Policy Statement	Quality processes, products and laboratory associates are the building blocks for a quality system within Saint Agnes Hospital (SAH), Laboratory and Pathology Services. This system supports and is concurrent with the ideals set forth in the mission, vision and core values statements of the organization. The scope of services provided by the Core Laboratory is monitored and evaluated by a planned and systematic process involving section-specific and hospital wide indicators.
Purpose	The Core Laboratory's Quality Plan provides details pertinent to the Core Laboratory and is organized under CLSI Quality Standards of Organization. The standards are Organization, Documents and Records, Personnel, Equipment, Purchasing and Inventory, Process Control, Information Management, Occurrence Management, Assessments, Process Improvements, Customer Services and Facility & Safety. This plan provides general direction and guidance to incorporate Process Improvement (PI) and Quality Assurance (QA) activities into the Core Laboratory operations. It incorporates systems that have been developed to document policies, processes, and procedures, to identify and document problems, corrective actions taken, and trending of indicators to monitor improvement. These findings are referred to the Quality Coordinator and Lead Technologist for reporting to higher-level QA committees in our system, i.e. Quality & Performance Improvement, Medical Staff Quality Assurance and Medical Executive Committee, as appropriate (See LADM 0000 QP).
Scope	This policy applies to all associates and physician affiliates in Core Laboratory. The Core Laboratory consists of Hematology, Chemistry, Coagulation, Urinalysis, Rapid Response, Special Immunology and Molecular sections.
Responsibility	The Core Laboratory Management Team, in cooperation with the Medical Director, 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.

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, AABB, Joint Commission, CLIA, OSHA, MOSH and FDA
- Participate in the selection of quality indicators and review quality reports from assigned section of the Laboratory
- Consult with physicians concerning laboratory services and test results
- Ensure that their section quality plan is implemented and sustained
- Review and approve all new and significantly revised Laboratory policies
- Delegation of certain duties, such as the annual review of unchanged policies and procedures and other tasks as described below
- Provide clinical on-call advisory coverage for the Laboratory during weekends, evenings and holidays

Laboratory Administrative Director (Designee):

- Monitor budgets and institute budget control processes
- Review Laboratory financial reports, investigate and follow up as appropriate
- In collaboration with Chairman, review and analyze department performance and indicators to identify trends or recurring variances, and coordinate the process to address an appropriate corrective action plan
- 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 • Support organizational goals and objectives **Quality Coordinator (Designee)** • Coordinate matters related to compliance and local, state and federal regulations in cooperation with the Department Chairman, Medical Directors, Administrative Director, and Laboratory Managers • Coordinate internal audits of the Laboratory in accordance with QSE 9 Assessments • Maintain, analyze, and update statistical data for decision making purposes • Compile reports for tracking and trending of quality indicators • Oversee proficiency testing programs • Identify, develop, and implement laboratory assessment tools to meet the requirements of accreditation, regulations, department programs, and laboratory customers • Pursue interdisciplinary relationships and activities • Support organizational goals and objectives **Laboratory Lead Technologists (Designee):** • Prepare and review policy, process and procedure documents • In collaboration with section Medical Director; prepare and maintain a quality plan for the section • 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 • Interview and make recommendations for hiring of qualified personnel • Perform audits as required for major systems • Validates new test systems and processes

	• Review and analyze quality control records, proficiency testing summaries, and perform statistical analysis to determine trends or recurring variances • Compile reports for tracking and trending of quality indicators • Ensure completion and documentation of required associate training, competency assessments, and performance appraisals within appropriate time frames • Participate in training, education and continuous competency review of students • Prepare, monitor and continuously control operations, personnel and budgets • Pursue interdisciplinary relationships and activities • Support organization goals and objectives **Technical Personnel:** • Perform job duties responsibly with a constant focus on patient safety • Process specimens and perform testing • Participate in training, competency and continuing education • Review QC for acceptability • Document issues related to laboratory quality on an Occurrence Report Form **Support Personnel:** • Perform job duties responsibly with a constant focus on patient safety • Documents issues related to laboratory quality on an Occurrence Report Form • Ensure requisitions and other documents support medical necessity for tests ordered on outpatients • Verify integrity and appropriateness of received specimens

Table of Contents:

The table of contents provides links to the Quality System Essentials (QSEs) for expedited maneuvering within the document.

