Policy	The Department of Pathology is committed to providing quality pathology services, pursuing excellence and striving to exceed the needs of our customers. Through the continuous review and improvement of processes the Laboratory strives to ensure: ♦ safe and appropriate patient care ♦ a safe environment for associates ♦ reduction or elimination of medical errors ♦ sustainable attainment of quality objectives ♦ procedures are followed consistently ♦ successful accreditation assessments ♦ customer needs are satisfied ♦ timely and accurate services ♦ document control is maintained ♦ effective and efficient use of resources ♦ fiscal goals are achieved or exceeded To attain these objectives, the Laboratory has chosen to implement quality standards developed by the Clinical Laboratory Standards Institute (CLSI), *Application of a Quality Management System Model* and *A Quality Management System Model for Health Care* as models in the development of a quality management system for the Laboratory. The quality plan provides the framework for the on-going development, implementation and monitoring of the quality management system. Laboratory policies are based on the quality plan and are designed to monitor, evaluate and improve the patient testing and consultative services provided by the Department of Pathology. Quality processes, products and Laboratory associates are the building blocks for a quality system. The quality plan supports, and is in keeping with, the ideals set forth in the mission, vision and core value statements of Saint Agnes Hospital.

Purpose	The quality plan outlines the scope of services and responsibilities of personnel through the implementation of the twelve quality system essentials as described in the CLSI standards. The plan is written with specific intent to provide direction and guidance on the development of the Laboratory's Quality Management System through the incorporation of Performance and Process Improvement, Proficiency Testing, Quality Assurance and Lean activities into each Laboratory section's daily practices and operations. Included in the plan are requirements for monitoring the processes and operations of the Laboratory through the performance of self-assessment audits, routine monitoring of quality improvement indicators, occurrence reporting and customer feedback. The plan includes employment of analysis tools and methods to identify, resolve and prevent problems, improve and provide safe patient care, reduce exposure to liability and enable cost containment. The plan is to be used as the basis for each Laboratory section's quality plan.
Scope	This policy applies to all associates and physician affiliates in all sections of the Laboratory.
Responsibility	The Laboratory management team, in cooperation with the pathologists, is responsible for the on-going development and implementation, evaluation and improvement of the quality plan. Management personnel will effectively communicate elements of the plan to all Laboratory associates. Laboratory associates are responsible for cooperative participation in the quality process, this includes knowledge of the quality program, supporting quality events, reporting occurrences and working with the management team to improve patient care.

Table of Contents

Quality System Essentials

The Quality System Essentials (QSEs) are the framework of the Quality Management System. The quality plan describes how the QSEs are deployed in relation to the control and operation of the Laboratory. Documentation in the department is structured around the QSEs; therefore, documents are numbered in relation to the associated QSE.

QSE #	Doc #	QSE
1	1000	Organization
2	2000	Documents and Records
3	3000	Personnel
4	4000	Equipment
5	5000	Purchasing and Inventory
6	6000	Process Control
7	7000	Information Management
8	8000	Occurrence Management
9	9000	Assessments
10	10000	Process Improvement
11	11000	Customer Services
12	12000	Facility & Safety

Quality Plan Review and Reporting

The Laboratory Council, consisting of the Chairman of the Department of Pathology, administrative Director, Anatomic and Outreach Managers, Quality Coordinators, Support Services Supervisor, and representative Clinical Lab Lead will review the quality plan annually to determine if the plan was effective for Laboratory operations and patient care; the results will be reported to the appropriate oversight. Adjustments to the plan will be made to accommodate changes in the Laboratory's goals and objectives, regulations

	and accreditation standards. Reports comprised of designated indicators from selected quality assessments and performance improvement projects are regularly submitted to Medical Staff Quality Assurance (MSQA) and Quality and PI Committees. Reports include a statistical representation of indicators and related goals and include follow up on related clinical and quality issues.
QSE 1 **Organization**	QSE 1 assures that there is strong departmental support and resources available to maintain the quality management system. The organizational structure of the Laboratory, including the relationships between the department chairman, section medical directors, Laboratory management, and associates is described. The Laboratory reorganizes its structure as needed to maintain, redesign and improve the quality management system. The Department of Pathology provides comprehensive laboratory services including anatomical and clinical pathology. **The Department Chairman:** As Medical Director (CLIA designation), the Chairman is responsible for the overall compliance of the Laboratory with the plan and is the directly responsible for the quality of laboratory services. The Chairman must engage pathologist staff, qualified by training, and experience, to: • Provide Anatomic and Clinical Pathology services • Medically direct Laboratory sections • Provide Medical Staff Consultations • Provide continuing education to Laboratory, Medical and Resident staff • Provide monthly pathologist staffing and on-call schedule to assure responsive and continuous diagnostic and consultative pathologist services

