PENINSULA REGIONAL MEDICAL CENTER
Part of Peninsula Regional Health System

Title: Point of Care Testing Quality Management Plan

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Approved by _____ Date _____

Lab Director _____ Date _____

Adopted by _____ Date _____

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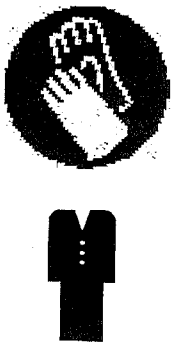

Point-of-Care Testing Quality Management Program Procedure

Principle:
To ensure consistent performance with documentation and review of quality control (QC). To ensure quality results for all sites performing Point of Care testing.

Procedure:
Accurate and precise test results obtained during point-of-care testing (POCT) depends upon the health care provider consistently following and successfully adhering to test procedures. Any test systems, devices and kits used within Peninsula Regional Medical Center and by the Peninsula Regional Medical Group must meet the standards set by Peninsula Regional Medical Center's Quality Assurance Program and not be brought in from home-use or from outside vendors. **Results derived from home-use meters i.e. glucometers may not be entered into documentation in the patient's record or used for any decision-making or treatment.*

Compliance with QC requirements and test procedures is mandated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA '88), the College of American Pathologists (CAP), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Responsibilities of Staff Performing POCT:

- Read and be familiar with location of procedures pertinent to testing performed in their department
- Demonstrate initial and then annual competency in the performance of waived POCT during unit orientation with a designated trainer or the POC Dept. During initial competency assessment, the operator has been trained and evaluated for proper test performance through direct observation of test performance and a quiz to evaluate understanding of material. Annual competency assessment includes review of test procedure with a quiz and control testing. Operators performing tests classified, as moderately a designated trainer (Technical Consultant), whose competency has been assessed by the POC department, will train complex. Competency is assessed initially and then semiannually the first year of testing and then thereon annually incorporating all six elements of competency. Individual records demonstrating satisfactory competence on all instruments/methods and specimen collection techniques applicable to Point of Care testing are maintained in the unit.
- Date all patient test kits, test strips, reagents, cartridges, cuvettes, QC materials, etc. when opened. * Expiration dates are written on all QC and/or reagent containers in which expiration date changes once opened, causing them to expire earlier than the manufacturer's date on container.
- For analyzers that are not interfaced to the POC database (RALS) there is documentation of all lot numbers of reagents and controls along with expiration dates of each.
- Ensure expired materials are not used for testing.
- Perform QC on POCT instrumentation each day patient testing is performed. Quality Control is analyzed by personnel routinely performing patient testing. *QC results must be reviewed and found to be acceptable, by the individual operator performing the test, before patient testing occurs. All automated Point of Care analyzers do not allow patient testing if a daily QC is not performed and within acceptable range.
- Determine that QC results fall within pre-defined limits before patient tests are performed. All automated Point of Care analyzers do not allow patient testing if a daily QC is not performed and within acceptable range.(For non-waived testing that has an internal quality control used to meet the daily QC requirements we have an approved individualized quality control plan (IQCP) in place to address the use of this alternative control system). **Note**: *An internal built in controls is performed before all istat blood gas testing. This internal built in control represents both high and low values.*
- Repeat out-of-range QC, document corrective action, either electronically, if applicable, or on a manual log, and document the actual result. POCT Office personnel should be notified when the second QC attempt fails or if operator needs further help troubleshooting a failed Quality control result. POCT office personnel should also be notified of instrument check failures.

- Notify POC and or designee of any unusual or unexpected test results in a timely manner.
- Obtain a lab draw if POC results do not match the clinical condition of the patient.
- Adheres to Point of Care procedures for each type of testing. Always identifies the patient with two patient identifiers and follow criteria set for patient preparation, collection and labeling. POC testing personnel are educated on the limitations set forth for each analyzer. POC testing personnel never perform POC testing on patients exhibiting any of the limitations set forth for each reagent/analyzer.
- Always label specimen container with two patient identifier, if the testing is performed away from the patient.
- Must notify POC of any errors detected after results have been reported. The results must be corrected on the patient's chart and the nurse/physician responsible for the patient must be notified.
- Perform CAP proficiency testing for each instrument system in use at each test site. It is the test site manager's responsibility to assign staff to perform the testing and coordinate this with the POC office in a timely manner.
- Follow test procedures defining the proper technique for specimen collection, operating an instrument and/or test system.
- Alert any instrument failures to the POCT office and take instrument out of service immediately.
- Clinical manager or designee will send QC data for POC testing to the POC office each month for secondary review.
- Aware that most analyzers can be borrowed from another area and if not specimens can be sent to the main lab for testing.
- Always adhere to wearing gloves during testing events, perform hand hygiene and change gloves between patients, according to Standard Precautions. Hands must be cleaned using an effective antimicrobial method.
- Adheres to manufacturer's guidelines regarding disinfection of handheld or portable testing devices. Disinfects handheld and/or portable POC devices after each patient use with the appropriate disinfectant. Devices and materials designed for single use must not be disinfected and reused.