QSE 1: Organization

The Core Laboratory is directed by a clinical pathologist designated by the Medical Director. There are four Lead Technologists that are responsible for assigned areas of expertise. Three Medical Technologist IIs provide additional support to the Lead Technologists, as needed. See CORE 1000 F for additional information.

QSE 2: Documents and Records

Documents:
The Core Laboratory maintains a document control plan in compliance with the Document Control Plan of the Department of Pathology (LADM 2000Q). Highlights are as follows:

1. Laboratory testing procedures are to be substantially in compliance with CLSI recommendations.
2. New procedures require Core Laboratory Medical Director approval. Subsequent annual reviews follow and are performed as designated. Substantial changes require a review by the Medical Director (See LADM 2101Q).

Record Retention:
Core Laboratory records are retained as listed below.

- Quality Control – 2 years
- Worksheets with patient results – 2 years
- Proficiency Test Results – 5 years

- Maintenance Logs – life of equipment
- Analyzer Validation – life of analyzer
- Training and Competency Records – indefinitely

QSE 3: Personnel

The Core Laboratory employs qualified individuals who meet the education, training and experience necessary to perform assigned tasks as defined in current job descriptions and in accordance with regulatory standards of CLIA.

Job Description and Employee 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, training, and experience.
- The candidate must fulfill all the requirements of the Employee Health Program prior to hire. Once employed, the individual must abide by all facility policies, all mandatory training, testing, and other activities as a condition of employment.

Orientation:

- New employees are provided orientation to the organization through the Human Resources and Education departments. Documentation is retained in Human Resources.
- Orientation to the Department of Pathology is completed by the Quality Coordinator, LIS Coordinator and the Safety Officer. Documentation is retained in the associate's administrative file in the Administrative Director's office.
- Orientation to the Core Laboratory is completed by a Lead Technologist or designee. Documentation is retained in the associate's technical file in the Lead Technologists' office.

Training:

- Training is provided as required per job description expectations and includes topics related to specific job requirements, safety, computer use, quality expectations, personal development and other skills as needed and identified. See CLIN 3008Q.
- Every associate completes the required training events demonstrating knowledge and competence during the probationary period. Training event completion is also required with implementation of a new procedure or instrument, or when cross-training into a different laboratory discipline.

- Associates will be notified of any subsequent changes to the procedures or instrumentation by electronic message (e-mail). Acknowledgement of the information is monitored electronically through quizzes on Medical Training Solutions (MTS).
- Associate development is provided to meet individual needs, regulatory and accreditation requirements, and changing needs of the organization.
- Re-training is initiated individually and when indicated.

Competency Assessment:

- Initial associate competence is assessed after completing training events.
- Ongoing competency for each new associate is assessed six months after completion of training and then at least annually thereafter. See CLIN 3008Q.
- Competency activities are designed to cover the six methods or elements of competency assessment as prescribed by CLIA 88. These elements include:
    1) Direct observation of routine test performance.
    2) Monitoring the reporting and recording of test results.
    3) Review of intermediate results, worksheets, quality control and maintenance records.
    4) Direct observation of performance of instrument maintenance and function checks.
    5) Assessment of test performance through testing previously analyzed samples, internal blind samples or external proficiency samples.
    6) Assessment of problem-solving skills.
- Every associate is assigned competency items on the MTS (Medical Training Solutions) program. This is a commercially available web based (www.medtraining.org) education, training, and competency assessment tool to which the laboratory subscribes. Assignments are based on job functions and the completed training events.

