Policy Statement	The Point of Care Testing (POCT) Department Quality Plan delineates a strategy to ensure that laboratory processes, procedures and practices are performed in accordance with regulatory and peer-review organizations. The POCT Department Quality Plan is an integrated strategy for providing a quality service through interlinked processes affecting patient care as related to diagnostic services and is written in accordance with the College of American Pathologists (CAP) and The Joint Commission (TJC) standards and the Clinical Laboratory Improvement Act (CLIA) regulations. Quality processes, appropriate services and products, with a focus on patient safety are the foundation of the quality plan of the POCT Department. The goals of the quality plan are outlined; these goals are reflective of the Laboratory's Quality Plan and of Saint Agnes Hospital's Philosophy, Mission, Vision and Core Values. This plan exists complimentary to the Saint Agnes Hospital administrative policy SYS HOS 038 - Point of Care Testing Program.
Purpose	The POCT Quality Plan provides guidelines for policies, processes and practices to continuously improve the POCT Department's services.
Scope	This plan applies to all policies, processes and procedures of the POCT Department. The plan also applies to the associates performing point of care testing as defined by CAP and TJC at Saint Agnes Hospital.
Responsibility	The POCT Quality Plan is carried out under the supervision of the Medical Director for POCT. The Medical Director has responsibility and authority over all clinical and technical policies, processes and procedures affecting POCT personnel and their

	testing performance. The Laboratory Medical Director is not responsible for competency assessment of physicians and midlevel practitioners. The POCT Lead Technologist is responsible for ensuring quality processes, procedures and practices are in place for point of care testing performed at Saint Agnes Hospital. The Medical Director initially approves the quality policies and quality essential process descriptions. Thereafter; the POCT Lead Technologist or designee performs an annual review of the plan and makes revisions; with Medical Director review, as needed.
Goals	The goals of POCT Department Quality Plan are: ▪ Maintaining an effective quality management system ▪ Developing processes to ensure patient safety. ▪ Improving the effectiveness and efficiency of current processes. ▪ Reducing process variations that can cause errors. ▪ Detecting, investigating, correcting and preventing POCT related errors. ▪ Assisting the Nursing Department with developing and maintaining competent testing personnel. ▪ Responding to customer needs related to POCT. ▪ Complying with all required regulations and accreditation standards. ▪ Adhering to the Mission, Vision and Core Values of Saint Agnes Hospital.
QSE 1: Organization	Saint Agnes Hospital Laboratory leaders are firmly committed to and support all activities inherent to the establishment and implementation of the POCT Quality Management System. The POCT Section Medical Director, as designated by the CLIA Medical Director, has ultimate responsibility for the quality of POCT services

	provided and activities carried out in support of the quality system. The Medical Director has the authority to request and/or approve changes required in support of the quality system. The Medical Director has the authority to discontinue POCT in any testing area of the hospital, when there is a concern that patient safety may be compromised. The role of the Laboratory Administrative Director is to create an environment that promotes creativity, productivity and critical thinking; and to manage the Department of Pathology's overall quality management system and lead the department's associates toward the program's quality objectives. The POCT Lead Technologist has responsibility for developing policies and procedures, that when properly carried out, ensure the quality of services provided to support patient care. These policies and procedures outline activities to support the goals of the quality system. The POCT Lead Technologist is responsible for ensuring that the POCT Quality Management System is in accordance with the overall Quality Plan for the Department of Pathology and meets accepted quality system principles. The Medical Technologists of the POCT Department are responsible for carrying out the policies, processes and procedures of the department. The Medical Technologists are expected to be proactive and engaged customer service representatives of the Laboratory, with an ongoing vigilance for maintaining patient safety in all activities of the department. Nursing and ancillary managers are responsible for implementation and compliance with, hospital policy SYS HOS 38 The Point of Care Testing Program, in their areas of responsibility where waived and/or non-waived testing is performed.