Responsibilities of POCT Office Personnel:

- All instruments, equipment in use and validations of have been approved by the laboratory director and validations can be found in the POC Supervisor's office
- For all waived testing POC at PRMC follows all manufacturer recommendations for calibration, calibration/verification and related functions.
- Monitor refrigerators housing POC reagents with a daily and a monthly report reviewed by POC and/or a designee. Each monitoring device (Aeroscouts) for POC reagents has been verified against an NIST Thermometer (*maintained by Transfusion Services).* The Aeroscouts utilized in POC were checked against the NIST thermometer initially. Acceptable ranges have been defined for all temperature dependent equipment. Humidity and ambient temperatures are monitored in the same manner.

- Monitor temperature/humidity logs, instrument flags, Quality control results, number of tests performed and instrument and equipment maintenance monthly. Through this monitor it is determined if further evaluation of the risk assessment is needed.
- Monitor compliance with QA standards: Temperature/humidity logs, instrument flags, validation of new lots/shipments, quality control review, corrective action, records of competency, operator errors, review of RALS, and any external/internal complaints. . Through these monitors it is determined if further evaluation of the risk assessment is needed.
- Defines acceptable control limits in the POC Database (RALS). The Acceptable Control Limits are loaded into RALS either manually (*Accuchek and Sig Elite*), uploaded electronically (*evas file for istat*) or manually into the analyzer (*AVOX, Siemen's Clinitek Urine Analyzer).* All limits for Point of Care testing are defined in the Hospital's Information System.
- Reviews Quality control for both waived and non- waived testing. For non-waived testing that has an internal quality control used to meet the daily QC requirements, we have an approved individualized quality control plan (IQCP) in place to address the use of this alternative control system. Monthly, the POC Supervisor determines whether further evaluation of the risk assessment and QC plan is needed based on the RALS review, number of quality code checks and failures to the Quality control plan for non- waived testing. The IQCP is reviewed annually.
- Troubleshoots test systems problems/failures.
- Assists with competency assessment of waived and non- waived POC testing.
- Teaches all initial glucometer classes and assesses initial competency. All records of initial glucometer testing are located in the POC training area. All other competencies for waived testing are located in the areas of testing.
- Assists with competency assessment for non- waived testing along with the technical educator on the units.
- Communicates any concerns with competency assessment, updates with testing, instrumentation and Quality control reports with each area performing POC testing.
- Continually documents competency assessment in the Corrective Action Log (*located in the POC Supervisor's office*). A RALS review aids in the assessment of operator performance. Operators with multiple errors in patient testing are brought to the attention of area supervisor for retraining/coaching.
- Stores initial competencies for glucometer testing in the POC Training area; all other competencies are located on the unit on which the testing occurs.
- Prepares monthly POC summary for laboratory medical director or other M.D./medical director designee. Summary is reviewed at Pathology Departmental Meeting.
- Calibration verification- Most POCT analyzers are calibrated by the manufacturer and do not allow the user to make adjustments to the calibration however for *moderately complex* testing calibration verification is performed every 6 months, along with patient specimen correlation, if applicable. This calibration is reviewed for acceptability by POC. Note: Calibration verification is the process of verifying

that the amount of analytic measured by the instrument is accurate. Calibration verification is accomplished by measuring a minimum of five solutions with known analytic values. The analytic values span the linear measurable range of values likely to be encountered. Through this process, the AMR (Analytical Measurement Range) is verified. *AMR does not apply to clot based coagulation tests. Procedures for Calibration/verification are located in the POCT Departmental Procedures.* If a test system were to ever fail a calibration the POC Dept. would take the analyzer out of service until it could be resolved with acceptable limits. Patient testing would never occur on an analyzer that failed a calibration. pO2, pH and pCO2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology reference materials.