	• Monitor and evaluate professional performance of individual pathologists according to the established criteria in the Medical Staff Rules and Regulations of the Department of Pathology • Approve Medical Staff credentialing and recredentialing of pathologists in accord with qualifications, performance and requested privileges • Ensure that the performance and competency of the pathologists' assistants is monitored • Collaborate and cooperate with Laboratory Administrative Director, Laboratory Managers and Supervisors in the development and delivery of timely and quality Laboratory services, planning, proficiency testing, budget, policy, organization, licensing/regulatory matters, inspection and accreditation • Participate in Laboratory Management meetings • Assign a pathologist to the Medical Staff Quality Assurance Committee (MSQA); reviews and approves the monthly report to the MSQA • Ensure pathologist participation with the various hospital review boards • Conduct pathologist/administrative monthly meeting to communicate and coordinate departmental policies, procedures and activities • Report to Executive VP/CMO regarding departmental services and performance • Review and approve all new and substantially revised Laboratory policies and procedures, test systems, and services • The Chairman delegates authority and responsibility to designees as outlined below: **Pathologists and Medical Directors of the Laboratory Sections as designated by the Department Chairman:** • Exercise authority in matters related to compliance with federal, state and local

	regulations including, but not limited to, CAP, The Joint Commission, CLIA, OSHA, MOSH and FDA • Participate in the selection of quality indicators and review quality reports from assigned section of the Laboratory including instrument comparability, linearity studies • Monitor and evaluate the performance of the pathologists' assistants • Consult with physicians concerning laboratory services and test results • Ensure that the assigned section's quality plan is implemented and sustained • Ensure that testing personnel are qualified and meet training and competency requirements • Review and approve all reports for proficiency testing including failures to ensure appropriate follow-up • On assignment as Medical Director of a Laboratory section, review all existing policies and procedures for the section • Review and approve all new and substantially revised policies and procedures for the assigned section, test systems and services • Communicate information related to improving Laboratory quality and patient safety • Provide on-call coverage for the Laboratory during weekends, evenings and holidays **Laboratory Administrative Director (Designee):** • Monitor budgets and institute budget control processes • Prepare and review policy, process and procedure documents • Review Laboratory financial reports, investigate and follow up as appropriate • Collaborate with identified executive administrative officials in administrative matters to advance Laboratory quality activities

	• Communicate quality concerns to various hospital management processes, committees and meetings to improve patient services • Participate in evaluations of direct reports to assess the overall quality of laboratory personnel • Facilitate the hiring of personnel within the frame work of regulatory and hospital based requirements • Pursue interdisciplinary relationships and activities • Communicate information related to improving Laboratory quality and patient safety to the Laboratory management team • Support organizational goals and objectives **Quality Coordinators (Designee)** • In collaboration with Chairman and administrative Director, review and analyze department performance and indicators to identify trends or recurring variances, and coordinate the process to address an appropriate corrective action plan • Coordinate matters related to compliance and local, state and federal regulations in cooperation with the Department Chairman, Medical Directors, administrative Director, and Managers. • Coordinate internal audits of the Laboratory in accordance with QSE 9 Assessments • Maintain, analyze, and update statistical data for decision making purposes • Oversee proficiency testing programs • Review proficiency evaluations • Prepare and review policy, process and procedure documents related to quality • Identify, develop, and implement laboratory assessment tools to meet the requirements of accreditation, regulations, department

	programs, and laboratory customers • Coordinate end of year quality assessment • Pursue interdisciplinary relationships and activities • Support organizational goals and objectives **Laboratory Managers (Designee):** • Prepare and review policy, process and procedure documents • Oversee selection and validation/verification of test systems and processes • In collaboration with Laboratory management and associates, review occurrence reports, monitor and respond to visual management tools, investigate/analyze system failures with potential to impact patient care, plan and implement corrective action • Compile reports for tracking and trending of quality indicators • Interview and make recommendations for hiring of qualified personnel • In collaboration with section Medical Director; prepare and maintain a quality plan for their respective section, documents an annual assessment of the plan • Perform audits as required for major systems, i.e. Environment of Care (EOC) and others required by regulatory bodies • Review and analyze quality control (QC) records, proficiency testing evaluations, and perform statistical analysis to determine trends or recurring variances • Review/Sign proficiency evaluations, attestation forms and provide required follow-up documentation related to proficiency failures • Perform competency assessments • Ensure completion and documentation of required associate training, competency assessments, and performance appraisals

	within specified time frames • Prepare, monitor and control operations and personnel budgets • Pursue interdisciplinary relationships and activities • Communicate relevant information to the Lab management team • Support organizational goals and objectives **Clinical Laboratory Lead Technologists (Designee):** • Prepare and review policy, process and procedure documents • In collaboration with manager/director oversee selection and verification/validation of test systems, services and processes • In collaboration with Laboratory management and associates, review occurrence reports, monitor and investigate/analyze system failures with potential to impact patient care, plan and implement corrective action • Compile reports for tracking and trending of quality indicators • Interview and make decisions for hiring of qualified personnel • In collaboration with section Medical Director; prepare and maintain a quality plan for their respective section, document an annual assessment of the plan • Review and analyze quality control (QC) records and perform statistical analysis to determine trends or recurring variances • Review proficiency evaluations, sign attestation for, and provide required follow-up documentation related to proficiency failures • Perform competency assessments • Ensure completion and documentation of required associate training, competency assessments, and performance appraisals