	Testing personnel (operators) are responsible for following the POCT policies and procedures related to laboratory testing. Testing personnel are expected to meet mandatory proficiency and competency requirements; non-compliance will result in loss of testing privileges. The POCT Department Quality Plan will be reviewed annually for effectiveness by the POCT Lead Technologist.
QSE 2: Documents and Records	The POCT Department is committed to developing, managing, maintaining, archiving and properly disposing of controlled documents and records in order to support the department's objectives and to help facilitate a quality system.
QSE 3: Personnel	The POCT Department is committed to obtaining and retaining associates that are best prepared for their respective positions and provide the highest quality services, using methods that meet or exceed the applicable legal and regulatory requirements; and maintain associates that are qualified and well-trained to support the Department's goals and customers.
QSE 4: Equipment	Based on organizationally identified needs and budget approval, the POCT Department will select the most appropriate equipment to attain its quality goals. The POCT Department adheres to, or exceeds the manufacturer and regulatory requirements for the implementation and maintenance of test systems including; requirements for calibration verification and method comparisons with the main Laboratory.
QSE 5: Purchasing and Inventory	The POCT Department controls expenditures for supplies and inventory items by minimizing changes in production lots for routinely purchased materials and whenever possible conforming to Ascension Health contracted vendors. The POCT Department establishes relationships with vendors who deliver high-quality products and services on a timely basis at reasonable prices. The POCT Department will follow vendor credentialing and selection as defined by Saint Agnes Hospital.

QSE 6: Process Control	The POCT Department adheres to, and continually reviews and updates detailed, clearly written procedures for all critical elements of POCT processes and services.
QSE 7: Information Management	The POCT Department is committed to providing the infrastructure to support the transfer of POCT information to the electronic medical record and provide technical support for the hardware and software associated with POCT devices.
QSE 8: Occurrence Management	The POCT Department promotes the detection, documentation, and classification of all occurrences to identify systematic problems and is committed to removing the cause to allow functioning in an error-free manner. The POCT Department is dedicated to ensuring that this is accomplished in a cooperative atmosphere. The POCT Department employs the Laboratory Occurrence Reporting System.
QSE 9: Assessment	The POCT Department monitors and evaluates its operations relative to established policies, procedures and objectives, and implements any changes necessary to meet or exceed its quality goals and/or the requirements of external quality assessment groups. 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. <u>Internal Assessments</u> The Point of Care Testing department utilizes internal assessments to verify that all processes meet regulatory requirements and to determine how well those processes are functioning. The following are examples of POCT department Quality Assurance Indicators: ED Troponin I Turn-Around-Time Report,

	POCT Rounds and POCT Chart Reviews. <u>External Assessments</u> 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 LADM 9005 R for more details.
QSE 10: Process Improvement	The POCT Department is dedicated to continually improving and monitoring operations in order to consistently increase effectiveness of internal and external processes and to meet or exceed quality objectives. 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, Point of Care Testing Administration and Associate Meetings. Refer to QSE 9 in LADM 0000 QP for communication and reporting of data.
QSE 11: Customer Service	The POCT Department continually determines, measures, and strives to improve customer satisfaction by providing products and services that are of value to the customer.
QSE 12: Facilities and Safety	The POCT Department is committed to providing a safe and healthy work environment for all of its associates and visitors. The facility space for the POCT Department is compliant with all applicable safety measures. Management provides all required

	safety training.
Supporting Documents	-LADM 0000 QP Laboratory Quality Plan -LADM 8000 Q Laboratory Occurrence Reporting System -POCT Procedure Manual -POCT Quality Plan, Appendices A, B and C -SYS CC33 Identification of Patients -SYS HOS 38 Point of Care Testing Program Policy -SYS HR01 Mandatory Annual Requirements -SYS HR03 Competency Assessment of Associates

Appendix A

Quality Policy

Quality Assurance

Point of Care Testing (POCT) is performed 24 hours a day, 7 days a week in the inpatient and outpatient care areas. Tests and analyzers in use are designated in the waived or moderately complex categories under the Clinical Laboratory Improvement Act of 1988. The main Laboratory performs all testing in the high complexity category; no highly complex testing is performed as POCT.

Point of Care tests must be ordered by a physician or other authorized person; an appropriate order must be documented in the patient medical record. Results are documented in the patient medical record by one of the following modes: transmitted by a computer interface or manually documented into the patient medical record, or onto patient care report forms that become part of the formal medical record.

The POCT program at Saint Agnes Hospital is accredited by the College of American Pathologists (CAP) as a section of the Department of Pathology.