Continuing Education:

- Annual organizational continuing education thru the hospital Education Department is mandatory. Mandatory annual training is required for continued employment. Topics include blood-borne pathogens, infection control, fire safety, workplace violence, corporate responsibility and additional subjects as determined by Human Resources. The courses are available on the hospital intranet.
- Annual laboratory continuing education is required to be completed by all technical associates. See CLIN 3010Q.
- Associates are encouraged to attend sponsored audio conferences throughout the year within the Laboratory. Teleconferences are available onsite on a frequent basis.
- Documentation of continuing education is maintained on the hospital network.

Performance Appraisal:

- A performance appraisal based on the position description in the areas of job accountability, objective measures, and pre-defined standards is completed for each employee, documented, and maintained.
- The Lead Technologists for each section and shift complete performance appraisals as designated.
- The Administrative Director or designee and Human Resources must approve all performance appraisals.

QSE 4: Equipment

Equipment in the Core Laboratory consists primarily of clinical testing equipment, designed specifically for laboratory use. Most of the instrumentation is automated and is intended for *in vitro* diagnostic use of human specimens only. Other laboratory equipment includes but is not limited to: centrifuges, refrigerators, freezers, stainers, pipettes, printers, barcode label printers, hand held scanning devices, computers, fax machines, time stamps, and other office related equipment. Instructions for use of standard laboratory devices (pipettes, glassware, etc) are included as fundamental skills utilized in laboratory procedures and required for quality performance.

The Core Laboratory maintains a history file for each piece of equipment that includes records of the following, where applicable:

Equipment Selection:

- Needs for equipment are based on data, technology and the associated patient care issues, Equipment options may be limited to vendors approved by Ascension Health.
- Associate and Medical Directors input and opinions are solicited,
- The specifications are shared with suppliers, vendors and hospital officials, where appropriate,
- Materials Management and Purchasing expertise is utilized in the competitive bidding process and the final decision making process. Materials Management and Purchasing approval is required.
- The supplier or vendor's ability to meet the specifications and other criteria are considered in the selection process, where appropriate.

Equipment Installation:

- Installation is performed according to supplier/vendor instructions, with assistance from Clinical Engineering (Bio-Med) and/or Information Services, as needed
- The equipment is properly installed and tested as part of the validation process and prior to final approval by the Medical Director.

Equipment Identification:

- Each piece of equipment is identified by a clinical engineering identification number. This number is assigned by Bio-Med.

Equipment Validation:

- A validation protocol must be created with the implementation of a new analyzer.
- Validation data must be reviewed and signed by the Medical Director prior to implementation.
- A Checklist for Implementing Pathology Service must be completed.

Equipment Initial Calibration:

- Initial calibrations are completed by the vendor.
- Documentation of calibration is kept within the laboratory or by Bio-Med

Equipment Maintenance:

- Preventive maintenance schedules are determined by manufacturer's recommendations, regulatory requirements, accreditation standards and internal requirements.
- Documentation of maintenance includes findings, actions taken, follow-up monitoring and notification of Bio-Med where appropriate.
- Technical personnel are responsible for routine maintenance and function checks of instrumentation as well as checking and verification of reagents. Lead Technologists are responsible for review of these checks on a monthly basis and additionally as appropriate.

Equipment Service and Repair:

- Associates are trained to troubleshoot analyzers in the event they do not operate properly. Certain associates are designated as key operators for some analyzers and normally will attend training classes at the manufacturer's facility.
- If an associate discovers that an instrument is not functioning properly, the equipment is immediately removed from service. He or she is expected to follow troubleshooting procedures as instructed or written in the equipment operator's manual.
- If the associate needs additional assistance to place the instrument back in service, it is then necessary to call the manufacturer's help desk. A representative is usually available 24 hours a day, seven days a week to assist in the troubleshooting process.
- Defective equipment is clearly labeled as such, taken out of service, repaired, replaced or discarded. Quality Controls must be run prior to putting the analyzer back in service. See CORE 6035R.