	within specified time frames • Prepare, monitor and control operations and personnel budgets • Pursue interdisciplinary relationships and activities • Communicate relevant information to the Lab management team • Support organizational goals and objectives **Clinical Laboratory Technologists MTIIs (non-floaters) (Designee):** • Provide support to Clinical Laboratory Leads for the following: o Policy or procedural review o Proficiency surveys o Orientation, training, and competency of associates o Scheduling o Inventory control o Quality control performance and review o Verification/Validation of test systems or services • Interview and make recommendations for hiring of qualified personnel • Participate in education, training and continuous competency reviews of associates and students • Communicate all relevant information to technical personnel concerning operations • Ensure the quality of daily operations to support patient safety • General daily oversight of the Laboratory section **Technical Personnel:** • Charge Tech responsibility as assigned • Quality and safety assignments as assigned • Perform job duties responsibly and in a safe manner with a constant focus on patient safety • Process specimens, perform testing and any

	required post-analytical follow-up related to the patients' results • Perform QC and maintenance documentation • Participate in continuing education and training of associates and students • Review QC to identify and monitor trends and deviations • Document issues related to Laboratory quality on an Occurrence Report Form • Report all safety issues related to patient and facility safety • Communicate to Laboratory management any conditions or malfunctions that may affect patient care and safety • Follow all policies and procedures to support quality operations and patient safety **Lab Support Services (LSS) Supervisor, Outreach Coordinator, Leads :** • In collaboration with their respective manager; prepare and maintain a quality plan for their section • Ensure the quality of daily operations to support patient safety • Schedule appropriately to meet the daily work load • Perform audits as required for major systems, i.e. EOC and others required by regulatory bodies • Prepare and review policy, process and procedure documents • Participate in education, training and continuous competency reviews of associates and students • Ensure the completion and documentation of orientation, training, and competency of associates including those external to the Laboratory • Perform Quality and safety assignments as assigned

- Perform job duties responsibly and safely with a constant focus on patient safety
- Participate in education, training and continuous competency reviews of direct reports and students
- Document issues related to Laboratory quality on an Occurrence Report Form
- Communicate all relevant information to personnel concerning operations

Support Personnel:

- Perform job duties safely and responsibly with a constant focus on patient safety
- Document issues related to Laboratory quality on an Occurrence Report Form
- Complete all required orientation, annual training and competency in a timely manner
- Assist with the training of new associates and students
- Participate in safety, quality projects and other initiatives as directed
- Ensure pre-analytical and post-analytical policies and procedures are practiced as written
- Ensure requisitions and other documents support medical necessity for tests ordered on outpatients
- Report all safety issues related to patient and facility safety
- Communicate to Laboratory management any conditions or malfunctions that may affect patient care and safety
- Follow all policies and procedures to support quality operations and patient safety

Pulmonary Laboratory

The Pulmonary Laboratory provides blood gas and limited chemistry testing services to the inpatients and outpatients of the hospital; the Lab is located in close proximity to the critical care units. The Department of Pathology Medical Director is

	responsible for ensuring the quality of laboratory testing provided by Pulmonary testing personnel. Oversight of the services provided is outlined in the Pulmonary Laboratory Quality Plan. **Committees and Meetings** To facilitate the cooperative management of the Laboratory, to maintain open lines of communication and enhance the exchange of information, the Laboratory has established standing committees and departmental and sectional meetings. Standing review committees will meet periodically. Committee members are selected by the Chairman, administrative Director, Laboratory Manager or as designated in the Hospital committee charter.
QSE 2 **Documents and Records**	QSE 2 assures that Laboratory associates and customers have the current documents and/or records relating to their specific activities and that changes to documents are controlled and records generated are managed appropriately. The Laboratory maintains a Document Control System to maintain: 1. A structure to link its policies, processes and procedures 2. A process to ensure uniformity of standard operating procedures that follows CLSI guidelines 3. A process to generate, review and approve documents 4. A process to archive, retrieve and destroy records **Quality System Documentation** The quality system's documentation consists of: • The quality manual; contains the quality plan for the Laboratory • The quality plan; includes documented statements of the quality policy, quality goals and objectives, and is developed cooperatively by the Laboratory Council • Documented policies; required by all applicable

	standards, that detail the implementation of requirements and guidelines for laboratory operations to ensure safe patient care • Procedures to ensure that associates have the required information to perform testing and successfully complete assigned tasks • Instructions that detail specific quality or accreditation information • Documents needed by the organization to ensure the effective planning, operation and management of its processes • Records required by all applicable standards per the Document and Records Policy **The Quality Manual** The Laboratory has established and maintains the quality manual as a repository for the quality plan and other documents that: • Define the structure of the quality system • Make reference to quality policy; the supporting processes and procedures • Define the roles and responsibilities of all associates in managing and maintaining the quality system **Each section of the Lab maintains the following -** Types of Documents: QP Quality Plan Q Policy P Process R Procedure J Job Aid F Form T Template L Label Document Map
QSE 3 **Personnel**	QSE 3 assures appropriate training and support of associates to meet departmental needs and to ensure the support of patient care and essential services.