Physicians, Nursing Services, ancillary services and the Laboratory work together to meet the goal of providing rapid, reliable test results at or near the patient bedside; following specific processes and procedures. The Laboratory is responsible for:

- evaluation of testing needs
- equipment and methodology recommendations
- writing policies and procedures

- test validation and implementation
- quality assurance
- occurrence management
- regulatory compliance-to include corporate, federal and state
- proficiency testing oversight
- assist with accreditation preparation-TJC and CAP

Non-sanctioned Testing

Any point of care testing performed without the prior authorization of the POCT Medical Director is considered “non-sanctioned” and is not overseen by the Laboratory. These areas are in direct violation of Saint Agnes Hospital Policy HOS 038 and are subject to corrective action as determined by Hospital Administration. At a minimum, when discovered, non-sanctioned testing will be immediately halted until the program has been reviewed by the POCT Medical Director for compliance with all required elements.

Occurrence Management Reporting

The POCT Department utilizes the Laboratory Occurrence Reporting System for documenting all events that are outside normal operations.

For occurrences internal to the laboratory, an Occurrence Report Form (ORF) is completed and sent to the immediate supervisor of the laboratory section impacted by the occurrence and the Lab Quality mailbox.

Additionally, ORFs regarding patient safety, regulatory and accreditation exceptions are sent directly to a member of the associated area’s leadership team by the POCT Medical Technologists.

The completed ORF includes who was spoken with and their location, a brief description of what occurred or is broken; when the problem occurred, how the issue was resolved, and who the resolution was reported back to. For equipment issues the serial # and device tag name are included in the description.

ORFs are utilized for reporting monthly QC outliers without comments and critical values without comments, for documentation of patient identification errors and procedure errors where the test is performed in repetition and a duplicate bill is produced.

Communication

The Laboratory provides updates to services, policies and test procedures utilizing various communication modes including: providing updates to the Nursing Practice

Council, emails to Nurse Managers, attending Nurse Manager monthly meetings, collaborating with nursing educators, and posting information to the Saint intranet; main web page.

Documents: Policies and Procedures

The POCT Department adheres to the Document Control policies and procedures of the Laboratory Quality Management System. Procedures applicable to the POCT performed are available electronically to testing personnel in each patient care area.

A complete hardcopy procedure manual is available in the POCT Office located inside the Core Laboratory.

The POCT Director/Designee reviews and approves all new policies and procedures as well as substantial changes to existing procedures. The POCT Lead Technologist performs an annual review of all policies and procedures. If there is a change in Medical Directorship, the new Medical Director ensures (over a reasonable period of time) that POCT procedures are well documented and undergo an annual review.

Manufacturer's instructions are incorporated into each test procedure; the package insert for each new lot of QC material, kit, reagent, cuvette, test pack etc., is reviewed for updated information. Manufacturer recommendations are incorporated into test procedures on the approval of the POCT Medical Director; the Medical Director may choose to adopt stricter standards than those supplied by the manufacturer.

Prior to performing any point of care tests, testing personnel are provided orientation and training; training documents include the applicable test procedure or training materials that incorporate all relevant information from the procedure document. Changes to policies and procedures are communicated through one or more of the following avenues; Nurse Manager meetings, Nursing Practice Council meetings, nursing educators, email, intranet announcements and the computer-based online training program.

The on-line annual competency exam contains questions related to the test procedure. All annual on-line competency exams will contain a question to document the testing personnel's familiarity with the associated procedure.

When a test or a device is discontinued, documentation will be maintained for two years. The document will contain the date of retirement on the review page. The original, signed review page is scanned into the Revised-Retired folder with the retired policy or procedure.

As part of the accreditation process; the Quality Coordinator notifies CAP when new

tests are added to the test menu or when any current tests are discontinued.

Equipment

Only equipment and reagents that have been approved by the POCT Medical Director are used to perform any laboratory testing. Prior to implementation, each POCT test method is validated using established laboratory protocols.

Instruments not currently in use or in the Laboratory for troubleshooting or implementation testing are labeled as “Not in Service” unless boxed.

When a device malfunctions, the patient care area places a call to the POCT Office at ext. 3276. The instrument is removed from use for patient testing until the issue has been resolved. When an instrument is removed due to malfunction the POCT department documents all service, repair or replacement using the Laboratory Occurrence Reporting System.

Testing Personnel, Supervision and Education

Point of Care Testing is performed by properly trained associates and affiliates of Saint Agnes Hospital, this may include: credentialed physicians, residents, credentialed midlevel practitioners (nurse anesthetists/practitioners, physician assistants), pharmacists, nurses, medical technologists, phlebotomists, radiology technicians, OR and anesthesia technicians, nursing technicians/assistants and other licensed personnel contracted by the hospital to provide patient care.

Patient testing is supervised by the patient care area’s nurse manager, team leader or their designee.