In the event of a Clinical Medical Device or System failure a call must be placed to Bio-Med at extension 2070. The caller will be asked to provide information to assist the technician. This includes the following:

- Clinical Engineering Identification number (CEID) located on the broken device;
- Caller's Name
- Phone Number
- Location of the Device
- Specifics of the Problem

The ticket number provided by Bio-Med should be noted on the pink, out of service form.

Associates are required to document all Clinical Medical Device or System failures on an Occurrence Report Form. The form should include the noted problem, the resolution, the service ticket numbers from Bio-Med and the manufacturer, where applicable. The form should also include the length or projected length that the equipment was out of service. Refer to QSE 8 for documentation of occurrences.

QSE 5: Supplies and Inventory

Vendor Qualification:

- SAH has defined the characteristics or functional requirements for materials.
- The Ascension Health Supply Chain, Materials Management/Purchasing Departments and the Laboratory sections assess both the ability of our vendors to meet our requirements and their actual performance
- See the hospital policy SYS HOS 32 – Vendor Credentialing and Visitation for details on vendor qualifications.

Contract review:

- Agreements to obtain laboratory equipment, supplies and services are reviewed to insure that each party's expectations are defined and agreed to and that any changes are appropriately recorded and communicated to essential persons with a need to know.
- The support from Materials Management, Purchasing and Legal Counsel are used as needed or indicated. See SYS CC 24 and SYS FI 41.

Receipt, Inspection and Testing of Incoming Supplies:

- The Core Laboratory has a process for receiving, inspecting, and storing incoming reagents and supplies. See CORE 5000Q.

Vendor Recalls:

- The Core Laboratory is aware of the responsibility to participate or assist in the recall by the FDA, manufacturer or other agencies of products, equipment and devices.
- Upon receipt of the recall notification, see LADM 12023Q and SYS CC20.
- The Lead Technologist for the affected section is responsible for documenting the recall by means of an Occurrence Report Form (ORF). This ORF should be submitted as per standard procedure.

QSE 6: Process Control

St. Agnes HealthCare Laboratory utilizes process control measures that include:

Pre-analytical:

- The Core Laboratory only performs testing on samples that have a written or electronic order from a healthcare provider.
- The Core Laboratory maintains an online test search that provides laboratory associates and clients with complete and concise instructions for the collection, handling and transportation of specimens. This online test search can be accessed through The Saint or www.testmenu.com/stagnes.
- The online test search includes:
  - Patient Preparation
  - Collection Container requirements
  - Minimum specimen requirements
  - Need for special timing for collection
  - Types and amounts of preservatives or anticoagulants
  - Proper specimen labeling
  - Need for clinical data
- Specimen integrity requirements for each assay are clearly defined. The Laboratory Assistants and Medical Technologists make decisions on the acceptability of specimens.
- Specimens determined to be unacceptable will be rejected. The appropriate comment stating the reason for rejection will be entered into the computer system and the patient care area involved will be notified by pager or telephone. Documentation of notification of rejection is made electronically in the Laboratory Information System.
- The quality of test results reported by any laboratory is dependent upon properly collected, labeled and stored specimens. Specimens submitted for testing, having the potential to compromise the clinical significance of the results, will be rejected. The specimen will not be returned. Special consideration is given, prior to specimen rejection, if the specimen is considered irretrievable. See CORE 6060Q.

Analytical:

- The Core Laboratory tests biologically human specimens only. Testing is not performed on veterinary, pharmaceutical or industrial samples.
- All testing requires an operating procedure. All new procedures brought into the laboratory are subjected to a review, validation/verification process, and assessment against the parameters of policy LADM 6002Q – Service Change or Addition.
- The order of test performance is based on the order of the following testing priorities:
    - STAT
    - Urgent
    - Routine
- All applicable maintenance must be performed prior to operating any equipment for testing purposes. The technologist assigned to that particular work bench must complete the maintenance log for that day.