	The Laboratory holds its associates accountable for following Hospital and Department policies. New or changed policies are introduced and explained to associates by one of the following methods: section meetings (or through meeting minutes), email, or electronic learning media such as Ascension Health University or Medical Training Solutions. The Laboratory employs qualified individuals who meet the education, training and experience levels necessary to perform assigned tasks as defined in current job descriptions and in accordance with regulatory standards of CLIA. 1. Job description and associate qualifications: • Job descriptions are written and maintained for each position • To be considered for hire, candidates must meet the minimum qualifications (education and/or experience) stated in the job description • The candidate must provide documentation of educational background, certification (as required), training, and experience • The candidate must fulfill all the requirements of the Human Resources Department prior to hire 2. New associates are provided orientation to the organization through: • Human Resources Department • Laboratory Department • Laboratory section specific to job position 3. Training: • Laboratory management ensures the competency of its associates • Appropriate supervision is provided during training • Mandatory annual training is required for continued employment including, but not limited to; blood borne pathogens, infection control, life safety, workplace violence and corporate responsibility • All training is documented

	4. Assessment of competence: • Technical positions - competency on each test or system is initially assessed during the associate's first 6 months in the position and annually thereafter • Non-technical positions - competency is assessed during the associate's first 6 months, then selected competencies are assessed annually thereafter • Interim competency assessments and remedial training may occur based on job performance issues • Individualized action plans for improvement on an as-needed basis to maintain acceptable levels of associate performance 5. Performance appraisal: • A performance appraisal based on job accountability, organizational values, objective measures, and pre-defined standards is completed for each associate, documented, and maintained • The performance appraisal review is performed six months after hire, annually and as recommended by Human Resources 6. Trainer qualification: Selected individuals, meeting high performance standards may be designated as a trainer by the Manager, Lead, or Supervisor. Trainers must meet the following qualifications: • Accurate knowledge of the process and procedures involved in the training event • Regular work experience with the specified training event • Good verbal, listening and observational skills 7. Continuing education: • Associate participation in continuing education is determined by sectional policy • Monthly Laboratory section meetings may contain a segment on continuing education

	• Associates are encouraged to attend all CME/CE (ASCP and CAP) audio/web conferences sponsored throughout the year within the Laboratory as scheduling allows • Scheduled specific lectures by pathologists, vendors, managers, leads, and hospital associates are provided periodically in response to a perceived or determined need • Off-site seminars may be approved based on the benefit to the individual and the hospital
QSE 4 **Equipment**	QSE 4 assures provision of state-of-the-art instrumentation and equipment for use by Laboratory associates to meet or exceed the needs of Laboratory customers. For this plan, the term equipment encompasses all instrumentation, test systems and medical devices used for patient testing. The Laboratory follows a standardized process to properly select the necessary and appropriate equipment; install the equipment and validate its function, maintain and calibrate the equipment according to established requirements, solve and document equipment-related problems, and maintain all required records to meet the requirements of regulatory agencies, Saint Agnes Hospital and Ascension Health. The processes to select, implement and maintain laboratory equipment include: 1. Selection: • A value analysis process to identify specifications for new equipment is followed • Needs for equipment are based on data, technology, corporate contracts and the associated patient care expectations • Attending staff and medical directors input and opinions are solicited • The specifications are shared with vendors and hospital management • The Ascension Health Resource Group and Clinical Engineering expertise is utilized in the competitive bidding and final decision making processes

	• Except for sole source contracts, the vendor's ability to meet the specifications, price, training and other criteria are considered in the selection process 2. Implementation/Verification/Validation • Installation of new equipment follows a documented verification or validation plan in accordance with CLIA, FDA classification and vendor recommendations for linearity, correlation or comparison studies and the determination of technical, delta, reportable, referent and critical ranges • The vendor will take an active role in the installation process of major instrumentation • The equipment is properly installed and tested as part of the verification/validation process • The Medical Director reviews the implementation documents and approves the release of the instrument prior to used for patient testing • Each Laboratory section maintains implementation documentation as required by regulatory standards 3. Operation and Maintenance: • Laboratory equipment is properly maintained in accordance with procedures for linearity, calibration, calibration verification, quality control and maintenance • Equipment is used or operated only when in a safe and reliable condition by personnel who are qualified and have been properly trained • Operation manuals for the proper use and maintenance of equipment are kept at or near the workstation • Equipment, including hardware, software, reference materials, and analytical systems are protected from adjustments or tampering that might invalidate examination results through security methods that include password protection 4. Calibration:

- All measurement devices that require calibration are recalibrated according to manufacturer's recommendations, regulatory requirements, and accreditation standards
- In addition to manufacturer recommendation, frequency of calibration is based on a review of calibration, QC, maintenance, and repair history.
- Equipment software is updated as indicated by the manufacturer

5. Preventive Maintenance:
   - Preventive maintenance schedules are determined by manufacturer's recommendations, regulatory requirements, accreditation standards and internal requirements
   - Documentation of maintenance includes findings, actions taken and follow-up monitoring
   - Clinical Engineering Department resources are utilized as appropriate

6. Defective Equipment:
   - Equipment found to be or thought to be defective is clearly identified as such, taken out of service, labeled, controlled until such time that it is repaired, replaced or discarded
   - An occurrence report is to be completed and copied to the section Medical Director
   - Clinical Engineering Department resources are utilized as appropriate
   - The Laboratory shall ensure that the function and calibration status of the equipment is satisfactory before the equipment is returned to service
   - The Laboratory determines the effect of defective equipment on any previous results and takes appropriate action if necessary
   - Notification of any delay of result reporting must be communicated to the appropriate patient care areas when in-house testing is referred