All associates performing POCT are assigned an Operator ID number. The POCT Department maintains an electronic list of operators including which tests they have been trained to perform.

Operator access to interfaced testing systems is controlled through middleware software and the Operator ID number. When training is complete, POCT personnel do not give an operator access to a test system without evidence of a properly signed training checklist.

CLIA regulations require that testing personnel performing waived testing must have at a minimum, a high school diploma or equivalent. Associates and affiliates performing moderately complex testing are required to meet the educational and training requirements as stated in CLIA. All testing personnel are screened to determine if they

have difficulty with visual color discrimination by Employee Health Services. Difficulty with visual color discrimination does not exclude an associate from performing testing.

Training and Competency

The Laboratory assists nursing and patient care areas with the development of training and competency documents. Hospital Nursing Management and the leadership of a patient care area performing POCT, are responsible for the day to day supervision of POCT testing personnel regarding; patient testing, training documentation, competency assessment compliance, and adherence to POCT polices and procedures.

Initial orientation and training is provided to associates during nursing unit orientation by the patient care area and/or the Hospital Education and Development Department. Testing personnel receive training specific to the testing that will be performed.

Annual competency requirements for point of care laboratory tests are part of the mandatory competency assessments assigned to nursing and ancillary personnel through Hospital Education and Development. Documentation of compliance is maintained by the Nurse Manager or manager for the patient care area or ancillary service. The Laboratory assists patient care areas with testing personnel competency assessment by providing and updating skills assessment documents and developing computer-based assessments.

Competency assessment is accomplished by a variety of methods including one or more of the following: direct observation of patient testing, successful completion of quality control testing (with QC monitoring) or proficiency testing material (blind specimen), monitoring the recording of test results and critical and evaluation of problem solving skills through a written test.

The competency assessment requirement for bedside glucose is met by successfully performing quality control at high and low levels every 6 months. Failure to meet this competency standard automatically locks the operator out of the system for performing patient testing on the glucose meter until the competency requirement is met. In addition to successful performance of QC; an online competency exam is required annually.

Certification - Only certified operators are permitted to perform POCT on automated devices. When training is complete, the operator is assigned an Operator ID number. For the bedside glucose meters, when 6 month recertification requirements are not met; the Operator ID number is automatically deactivated by the computer software; the operator is locked out of the device.

Certification involves a training session with an identified trainer, which includes the

completion of a written test and/or a proper testing demonstration.

Trainers include: unit based nurse educators, designated nursing trainers, designated personnel in ancillary areas and manufacturer technical personnel.

Assessments - Proficiency Testing

The POCT program is enrolled in proficiency testing (PT) programs to encompass the scope of the tests performed and devices in use. When necessary, alternate methods of proficiency testing may be employed. The POCT technologists manage the distributions of PT samples.

To the extent that it is possible, PT specimens are handled like patient samples and are integrated into the routine workload; analyzed by personnel who routinely test patient samples; using the same primary method of test system. Testing personnel are randomly selected to participate in each challenge. PT results are only considered acceptable for submission when the testing has been performed by appropriately trained associates or contracted associates at Saint Agnes Hospital

PT specimens are not outsourced to a reference laboratory or any other testing facility. PT results are not shared among testing personnel or discussed with other facilities until the result report is available from the PT provider.

PT result reports are reviewed by the Laboratory POCT Lead Technologist. All ungraded proficiency testing results require review for acceptability. All unacceptable results require investigation, retesting if stored specimens are available and if necessary corrective action, such as process evaluation and/or re-education of testing personnel.

Assessments - Interface Monitoring

Middleware software rules are in place to capture instances when: duplicate testing occurs, invalid patient identifiers are entered or scanned into a device, procedure errors resulting in ridiculous values occur, results fall outside an instrument's testing parameters, and when invalid Operator ID numbers are utilized. When testing is performed in duplicate for result verification or validation, and the 2 or more events are within a time period that is not considered medically necessary, POCT techs enter a credit to the patient account for the repeat test(s). When the test results are significantly different indicating that a procedure error may have occurred, an ORF is initiated in addition to the credit to the account.

Assessments - Test/Method Comparisons

For moderately complex devices, result comparisons are performed between multiple devices of the same model and also between devices that use different methodologies for the same analyte, two times per year. Matrix appropriate commercial material is purchased or remainder proficiency testing material is used to perform the comparisons. Patient specimens can be used for performing comparisons; however, due to infection control concerns patient specimens are not the preferred specimen type.