Turnaround Times:

- The turnaround time for inpatient routine testing performed in the Core Laboratory is approximately 2 to 4 hours.
- Stat chemistry and coagulation test results are available within 40 minutes of receipt in the lab, 90% of the time.
- Stat CBC and urinalysis test results are available within 30 minutes from time of receipt, 90% of the time.
- Stat molecular diagnostic testing results are available within 165 minutes from the time of receipt, 90% of the time.
- The Laboratory Information System provides a tool (Pending Specimen Tracking Log) that allows each technologist to track specimen throughput at their workstation.

Calibration:

All automated equipment is calibrated according to procedures written in accordance with the manufacturer's recommendations, regulatory requirements, and accreditation standards.

Quality Control:

- Quality control must be run and meet acceptability criteria before patient samples are reported. Corrective action must be taken when control results are out of range.
- Commercial control materials are used in most tests done in the Core Laboratory and are tested in the same manner as patient samples. In the event that a test does not have an available commercial control, patient samples or other appropriate substitutes are used as controls. Acceptability limits (numeric and/or nonnumeric) are defined for each test or procedure.

- Numeric ranges are typically posted electronically in the instrument or in the Laboratory Information System. Some ranges are posted on log sheets and data is captured manually. If any control is outside of the acceptable range, corrective action must be taken and documented. The controls must be in the acceptable range before reporting any results. The technologist performing the test must notify the Lead Technologist if corrective action is not effective.
- Daily Quality Control decisions must be based on CORE 6035 R.
- Lead Technologists conduct monthly review and management of the Quality Control. All of the numeric QC data in the Core Laboratory is evaluated monthly for mean, S.D. and C.V. values. Each month the data is reviewed for any problems or significant changes from previous data. If the precision statistics reveal a significant change from previous data the following action(s) should be taken:
    - Check for patterns in both previous and current lots of control.
    - Check for patterns by comparing other levels of the same parameter on the report.
    - Check for patterns by comparing same assay on alternate analyzer.
    - Verify if there is a drift or change in the comparison of your data with the peer data, if available.
    - Verify precision, electronic references, and calibration as specified by vendor references.
    - Review maintenance logs
    - Review handling techniques of the control material.
    - Call vendor support.
    - Review findings with the Medical Director or designee

Comparability Studies:
Comparability studies of patient results are reviewed by the Medical Director at least twice yearly for assays done by different methodologies or instruments. See CLIN 6000Q.

Post-Analytical:

- The overall format of the lab report is reviewed and approved by the Medical Director. Reports are reviewed annually for completeness, appearance, format and accuracy. Revisions occur as necessary.
- Alert Value Results: An **ALERT** value is a laboratory result that in and of itself may indicate a potentially dangerous or life-threatening situation of imminent nature. *The term "imminent nature" indicates significant patient harm may occur within a period of twelve hours if intervention is not initiated.* For a list of Alert Values and complete instructions see LADM 6005Q.
- All blood samples and urine drug screens are archived using the Instrument Manager software for seven days. Archived samples are kept in a refrigerator in the specimen processing area.

Delay of Reporting:
It would be highly unusual for the lab not to perform an internal test, but if a situation arises where a test is unavailable, the following actions should be taken depending on the projected severity of the delay:

- Notify the Charge Technologist on duty of the problem.
- The Charge Technologist should notify a pathologist, if the situation warrants.
- Contact contracted reference laboratory to see if they will be able to perform the tests for our laboratory.
- Notify the Charge Nurse in the Emergency Department and the Nursing Supervisor of the expected delays.
- Notify the Outreach department so that they may alert their clients of any delay.
- Document the incident with an Occurrence Report Form.

QSE 7: Information Management

The Core Laboratory follows and abides by all administrative policies as set forth by the Information Systems Department and in accordance with HIPPA regulations. See copy of SAH Information Systems HIPPA policies and requirements. All associates of the Laboratory and SAH are assigned levels of computer accessibility according to the specific needs of their job position.All associates at hire are required to read the system access request form and give written signature that they agree to follow the requirements of the facility regarding knowledge of and use of any and all information only as it pertains to their specific job position. In addition the agreement addresses use of computer system for no other use than that related to job performance.