	7. Retirement or Disposal
	• Different courses of action will be followed depending on if the equipment was purchased or leased
	• If purchased, the equipment is:
	  ○ Decontaminated following manufacturer's recommended procedures
	  ○ Removed from the Clinical Engineering inventory database
	  ○ Disposed of or sold, the decision is based on residual value and recommendations from Finance and Clinical Engineering
	• If leased, the equipment is:
	  ○ Decontaminated by the vendor
	  ○ Removed from the Clinical Engineering inventory database
	  ○ Removed by the vendor
	• Documentation regarding disposal, removal or end of lease is submitted to Finance
	
	8. Documentation:
	• Equipment is inspected by Clinical Engineering on receipt and labeled with an inventory number if appropriate
	• Maintenance, calibration, repair, retirement and other records for equipment are retained as required by accreditation standards

QSE 5 **Purchasing and Inventory**	QSE 5 provides for an adequate inventory of supplies, products and services for use by the department and to ensure that the Laboratory achieves the lowest possible cost in conjunction with the highest quality of appropriate materials. The Laboratory identifies critical supplies and purchased services used for patient care and defines the criteria to be met by vendors for each critical supply, service or supplier. Policies and procedures include those for receiving, inspecting and testing purchased materials. Purchasing and Inventory

	1. Supplier qualifications: • The Ascension Resource Group and the Laboratory sections assess the ability of suppliers to meet Laboratory requirements and expectations • Actions are taken as necessary when suppliers and/or products do not perform according to contract requirements • The Laboratory will adhere to applicable vendor credentialing processes as defined through policy of Saint Agnes Hospital • The Laboratory will comply with vendor selection as defined by Ascension Supply Chain contracts 2. Contract review: • Non-Ascension agreements to obtain laboratory equipment, supplies and services are reviewed to ensure that each party's expectations are defined and agreed to and that any changes are appropriately recorded and communicated to essential persons • The laboratory/supplier is required to inform the affected party of any deviation from the contract • Records of reviews of requests, tenders and contracts (including significant changes) are maintained. During the period of execution of the contract, records are maintained concerning pertinent discussions with the supplier relating to the requirements and the results of the work • Resources from The Resource Group and legal counsel are used as indicated • Contracts for signature are forwarded by the administrative Director to appropriate Executive Group designees • If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to all affected parties 3. Receipt, inspection and testing of incoming supplies: • There is a process for receiving, inspecting, testing

(where required) and storing of incoming critical materials and products
- Criteria have been established for accepting critical materials and products
- Critical materials, tissue, blood and blood products not meeting acceptance criteria are returned with disposition documentation retained of all actions taken
- There is a process to ensure traceability of critical materials and products prior to use
- Support of The Resource Group and other internal resources are utilized as needed or required

4. Vendor Recalls
   - The Laboratory is aware of its responsibility to participate or assist in recalls by the FDA, manufacturers or other suppliers of products, equipment and devices, including pharmaceuticals
   - The Laboratory has developed a laboratory specific recall policy that is coordinated with the hospital recall policy

5. Purchased Laboratory Services
   - Reference laboratories are validated prior to selection and annually thereafter. Documentation is maintained
     - The complete list of reference laboratories will be submitted annually for review and approval by the Medical Executive Committee
     - Requests to expand the reference laboratory list will be considered and evaluated. In addition to meeting regulatory requirements, approval will depend on the value of the testing requested in relation to patient care
   - Tests or services performed in reference laboratories are (as appropriate):
     - Accredited by the CAP or other equivalent accrediting body
     - Certified by the CMS
     - Hold a Maryland Laboratory Permit

	○ Licensed and/or registered by the FDA ○ Non-FDA approved tests are validated internally at the reference laboratory through documented in-house studies; results are accompanied by disclaimer comment
QSE 6 **Process Control**	QSE 6 assures due process and adherence to the hospital's mission, core values and patient safety, it assures an adequate and safe work environment, and consistent, productive, efficient operations that meet the needs of the hospital. The Laboratory's work processes are designed to function in such a way as to meet requirements and customer expectations. Process control is about identifying, documenting, managing, and controlling the Laboratory's pre-analytic, analytic, and post-analytic technical work operations. The Laboratory utilizes process control measures to implement new processes and services, change established processes/procedures, to select appropriate statistical tools to monitor and document process improvement, to validate or verify performance specifications of equipment and to develop and maintain quality control systems throughout the department. Process control activities include: 1. User testing and acceptance activities for Laboratory computers and software are performed for new or revised software. 2. Process validation/verification for new or changed processes and procedures include: • The Document Control System policies and procedures • Use of written validation/verification protocols • Implementation activities for equipment installation and documentation that the process works as intended prior to actual use • Verification of performance when process changes

	occur that could affect the outcome of a process • If necessary, retrospective validation/verification is performed for well-established processes using historical data • Review of validation/verification results prior to process implementation • Training of the majority of personnel involved • Approval by the medical director of the section • Documentation and retention of all implementation activities including training of personnel 3. Unique specimen identification, positive patient identification, bar code scanning and unique labels: • A process is maintained for all activities related to labeling laboratory specimens beginning with the patient identification process and finishing with label placement on the specimen tube, vial, container, etc. • A process is maintained to ensure recurrent patient identification and label problems are detected, evaluated and remedied 4. QC processes include established schedules and procedures to be followed for QC of equipment, reagents and testing within each Laboratory section. 5. The overall format of the Laboratory report is reviewed and approved annually by the Medical Director. Revisions occur as necessary. Reports are reviewed periodically for completeness, appearance, format and accuracy. 6. Timeliness of reporting of test results is monitored by turn around time (TAT) reports, if needed, corrective actions are implemented. An Alert Value Notification Process is maintained; this process allows for the monitoring of critical value reporting to patient care areas. 7. Proficiency testing is performed in the respective Laboratory sections and incorporated into the routine workload.