- Every 6 months correlations to the reference method are performed on non-waived testing devices and reviewed for acceptability.
- Daily RALS Review of each Test System and the results associated with each.
- Constant communication with Lead Techs/Nursing Leads in areas of POCT with follow up documentation in the corrective action log.
- Available to POC testing personnel is an on call Lab Supervisor to address immediate POC problems that may arise when the POC Dept. is not available.

Consequences of Failure to Comply with POCT Quality Assurance Standards:

- The POCT Office will notify the clinical manager/clinical nurse specialist or their designee of noncompliance with QA or other regulatory standards. *Dependent upon the source of non-compliance data, notification will be either immediate, monthly or quarterly. *In response to the notification, the manager of the test site is expected to investigate the situation and report his/her findings to the POCT supervisor in a timely manner (within two weeks of receipt of the notification). Failure to respond to the notification within the specified time frame may ultimately result in the removal of the test system from the test site.*
- Upon removal of a POC test/test system the POCT supervisor will collaborate with the test site's manager, the laboratory medical director, and the POCT Steering Committee to achieve reinstatement of a test system after submission of an action plan.

Provider Performed Testing (PPT)

- For Provider Performed Testing (PPT) there is an initial competency with documentation of review of test procedure and a quiz.
- There are records demonstrating that all providers performing PPT have satisfactorily completed initial training on the performance of waived PPT.
- There are records demonstrating that all providers have satisfactorily completed initial training and that competency was assessed at 6 months for non -waived

PPT (*Provider Performed Microscopy in Labor and Delivery*). This competency includes all 6 elements of competency assessment as follows:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing. This is initially accomplished through a one on one with the POC Dept. One of their peers who have been deemed a trainer assesses all new providers.
2. Monitoring the recording and reporting of test results are accomplished through a log from which audits are conducted monthly.
3. Direct observation of performance of instrument maintenance and function checks.
4. Assessment of test performance through a training module with slides (MTS) and direct observation of testing is performed twice a year at the OB/GYN monthly meeting.
5. Evaluation of problem solving skills

- For PPM (Provider Performed Microscopy), there is a monthly audit to verify the system for reporting results is adequate.
- POC Dept. is responsible for monthly cleaning/maintenance on the microscope in Labor and Delivery. Biomed is responsible for the annual preventive maintenance.

Proficiency Testing

The POC Dept. participates in proficiency testing for all analytes that are performed under the Point of Care Department at PRMC. All Proficiency Testing is received into the Point of Care Department. The POC Dept. then notifies the department in which the testing needs to occur. For those departments, which share testing, the PT event is rotated among departments. The POC Dept. along with the lead tech/Clinical Quality Specialist determine the best time to incorporate the proficiency samples into daily testing, as appropriate. Results are obtained by the staff performing the testing and entered online by the POC Dept. Unacceptable proficiency testing results are brought to the attention of the staff performing the test and the Lead Tech/Clinical Quality Specialist of that area. The unacceptable PT is investigated and reviewed for why the failure occurred and an investigative report is filed with the PT failure (located in the POC Supervisor's office). There is a strict prohibition of inter-laboratory communication regarding Proficiency testing and it does not occur. There is also a strict prohibition of referral or acceptance of Proficiency Testing material from another laboratory. POC uses an alternative performance assessment for eye pH testing. Eye pH proficiency testing is not available from the College of American Pathologists. After the evaluation deadline occurs we perform pH testing on the CAP gastric occult samples which we obtain from the Microbiology Dept. We then compare our results with the printed evaluation from CAP for acceptability.

Health Awareness Testing:

All POC QA/QM measures apply to all Health Awareness testing performed for Peninsula Regional Medical Center. Health Awareness Testing at Peninsula Regional Medical Center is limited to tests that are performed solely for the purposes of screening medical conditions and are not to be used for diagnostic or management of healthcare conditions. Temperature and humidity logs are monitored at each event to ensure temperatures/humidity are within range for testing at each event. Each person who performs testing at a screening event shall test both levels of quality control samples. At the Health Awareness event, the patient tested will be provided their tests results in writing with the appropriate reference range consistent with the current nationally recognized standards. The laboratory providing Health Awareness testing will provide the patient a written explanation of all Health Awareness testing the patient had performed. Our Health Awareness personnel adhere to all pertinent State laws and local ordinances.