Discussion of any and all patient information and/or business information of SAHC for any purpose other than patient care or business operations is prohibited. Any and all violations are subject to disciplinary actions up to and including termination.

The laboratory must maintain patient services during disruption in the Laboratory Information System (LIS). Computer downtimes may be scheduled or unscheduled. See CORE 7050 R.

QSE 8: Occurrence Management System

The laboratory maintains an occurrence management system designed to identify, for the purpose of finding and removing the root causes, pre analytical, analytical and post analytical problems of laboratory operations (LADM 8000 R).

The essential components of the system are as follows:

- An Occurrence Report Form (ORF) is available on most Laboratory PC desktops as an icon.
- The ORF is designed to capture all elements indicative of untoward events in laboratory operations, spanning pre-analytical, analytical, and post-analytical variables.
- Any problem that could potentially interfere with patient care is to be documented.

The ORF is also designed to capture associate concerns regarding but not limited to the following; Safety, Patient Safety, Complaints, and Process Improvement needs.

All laboratory associates are mandated to file an electronic ORF to report any such event. The associate completing the ORF sends the form to the Supervisor and/or Lead Technologist, and LabQuality mailbox. The ORF is categorized and entered into the database for further follow up and review.

QSE 9: Assessments

The Laboratory uses external and internal assessments to verify that processes meet regulatory 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.

1. Internal Assessments:
   Quality Control and Quality Assurance Indicators are provided as planned and systematic activities to ensure operational techniques are used to fulfill quality requirements. See Appendix A for specific Quality Assurance Indicators.
2. External Assessments:
   The laboratory participates in Quality Assurance Surveys administered by the College of American Pathologists (CAP). The department is inspected and accredited by CAP. The Laboratory participates in external assessments conducted by FDA, CMS and State as required. The Laboratory participates in voluntary external assessments of the CAP and TJC accreditation programs. See CLIN 6005R for more details.

QSE 10: Process Improvement

Quality indicators are typically developed using the data retrieved from the Occurrence Report database and identified through audits and customer surveys to coincide with CAP's patient safety goals. Process Improvement initiatives are often isolated through the Occurrence Management System. A plan of action is developed and placed into

effect. Performance improvement progress is discussed at the Laboratory Management Meeting, Core Laboratory Administration and Associate Meetings. Refer to QSE 9 in LADM 0000 QP for communication and reporting of data.

QSE 11: Customer Service

The Core Laboratory is in continuous operation performing routine and stat hematology, coagulation, chemistry, special immunology, molecular diagnostics and urinalysis testing. Additional information regarding specific testing is contained in the online test search, (www.testmenu.com/stagnes).

The Core Laboratory utilizes input from physicians, nursing staff, administrators, other hospital departments and financial data to determine the need for changes in service. This includes: providing new services or new testing, deleting old services or processes, amending or adopting changes to current services.

The Laboratory receives input from physicians, nursing staff, administrators, other hospital departments, satisfaction surveys and other individuals to determine levels of satisfaction. Using the performance improvement process, priorities are set and improvement plans are developed, implemented, monitored and evaluated. All complaints and problems are reported using the Occurrence Management system. Investigations are made as appropriate, with the responsible lab or operational department, and corrective actions instituted as necessary. Any trends or clusters are further investigated to identify areas for improvement. Feedback is provided back to the associates, when applicable.

QSE 12: Facilities and Safety

The Core Laboratory complies with the SAH Environment of Care policies and regulations for safety.