	• As is possible, specimens are handled as if they were patient samples and run as part of the routine flow of work • Test results are not to be shared among testing personnel in the Laboratory or with persons at other laboratories until after the submission deadline. • A pathologist may be requested to consult on the results of a proficiency sample when it is within the normal practice to do so • Proficiency testing specimens are not referred to any other laboratory, internally or externally for testing
QSE 7 **Information Management**	QSE 7 ensures that users are provided with the appropriate hardware, software, internet and database systems necessary to perform required tasks to support Laboratory operations. With the support of the Health Information Management Department and Ascension Information Services, the Laboratory protects and manages the confidentiality, privacy, security, and accessibility of information that is transferred or stored in paper-based and electronic record keeping systems. The Laboratory maintains policies and procedures related to the computer system operations, laboratory module validation, security and maintenance. Each Laboratory section maintains procedures to enable continuation of services in the event that the computer system is unavailable due to scheduled or unscheduled downtime. The Laboratory follows and abides by all administrative policies as set forth by the Health Information Management Department and in accordance with HIPAA regulations. 1. All associates of the Laboratory are assigned levels of computer accessibility according to the specific needs of their job position. 2. Procedures are maintained and training provided for the

	following: • Corporate Responsibility and Confidentiality • Laboratory Compliance
QSE 8 **Occurrence Management**	QSE 8 minimizes risk to the hospital through establishment of an occurrence tracking system that recommends corrective and preventive action steps to ensure continuous quality improvement and patient safety. The Laboratory is dedicated to ensuring that this is accomplished in a cooperative atmosphere. The Laboratory maintains its Occurrence Reporting System to detect, investigate, report, track and trend events that do not conform with established policies, processes, and procedures. Occurrence reports submitted by Laboratory associates are entered into a database, classified and analyzed with follow-up actions as required. Information compiled from the database is used to guide Laboratory quality and process improvement activities. The Occurrence Reporting System includes the following activities: 1. Documenting the specific event and investigating those events that have potential to affect the quality and safety of Laboratory services, personnel and patient safety. Where appropriate, resources outside the Laboratory are used to achieve resolution (i.e. Employee Health, Risk Management, Human Resources, Facilities Management, etc.). Specific and recent incidents may be reported at daily executive safety huddle. Follow up and resolution may be assigned by a member of the executive team for reporting at a subsequent huddle. 2. Taking corrective actions to eliminate the root cause and prevent recurrence. 3. Monitoring the corrective actions for effectiveness. 4. Continuous updating of the system database to allow for trending of events to aid in prioritizing performance improvement (PI) opportunities.

	5. Management of event reports to include collaboration with other hospital departments to resolve issues and may entail participation in a root cause analysis panel. 6. Reporting identified trends and corrective actions to the appropriate oversight (i.e. Quality & PI and/or MSQA Committees, etc.). Quality and PI Committees and MSQA report to the Patient Safety Committee.
QSE 9 **Assessments**	QSE 9 ensures that the Laboratory meets or exceeds it quality objectives and remains adaptable to the changing needs of its customers and the healthcare environment. The Laboratory uses external and internal assessments to verify that its processes meet requirements and to determine how well those processes are functioning. The term assessment is used to refer to self-inspections or surveys, inspections by outside entities, proficiency testing, quality assurance reviews, and other evaluations and audits of Laboratory operations and services. **External Assessments:** 1. The Laboratory participates in external assessments conducted by FDA, CMS, and State (CLIA) as required. 2. The required processes are followed to conduct; report and follow up on external inspections, assessments or investigations. 3. The Laboratory participates in voluntary external assessments of the CAP, and The Joint Commission (TJC) accreditation programs as outlined below: The Laboratory participates in proficiency and educational programs such as: • CAP PT Programs for all Laboratory sections performing testing • CAP Anatomic Pathology Program (PIP) • CAP Anatomic Pathology Digital PT

	• American Proficiency Institute Program • Medical Laboratory Evaluation Proficiency Program • Maryland State Cytology PT Program (Pathologists and Cytotechnologists) • CAP Gyn and Non-Gyn Proficiency Programs • Wisconsin State Laboratory Hygiene Laboratory PT Program • MD DHMH State Lab Assessment • CAP Self-assessment • TJC Self-Assessment Proficiency testing (PT) measures and compares testing systems of laboratory tests with the outcomes of testing performed by other laboratory peers, as appropriate, for the services offered. Annual review takes place to ensure the Laboratory is enrolled in the appropriate PT programs to support the test menu. When commercial PT is unavailable, an alternate PT process must be developed, documented and implemented in compliance with accreditation standards. For each PT event, survey kits are received, logged by date and then distributed to the appropriate testing Laboratory section. PT results (graded, ungraded and educational) are reviewed for acceptability; unacceptable results are investigated. At a minimum, each result exception (less than satisfactory) must include an explanatory comment and supervisory initials. The section Medical Director reviews unacceptable PT results; the explanation for the exception, adds comments as appropriate and initials the result report. For required responses, the report goes to the Chairman of Pathology for final approval and signature. The result report, documentation and exception response are placed in the appropriate survey binder and retained for a minimum of two years. **Internal and Operational Self-Assessment:**

