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Title: POC GEN QC program

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TITLE: Point of Care Testing Quality Control Program

Purpose: A successful Quality Control program is designed to establish procedures that help identify system errors during the pre-analytical, analytical, and post-analytical steps for all laboratory testing. Optimum patient specimen and result integrity must be ensured throughout these processes. To accomplish this, a QC/QA program must outline specific guidelines, as well as opportunities for on-going improvement.

PRE-ANALYTIC PROCESS: This includes test requests, specimen collection and labeling. Proper patient identification is mandatory to ensure quality patient care. Refer to the policy titled "Criteria For Patient Identification". Collection and handling requirements for all specimens are written in the *Laboratory Service Handbook*. The Point of Care Testing procedure manuals also specify specimen requirement and handling conditions for optimal testing for each procedure. Included is information for patient preparation, specimen collection, stability and storage, compromising physical conditions, and any special handling conditions.

Some Point of Care tests do not require specimen labeling (i.e. glucometer testing). Urine containers and swabs are an exception. Test cassettes and tubes must also be labeled while a test is being performed.

Rejection criteria for POCT specimens:

- Unlabeled urine specimen or swab
- Patient information on specimen label does not match information on accession label or patient chart
- QNS for analysis
- Grossly abnormal results may justify a request for a repeat sample

Specimens unsuitable for testing are to be recollected or cancelled if a new sample cannot be obtained. The reason for cancellation must be documented in LIS or patient chart and the RN or MD notified.

ANALYTICAL PROCESS: This includes testing, review and interpretation. Quality control (QC) is a mandatory component to any Point of Care test. It ensures the medical reliability of each measurement performed on a patient sample by monitoring the performance of an analytical process or instrument. Quality control material is handled in the same manner as a patient sample. Quality Control for Point of Care testing includes the use of treated stabilized human

blood and urine, lyophilized human plasma and electronic QC for the various tests performed in this program. Frequency of running QC is stated in each POC testing procedure. This may include running two levels of controls per 24 hours on each day of patient testing, two levels of controls per 8 hours on each day of patient testing, or two levels of controls on each new test kit when the box is opened before performing any patient testing on that box or to troubleshoot as needed. Expected acceptable ranges are given for each reagent lot number, or test procedure.

When a new lot number of reagent/quality control arrives, the new and old lot numbers are run simultaneously, when applicable and results documented. When applicable, one data point is initiated and then monitored during the first month of use to establish a statistically valid target range by repetitive analysis. If applicable, all areas of POCT use the same lot # of quality control and test reagents for a 6 month period. If there are multiple components of a reagent kit, testing sites use only components from the same kit unless otherwise specified by the manufacturer.

Results that are not within acceptable range will be rerun. If results are still not acceptable for the new lot number, a different vial will be opened and run from the new lot number. If results still fail, the entire shipment will be sequestered and the company called to resolve the issue. The unacceptable lot number of reagents/quality control will be returned to the distributor if necessary. Patient testing will not be performed until both levels of QC fall within acceptable ranges.

QC is reviewed daily by the testing personnel and must be within expected ranges. This is done prior to reporting out any patient results. Investigation by testing staff and/or POC Specialist, to resolve unacceptable QC must be taken before patient results are released. QC results are recorded either electronically or manually on log sheets. The Point of Care Specialist reviews these reports and log sheets. An investigation is made and documented when an analyte(s) is flagged. Any incidence of QC or instrument failure is documented on a corrective action log.

Action steps (any or all may apply)

- Review raw data for clerical errors
- Compare other levels of the same parameter for patterns
- Compare current month's QC data to previous month's reported data
- Review for changes in comparison of data with peer data
- Run previous QC lot# material, if available
- Discuss data with instrument/reagent manufacturer for possible reagent instability
- Consult with Pathologist
- Document review process, and conclusions

Tolerance limits are defined for each applicable test system. Specifics are written in each Point of Care testing procedure defining type of QC used, handling/storage requirements, frequency of use, tolerance limits, corrective action steps, and record/review process.

Positive and Negative controls are used where appropriate.

A reportable range is established for each test program by performing linearity on each analyzer with the use of an external linearity product such as a linearity test kit or other manufacturer material. These products are to be run before a new test/instrument is initiated. This procedure may be performed by the vendor prior to installation of a system. The documentation of the reportable range for all tests may be found in the POC testing procedures. Note: If material is not

available for a test, the upper limit is defined as the highest calibrator for that analyte, and the lower limit, the lowest point that can be accurately measured either by standard or by some other means (example, dilution of a low standard).

In addition to daily quality control checks, proficiency testing samples are utilized three times a year. These samples are incorporated within the routine workload for all shifts, are handled in the same manner as a patient sample, and are rotated among the testing staff. Inter-laboratory communication regarding proficiency testing results, prior to result submission is prohibited. Proficiency testing specimens run in this laboratory are prohibited for referral to another laboratory.
Properly maintained instrumentation is also important for accurate patient testing. Preventative maintenance schedules support well functioning equipment. Maintenance logs are manually or electronically kept.

Instruments that perform the same assay are checked twice a year for calibration agreement and correlation of patient results. The results of the POCT analyzers are also compared to the results of the Laboratory analyzers twice a year for correlation.

POST-ANALYTICAL PROCESS: This includes reporting results and post-test specimen management. An LIS report listing all of the point of care tests resulted in the LIS within the previous day is printed. This report is reviewed by the Point of Care Specialist or designee, for clerical errors, analytical errors/interferences and unusual results. Erroneous or corrected results are investigated and action taken as required. This may include feedback from clinicians or monitoring patient results for unusual patterns.

Manual result log sheets are also reviewed. In the absence of the POC Specialist, the results are reviewed by a technical supervisor or designee. All QC and patient results are kept for a minimum of two years.

Selections for Quality Improvement and Assurance are chosen annually to measure important aspects of patient care. Designed for each of the analytical processes, they measure improvement goals as documented in the *Laboratory Plan of Service*. The Laboratory's QI monitor schedule is reviewed each year, and is amended as warranted.

In the event there is a change in directorship, the new director will ensure that all procedures are well documented and undergo annual review.

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