Associate Training:

Laboratory procedures are maintained and training provided for the following:

- Emergency Preparedness Response Plan and Specific Section Function
- Chemical Hygiene Plan (Right to Know)
- Chemical List
- Access to MSDS
- Blood Borne Pathogens Policy
- General Safety Training

Associates complete annual training and competencies for the following safety topics:

- Biosafety
- Chemical Safety
- Electrical Safety

- Ergonomic Safety
- Fire Safety
- UV Safety

Standard Precautions:
The Department of Infection Control provides detailed information on Standard Precautions on the SAINT. All Core Laboratory associates are responsible for review of this information. All samples that come into the Core Laboratory are presumed to be infectious. Standard precautions should be used with each sample. See CORE 12000 Q for additional information.

Some of the applicable Standard Precautions are as follows:

1. Hand washing
    - Wash hands after touching blood, body fluids, secretions, excretions, and contaminated items, whether or not gloves are worn.
    - Wash hands immediately after gloves are removed, and when otherwise indicated to avoid transfer of microorganisms to other environments
2. Personal protective equipment
    - Wear gloves (clean, non-sterile are adequate) when touching blood, body fluids, secretions, excretions, and any contaminated items.
    - Wear a mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures that are likely to generate splashes of blood, body fluids, secretions, and excretions.
    - Wear provided lab coat. A soiled lab coat is to be discarded as promptly as possible.
3. Equipment
    - Single use items are to be discarded immediately after use
4. Sharps
    - Do not accept samples in the laboratory that have an attached sharp.
    - In the event that a sample arrives with an attached sharp, the sharp should be removed by a representative from the patient care area.
    - Place any broken glass in puncture resistant containers.

References

LADM 0000 QP Lab Quality Management Plan
LADM 200 Q Documents & Records Policy
LADM 2101 Q Document Control Policy – Creation to Destruction
LADM 6005 Q Alert Value List and Notification Process
LADM 8000 Q Laboratory Occurrence Reporting System
LADM 12023 Q Device Related Adverse Event and Recall Notification Policy
CORE 1000 F Organizational Chart

CORE 5000 Q Inventory Control
CORE 6000 R Equipment and Process Validation
CORE 6035 R Daily Quality Control Procedure
CORE 6060 Q Unacceptable Specimen Rejection and Delta Review Standards
CORE 7050 R Meditech Downtime Procedure
CORE 12000 Q Biosafety
CLIN 3008 Q Clinical Laboratory Training and Competency Plan
CLIN 3010 Q Continuing Education
CLIN 6005 R Proficiency Testing Handling

Saint Agnes Hospital Policies:

- SYS CC20
- SYS CC24
- SYS CRP9
- SYS FI41
- SYS HIPAA18
- SYS HIPAA 20
- SYS HOS16
- SYS HOS32
- SYS HR01
- SYS HR04
- SYS HR15
- SYS HR64
- SYS PI01

The Core Laboratory utilizes internal assessments to verify that all processes meet regulatory requirements and to determine how well those processes are functioning. The Core Laboratory has identified the need to monitor the following indicators based on clinical necessity:

Turnaround Times:

Test Description (Mnemonic)	Receipt to Verify Goal
Basic Metabolic Panel (BMP)	40 minutes
Complete Blood Count (CBC)	20 minutes
Prothrombin Time (PT)	40 minutes
Urine Qualitative Pregnancy (UPREG)	20 minutes
Serum Qualitative Pregnancy (PREG)	30 minutes
Urinalysis (UA)	30 minutes
Group B Strep (GBSPCR)	70 minutes

Turnaround time indicators will be monitored to ensure that the parameters are met 90% of the time with all inpatient STAT requests. Turnaround time reports should be pulled from Meditech monthly by the Lead Technologist. Reports will be broken down by shift and include notable outliers. The percentage of corrected reports should be pulled from Meditech monthly and given based on the assay. The Lead Technologist of the section should review all data. A quarterly review should be completed by the Lead Technologist, summarizing all of the data from the previous three months. An investigation will be held to determine what caused problems leading to samples falling outside of the defined goals. This investigation could lead to possible process improvement projects. If an indicator consistently meets the defined goal for three consecutive quarters, a new indicator will be selected for review.