	1. The Laboratory has identified applicable operational systems. These systems are outlined in each Laboratory section's quality plan. 2. Procedures and processes are in place for Laboratory personnel to capture data on identified quality indicators for operational systems specific to each section. 3. The Laboratory maintains a system of planned and documented internal audits specific to each section to: • Ensure operational systems meet regulations and standards • Evaluate the effectiveness of the section's quality plan • Provide a basis and direction for quality improvement 4. Periodic reporting takes place by: • Formal reports outlining the quality findings; results are reported to the Board of Directors via the following routes: o Clinical Pathology indicators are reported to Quality and PI Council with selected indicators reported to MSQA o Anatomic Pathology indicators are reported to MSQA • Compiling results of self-assessment data and operational systems into summary reports communicated to the following hospital committees: Quality and PI: **<u>Clinical Laboratory</u>** Reporting includes at least two indicators/measures of quality assurance and two indicators/measures of quality improvement. Indicators are selected by the Medical Director, administrative Director, Laboratory Managers, and Quality Coordinators. The Quality and PI leadership must approve the indicator selections made by the

	Laboratory. Data is compiled monthly and reported quarterly. MSQA: **<u>Anatomic Pathology</u>** Indicators for: Amended Diagnosis Frozen Section/Final Diagnosis Outside Review Correlation TAT of final reports Frozen Section TAT Autopsy TAT (Autopsy Report Quality) Identified PI Projects 5. Process improvement priorities are established by historical comparison and trending analysis. 6. Follow-up is achieved by assessing the effectiveness of any changes or action taken to improve or correct operations. 7. Management involvement occurs by submission of formal monthly and quarterly reports to the appropriate oversight entity for review and comment. Follow-up occurs as indicated and appropriate.
QSE 10 **Process Improvement**	QSE 10 supports improving customer satisfaction, service development and delivery, and creates an opportunity for interdisciplinary input. The Laboratory uses quality measurement tools to demonstrate the effectiveness of meeting the quality objectives and to outline areas that require improvement and problem prevention. The following sources are used to obtain information and opportunities for process improvement activities: 1. Reports and findings of internal and external assessments by the FDA, CMS, TJC, CAP, MD State Office of Health Care Quality 2. Review and analysis of quality indicators that include:

- Surgical Pathology Cases
- Cytology Cases
- Autopsy Quality Assessment Program
- Clinical Pathology
- Transfusion Services

3. Reports of customer and physician complaints.

4. Analysis of incident, error and associate reporting from within the Laboratory and hospital-wide, i.e. Occurrence Report Form (ORF), Event Reporting System (ERS), and Medication Variance (MEDVAR).

5. Knowledge gained through the inspection of other CAP accredited laboratories.

6. Review of specific processes for improved efficiency and/or effectiveness.

7. Review of hospital-wide quality improvement functions/variances that involve the Laboratory may include:
   - Infection Control Committee referrals related to patient care, surveillance and Microbiology reports to the committee that would include monitoring studies
   - Risk Management referrals of patient complaints or events with potential legal involvement of the Laboratory
   - Blood usage review of transfusion reaction and transfusion criteria
   - Recommendations or mandates by hospital committees
   - Medical/Surgical Case Review and presentation for departments and tumor boards such as:
     - Department of Medicine Resident Teaching Conferences
     - Department of Surgery M & M Conferences
     - AICU M & M conferences
     - Medical Tumor Board

	○ Pulmonary Tumor Board ○ GI Tumor Board ○ OB/GYN Tumor Board ○ Breast Tumor Board 8. The Laboratory uses a quality systems approach to problem resolution that includes: • Identification, prioritization and selection of problems/issues to be resolved • Use of data and statistical tools to analyze numeric data when appropriate • Implementation of process changes when appropriate • Monitoring and evaluation of changed processes to determine effectiveness • Use of professional consultants when appropriate
QSE 11 **Customer Service**	QSE 11 assures identification of customers, understanding their respective needs, structuring processes and procedures to meet these needs and expectations to the customers' satisfaction, and actively seeking customer feedback to determine if the needs are being met. Increasing customer satisfaction is directly related to positive interactions with associates. Providing world-class service is the key to increasing customer loyalty and market share. 1. The key factor to ***Amazing Customer Service*** is to empower associates at each point of contact to provide exceptional customer service so every interaction exceeds customer's expectations. 2. Anticipate the needs, wants and emotions of the customer in order to exceed their service expectations. 3. The Laboratory uses input from patients, physicians, nursing staff, administrators, other hospital departments and financial data to determine needs for changes in service. This includes: • Providing new services or new testing • Discontinuation of old services or processes