Quality Control and Reagent Handling

Quality Control: Quality Controls are utilized to assure that:

- Equipment is functioning; accurately and precisely;
- Operators are capable of using the equipment in the manner designated to produce accurate patient results;
- Reagents used are valid and produce acceptable patient results for each analyte.

The personnel performing QC evaluate the data to detect instrument or process failure.

Regulations require that QC specimens are to be tested in the same manner and by the same personnel as patient samples. Due to packaging and handling limitations for some QC material, not all commercially prepared QC can be handled in exactly the same manner as patient samples.

All QC results must be reviewed for acceptable performance when performed. QC results are documented by testing personnel for manual methods. QC results are documented electronically for interfaced devices.

When QC results exceed defined tolerance limits, patient testing is suspended for that device; testing personnel are to troubleshoot the problem. Issues to check include: the procedure was followed; reagents and quality control are not expired, and instrument cleanliness.

For QC failures; a corrective action or comment is documented on the QC log or entered as a comment in the device. Testing personnel are instructed to repeat quality control testing after a failure. For most quantitative test devices in use, the device will lock out patient testing modes when QC testing is not successful. When QC results remain outside of the acceptable range after troubleshooting and repeat testing, testing personnel are to report the problem to the POCT Department.

Reagent Handling: Reagents, test kits and QC material are stored and maintained in the manner recommended by the manufacturer. All reagents and QC materials are used within the printed expiration date. When the initial opening of a container or a storage

requirement changes the stated expiration date, the new expiration date is to be written on the container. An open date should be placed on all reagents, QC and containers. In the case where a reagent test kit has multiple components, these components should only be used within the same kit lot #, unless otherwise specified by the manufacturer.

The Laboratory performs new lot # to old lot # comparisons on reagents and control materials prior to placing the new testing materials in use. Criteria for acceptability have been established for new reagent lots or shipments to ensure that patient reference ranges and QC ranges are similar to those from the previous lot.

The acceptability of manufacturer recommended ranges or tolerance limits for liquid QC material and reagents are verified when necessary by repetitive analysis. Manufacturer product inserts are reviewed for updates with each change of lot number of material.

Quality Control Management

QC records are collected from all POCT locations; QC records are maintained by the Laboratory for 2 years.

Manufacturer recommendations are followed concerning the frequency of QC testing and the type of controls used. QC processes are outlined in the individual procedures; but can include electronic, equivalent and liquid quality control materials.

The POCT Department is responsible for the review of monthly QC records. QC and Critical Value Comment exception reports are sent to the patient care areas for follow-up using the Laboratory Occurrence Reporting System. It is the responsibility of the leadership team of the patient care area to respond to the deficiencies noted by the problems or issues identified by POCT personnel.

Analytical Errors: When a QC value falls outside the acceptable range, the QC test must be repeated. If the QC value continues to be out of the acceptable range, the device or test kit/pack must be taken out of service. A determination is then made as to what caused the repetitive QC failures. When the POCT Department determines that a failure is due to operator error, contaminated QC material or bad reagents, the device is returned to service. In cases where the device produces QC results that are unacceptable due to a mechanical or electrical malfunction the device is returned to the manufacturer for repair or replacement. If the QC failures are due to bad reagents, cassette packs or strips, the reagent, cassette or strips must be replaced with fresh and the QC test repeated.

If the QC test continues to fail; the Laboratory, the nursing team leader or other on-site supervisor must be notified, no patient testing is to be performed when the QC is outside of acceptable limits.

Suspected analytical errors due to device malfunctions or bad reagents/strips are to be reported to the Laboratory immediately. Any unexpected test result and/or critical result is to be repeated, if suspicions remain that the result is inaccurate or invalid a specimen should be collected and sent to the main Laboratory; report the problem to the POCT Office. POCT personnel will document all maintenance, service, repair and replacement events through the Laboratory Occurrence Reporting System.

Patient Management

Patient Identification: Proper identification of the patient is the first step to ensuring that the test results are posted to the correct patient medical record.

In order to ensure consistent quality control/quality management, identification of patients is to be in compliance with the Saint Agnes Hospital Policy, SYS CC 33 Identification of Patients.

For devices that have barcode scanners; the scanning unit is always to be used to enter identification information, rather than attempting to manually enter the Operator ID and patient identifier.

