software is being considered the Laboratory Director or designee is involved in the system and or software choice.
Reporting Systems	Each division has adequate systems in place to report results in a timely, accurate and reliable manner.
Report Format Review	Each division has a process for the annual review/approval by the Laboratory Director or designee of all types (paper and 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 automated result entries are verified before final acceptance and reporting by the LIS.
 - Where the laboratory employs auto-verification procedures for test results, there is 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 Calculation routines are verified annually and after any changes to the LIS that may affect the calculations.

10. Equipment

Purpose Johns Hopkins Department of Pathology 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 for each instrument. Additional repair work is performed as needed.

PM/Function Check Review PM records and function check documentation are routinely reviewed 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 Isensix as applicable.

Equipment Checks and PM Each 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.

The equipment monitored includes but is not limited to:

- Thermometers (checked against an NIST-certified thermometer)
- Balances
- Timers
- pH meters
- Centrifuges
- Pipettes/Dilutors
- Spectrophotometers
- Densitometers
- Autoclaves
- Microscopes

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

Room Temperature and Humidity Each laboratory/division has an established system for monitoring room temperature and humidity where applicable and corrective action as needed.

11. 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 Johns Hopkins Medical Institution 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 determined by Johns Hopkins Health Safety and Environment (HSE) 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 Johns Hopkins Department of Pathology is committed to maintaining a safe and secure workplace. Health Safety & Environment (HSE) programs address (at a minimum):

- Blood borne Pathogens, Fire Safety and other Occupational Safety and Health Administration (OSHA) standards
- Chemical hygiene and “Right to Know” 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 Environmental Safety.

12. 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 department works through SAP, the brand name of the software package implemented by Johns Hopkins Hospital 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).

Reagent Specifications As necessary, procedures contain specifications such as supplier and catalog number, storage and handling instructions (including temperature and humidity requirements), precautions and other information necessary for handling or 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 otherwise 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. Current versions of package inserts for reagents/testing materials are available in the laboratory.
Microbiological Media	Each new batch or shipment of microbiological media is checked according to CLSI guidelines. Any deterioration in the media is reported to the manufacturer.

Related Documents

Quality Management Program
Quality Management Plans (division)

References

www.pathology.jhu.edu

NCCLS. *A Quality Management System Model for Health Care; Approved guideline – Second Edition*. NCCLS document HS1-A2 (ISBN 1-56238-554-2). NCCLS, 940 West Valley Rd, Suite 1400, Wayne, PA 19087 USA, 2004.

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.