	• Amending or adopting changes to current services 4. The Laboratory receives input from patients, physicians, nursing, Laboratory associates, administrators, other hospital departments, satisfaction surveys and other individuals to determine levels of satisfaction. Using the performance improvement process the Laboratory sets priorities and develops plans to improve services. 5. The Laboratory responds to concerns of perceived failures of service. The associate who receives the complaint is responsible for documentation of reported problems by use of the Occurrence Reporting System. The documentation is directed to the Quality Coordinator who will refer the reported issue to the appropriate member of the Laboratory Management Team. An investigation will be made into the issue; corrective actions are instituted as necessary. Any trends or clusters are further investigated to identify areas for improvement. 6. Service recovery is paramount to ***Amazing Customer Service***. If appropriate, feedback may be provided to the associate who received the complaint, as well as resolution to the customer, where applicable.
QSE 12 **Facility and Safety**	QSE 12 provides general guidelines for safety activities within the Laboratory and ensures a safe working environment. The Laboratory evaluates its available physical space to plan the workflow, and as necessary, designs work cells that are optimal for efficiency and productivity. The Laboratory supports the maintenance of the physical space and the safety programs to educate Laboratory associates. All Laboratory associates and affiliate physicians are required to follow hospital and Laboratory infection control and safety policies. Personal protective equipment and garments (PPE) are provided to Laboratory associates, as appropriate. The Laboratory supports the activities of the EOC Committee;

	the Laboratory Safety Officer is assigned to the committee and participates fully in EOC business. Hospital procedures are maintained and training is provided to associates based on job tasks for the following areas: • Emergency Preparedness Response Plan with specific section responsibilities • Hazard Communication (Right to Know) • Computer and hard copy access to Material Safety Data Sheets • TB testing through Employee Health for designated associates • Mask-fit Testing through Employee Health, annually for designates associates • Department of Transportation Hazardous Materials Shipping and Packaging training, annually for designated associates • Blood Borne Pathogen Exposure Control training, annually • General Laboratory Safety training specific to section • Workplace Violence training, annually • Fire Safety and Laboratory evacuation, annually
References and Supporting Documents	1. Application of a Quality Management System Model, CLSI, current version. 2. The Clinical Laboratory Improvement Amendments of 1988, current version. 3. Comprehensive Accreditation Manual for Hospitals, The Joint Commission, current version. 4. Laboratory Checklists, Laboratory Accreditation Program, College of American Pathologists, current version. 5. A Quality Management System Model for Health Care, CLSI, current version. 6. Saint Agnes Hospital Policies and Procedures, current

	versions.
Appendix A **Glossary**	Audit: A planned and documented assessment to determine whether agreed-upon requirements are being met. Competence: Demonstrated ability to apply knowledge and skills. Corrective Action: Steps taken to eliminate the cause of a detected nonconformity or other undesirable situation. Critical Supplier: A critical supplier provides an essential service or supply needed for continued service, as well as patient and associate safety for which an agreement is maintained. Customer: Any recipient of a Laboratory product or service. Document: Information and its supporting medium. Document Control System: Provides the framework for the quality system's documents and records - from creation to destruction. Document Map: A structured spreadsheet of all documents currently in use; with references to retired documents. Documented Procedure: The procedure is established, documented, implemented, maintained and archived until time of disposal. Error: A deviation from truth, accuracy or correctness; a mistake. Form: A paper or electronic document on which information or results are captured; once completed a form becomes a record. Incident: An individual occurrence or event.

	Occurrence: Something that happens that is outside of normal operations; an event or incident. Policy: A written statement of intentions defined and endorsed by the Laboratory. Procedure: A specified, written set of instructions for carrying out an activity or process. Process: A set of interrelated resources or interacting activities that transforms inputs into outputs. Process Control: Operational techniques and activities used to fulfill requirements for quality. Process Improvement: Part of process management; focused on reducing variation and improving process effectiveness and efficiency. Quality: The degree to which a set of inherent characteristics fulfills requirements. Quality Assurance: Part of quality management focused on providing confidence quality requirements will be fulfilled by monitoring quality activities. Quality Management: Coordinated activities to direct and control the Laboratory with regard to quality. Quality Management System: A system to direct and control the Laboratory with regard for quality; the system includes examination of processes, people and specific indicators. A quality system provides tools to evaluate, monitor, and improve services. Quality Policy: The overall intentions and direction of the Laboratory related to quality as formally expressed by Laboratory management. Quality System Essential: A fundamental element inherent in

	the CLSI quality system that defines an “essential” organizational quality policy. Record: Document stating results achieved or providing evidence of activities performed. Review: In the context of this document; anyone designated as a reviewer by the Chairman is also authorized to sign related documents Service: The result generated by activities at the interface between the provider and the customer and by provider internal activities to meet the customer needs. Statistical Tools: Methods and techniques used to generate, analyze, interpret and present data. Validation: A defined process by which a laboratory confirms that a laboratory developed or modified FDA-cleared/approved test performs as intended or claimed. Value: Degree of worth relative to cost and relative to possible alternatives of a product, service, process, asset or function. Vendor: An outside organization that provides a product or service to the Laboratory; a supplier. Verification: The process by which a laboratory determines that an FDA-cleared/approved test performs according to the specifications set forth by the manufacturer.