When testing personnel recognize that the wrong patient information has been entered into a testing device, the POCT Office must be notified with all pertinent patient information. An Occurrence Report will be initiated when these events occur.

Patient Preparation: The criterion for patient preparation depends on the type of testing to be performed. Any required patient preparation information is outlined in the individual test procedures.

Patients are identified prior to obtaining a sample, by following the hospital patient identification policy of requesting that the patient state their name and date of birth and checking the patient's identification bracelet, or by using the accepted alternate methods of patient identification when the patient is unable to state their name and date of birth.

Specimen Handling: All specimens for POCT are tested immediately and are usually performed at or near the patient bedside, one patient test at a time.

Specimen Collection and Labeling: Standard precautions apply to all point of care tests. Disposable gloves must be worn when collecting specimens and performing tests. Venous and capillary blood specimens should be collected per clinical protocol. Special considerations for sample collections are outlined within the individual procedures.

Any POCT assay that is implemented will be reviewed to assure that the minimum amount of blood is taken from patients.

In the event that POCT is not performed at the patient's bedside, the sample must be labeled with two identifiers by the person collecting the sample according to the established procedures.

All POCT urinalysis specimens are referred to the Core Laboratory for definitive testing; therefore, no urine specimens are saved by the patient care area following Core Laboratory instructions for maintaining specimen integrity.

Patient Result Documentation

Electronic documentation of results includes the result, the name of the person performing the test, and the serial number of the testing device. Manual test results are documented by the operator in the patient's medical record. Where applicable, the reference ranges are reported with the patient result.

Critical Results

Test results considered critical are to be repeated, if confirmed by repeat, these results are to be reported to the patient's physician, unless a treatment protocol/standing order is in place. Physician notification and follow-up orders are to be documented in the patient's medical record.

On certain test devices, a comment is entered into the device to document physician/RN notification of a critical result in addition to documentation in the medical record. Test results considered critical or questionable should be repeated for verification. If the validity of the test result remains questionable, a specimen should be collected and sent to the main Laboratory.

Detection of Clerical Errors

The person recording the result is to double check for clerical errors. The Patient Identification/Quality Management policies and procedures are defined in order to eliminate and detect clerical errors. Any results that are not consistent with the patient's presentation should be documented as such by testing personnel. A pattern of inconsistent results as related to patient condition, on a specific device or test system, should be discussed in a timely manner with the POCT Department. Interfaced test results are flagged when performed in duplicate within specified time periods depending on the test type; these results are monitored by POCT personnel to determine if a clerical error has occurred. Suspicious, spurious and ridiculous results are documented using the Occurrence Reporting System.

In the case of a misidentified patient, the patient care area is to provide pertinent patient information on both patients, to include; names, account numbers, results and time of testing. The POCT Department will take the necessary steps to flag the results as misidentified; an ORF will be initiated and sent to the manager of the patient care area.

Unexpected Results

Testing personnel are instructed to perform a repeat test in the case of any unexpected patient result. As needed, the patient is treated according to physician's orders or standing protocols. A specimen may be sent to the main Laboratory for confirmation of any result if any questions remain as to the correctness or validity of the result.
In the case where an unexpected result occurs due to the wrong patient being tested, the POCT Office is to be notified by telephone; corrective actions will be taken by POCT personnel and the patient care area to correct the medical record; records of all incidences will be maintained within the Laboratory Occurrence Reporting System.

Calibration Verification - The Analytical Measurement Range

Calibration verification material that is matrix appropriate and provided by the device manufacturer or other commercial provider is used. In cases where calibration material is not available, proficiency testing material may be used. The spiking of patient specimens to create calibration material is not a recommended practice at Saint Agnes Hospital due to risk of Hepatitis and HIV. Except for correlation and comparison studies, the handling and opening of patient specimens should be limited to testing for the treatment of the patient.

Calibration verification is not required for FDA cleared/home use waived devices. Calibration verification, when required, is performed at the following intervals; when a device is placed into service, when a new lot of reagent or control material produces a significant variation from the previous lot, and/or, at the interval recommended by the manufacturer. Calibration material will include, when possible, samples at the minimum, midpoint and maximum values of the analytical measurement range (AMR).

For POCT devices the AMR is established by the manufacturer and verified by the Laboratory. When calibration verification fails, the device is taken out of service for repair or replacement. Calibration verification is limited to moderately complex devices that measure the concentration or activity of an analyte; therefore, calibration verification does not apply to coagulation testing.

Clinical Reportable Range

The Clinical Reported Range (CRR) has been established for the analytes tested based on the intended clinical use by the manufacturer. Devices currently in use in the hospital do not allow for the dilution, concentration or pretreatment of patient specimens.

Physician and Midlevel Practitioners

The Laboratory Medical Director is not responsible for the competency assessment of physicians and midlevel practitioners. The competency of physicians and midlevel practitioners is established and monitored by the credentialing process of the medical staff. Certain tests, i.e. occult blood, are performed by physicians and midlevel practitioners in the Emergency Department; Provider Performed Microscopy and Nitrazine pH are performed by physicians and midlevel practitioners in Maternal Child Health Services. These and other tests are performed by the physicians and midlevel practitioners during the course of a patient medical exam and results should be documented in the patient medical record by the provider.

Physicians and midlevel practitioners who perform waived testing are required to have documented training. Physicians and midlevel practitioner who perform waived testing that requires the use of an instrument must be trained on the use and maintenance of the instrument. The training on the use and maintenance of the instrument must be documented.

Appendix B

POCT - Test Menu

Activated Clotting Time

Quantitative test – performed on whole blood, the test has been designated as non-waived, moderately complex. As used at Saint Agnes Hospital, this test has no associated reference ranges. Results are classified as above or below an established threshold as determined by the cardiologist. The cardiologist uses this test as a monitoring aid to determine the heparinization status of the patient prior to cardiac catherization and prior to stent removal post procedure.

Performance of this test is limited to testing personnel in these job categories: nurses and Diagnostic Imaging technical personnel.

Temperature checks and an internal function check are automatically performed each time the instrument is turned on. If either test fails, the device will lock out patient testing until the issue is resolved.

Equivalent QC: Performed automatically, at two levels; once per 8 hours of patient testing by the testing personnel. Three successive EQC failures will lock the device to prevent patient testing. Testing personnel performs QC testing weekly using an external liquid control material at 2 levels.

This test system does not require calibration verification.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

BNP

Quantitative test – performed on whole blood. The test has been designated as waived. BNP test result is used to assist in rapid diagnosis and/or monitoring of congestive heart failure in the Emergency Department and the Congestive Heart Failure Center.

Performance of this test is limited to testing personnel in these job categories: nurses, patient care technicians and phlebotomists.

Equivalent QC: Each test device has on-board equivalent QC monitors to verify that the test device is functioning properly. Failure of the onboard QC will invalidate the specific test(s) and results will not be reported. A QC test device with 2 EQC levels is performed

by testing personnel daily. Testing personnel perform 2 levels of external liquid QC once per week.

This test system does not require calibration verification.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Cardiac Markers

Quantitative test – performed on whole blood for Troponin I. The test method (unit use device) has been designated as non-waived, moderately complex; however, the Biosite Triage reader is designated as waived. Cardiac enzyme test results are used to support rapid diagnosis and monitoring of patients in the Emergency Department that present with the signs and symptoms of a myocardial infarction. The manufacturer's reference ranges are used and have been validated by POCT personnel.

Performance of this test is limited to testing personnel in these job categories: patient care technicians and phlebotomists.

Equivalent QC: Each test device has on-board equivalent QC monitors to verify that the test device is functioning properly. Failure of the onboard QC will invalidate the specific test(s) and results will not be reported. A QC test device with 2 EQC levels is performed by testing personnel daily. Testing personnel perform 2 levels of external liquid QC once per week.

Calibration verification of the test system is performed once per 6 months period and as recommended by the manufacturer.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Glucose

Quantitative test – performed on whole blood, the test method has been designated as waived. Reference ranges are those published by the main Laboratory. This test is used for monitoring patients diagnosed with diabetes and for screening those patients suspected of being hypoglycemic based on symptoms.

Performance of this test is limited to testing personnel in these job categories: physician assistants, nurse practitioners, nurses, patient care technicians and phlebotomists.

QC testing is performed by testing personnel once per 24 hours of patient testing using 2 levels of QC material. The glucose device will lock testing personnel out from performing patient testing until QC testing has been successfully completed.

The meter flags any result above the established critical value set point; testing personnel are expected to enter a comment concerning follow-up of the critical result. An exception report is checked monthly for critical values and out of range QC results lacking comments. The interface is monitored Monday – Friday for duplicate results and clerical errors, with documentation through the Occurrence Reporting System.

This test system does not require calibration verification.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Hemoglobin

Quantitative test - performed on whole blood, this test method has been designated as waived. This test is used to screen and monitor patient hemoglobin levels. Reference ranges are those published by the main Laboratory.

Performance of this test is limited to testing personnel in these job categories: physicians, nurse practitioners, nurses and operating room/anesthesia technicians.

Equivalent QC: An electronic QC monitor is performed on every day of patient testing by the testing personnel. QC testing is performed as recommended by the manufacturer. External liquid QC testing is performed by testing personnel once per 24 hours of patient testing using 2 levels of QC material.

This test system does not require calibration verification.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Occult Blood

Qualitative test – performed on feces, this test method has been designated as waived. This test is used as a screening tool to detect blood in feces.

Performance of this test is limited to testing personnel in these job categories: physicians, nurse practitioners and physician assistants as part of a patient medical exam.

QC testing is performed by the testing personnel on each day of patient testing. Positive and negative QC materials are located on each test pack; the QC monitors are developed with each patient tested. Documentation of patient results in the medical records provides evidence that the QC for the test pack was acceptable.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

pH by Nitrazine Paper

Qualitative test – performed on vaginal secretions, this test method has been designated as waived. This test is used as a screening tool for the presence of amniotic fluid.

Performance of this test is limited to testing personnel in these job categories: physicians, nurses, nurse practitioners or physician assistants.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Prothrombin Time and International Normalized Ratio (INR)

Quantitative test – performed on whole blood; collected by fingerstick method; the test has been designated as non-waived, moderately complex and is used as a monitoring tool. The nurse/physician uses the test results in conjunction with patient history to monitor and adjust the warfarin dosage. When a patient INR result is > 5.0, a venipuncture specimen is collected and sent to the Core Laboratory for confirmation.

Performance of this test is limited to testing personnel in these job categories: nurses and patient care technicians.

Temperature checks and an internal function check are automatically performed each time the instrument is turned on. If either test fails, the device will lock out patient testing until the issue is resolved. The nurse or nursing technician performs QC testing once per week using an external liquid control material at two levels. Failure to perform external liquid QC will result in the device locking out testing for patients until the QC has been performed.

This test system does not require calibration verification

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Provider Performed Microscopy (PPM)

Microscopic examination of body fluid is classified as non-waived and is considered to be a screening tool. Vaginal or cervical secretions are examined to determine the presence or absence of trichomonas, bacteria and yeast, etc. The wet mount preparation is an aid to the healthcare provider in the diagnosis and immediate treatment of a patient's infection. The Fern Test is used to confirm the presence of amniotic fluid secretion in a patient suspected of premature rupture of the membranes (PROM) or amniorrhexis.

Performance of these procedures is limited to testing personnel in these job categories: physician, certified nurse midwife, nurse practitioner or physician assistant. Competency and assessment is established and monitored by the credentialing process.

Photomicrographs of positive and negative results are provided as QC at the microscope workstation to assist in the identification of cellular elements, organisms, yeast, etc. when viewing wet mount preparations and as positive and negative representations of the Fern Test.

Urine Macroscopic

Qualitative – performed on urine, this test method has been designated as waived. This test is used to screen for abnormal urinary chemistry constituents. All urine specimens are sent to the Core Laboratory for complete, definitive testing. Reference ranges are those published by the Core Laboratory.

Performance of this test is limited to nurses in the Women's Health Center.

QC testing is performed by the testing personnel on each day of patient testing. The external liquid QC materials are at levels equating to normal and abnormal results.

Consideration has been made for common interferences as recommended by the manufacturer and published data.

Appendix C

POCT – Quality Assurance Indicators

The Point of Care Testing department will monitor the following Quality Assurance Indicators:

- ED Troponin I Turn-Around-Time Report
  - Turn-Around-Time goal of <60 minutes from Order to Verify
  - Report will be monitored monthly and presented at the Emergency Department's EPIC meeting
  - Follow-up will be documented in the EPIC meeting minutes

- POCT Rounding Charts
  - Acceptable compliance goal of ≥ 90%
  - Rounds will be performed on a monthly basis and charts updated accordingly.
  - Information will be incorporated into the monthly ORF quality assurance reports submitted to nurse managers

- POCT Chart Review Charts
  - Acceptable compliance goal of ≥ 90%
  - Chart Reviews will be performed on a monthly basis and charts updated accordingly.
  - Information will be incorporated into the monthly ORF quality assurance reports submitted to nurse managers