Point of Care Testing (POCT) Quality Management Policy
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

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Point of Care Testing (POCT) Quality Management Policy
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1. POLICY

1.1. The Clinical Laboratory Quality Management (QM) Program for Point of Care (POC) testing involves a centralized, systematic process for the improvement of testing performance. The program integrates all activities defined in the Clinical Quality Management Plan to deliver effective, optimal patient care.

1.2. The Quality Management program involves ongoing continuous monitors of key indicators to investigate problems throughout the entire method. (pre, post and analytical)

1.3. The Point of Care department has established meaningful criteria, assessments, indicators and control processes to evaluate, monitor and improve the quality of test results.

2. PURPOSE OF DOCUMENT

2.1. The purpose of this document is to establish a written quality program for the Point of Care Department to meet the requirements as specified by CLIA, CAP and JCAHO.

3. SCOPE OF DOCUMENT

3.1. This Point of Care Quality Program applies to all Point of Care testing CLIA sites, testing personnel, and tests. The Point of Care program coordinates with the Clinical Laboratory Quality Management program.

4. RESPONSIBILITY

4.1. The Laboratory Medical Director or designee who meets the CAP qualifications determines the criteria, limitations and frequency for each test.
- 4.1.1. Proficiency testing
- 4.1.2. Quality Control
- 4.1.3. Quality assessments with Blind samples
- 4.1.4. Correlation studies (Comparability)
- 4.1.5. Quality Indicator reports
- 4.1.6. Discrepant results, Errors and Corrective action follow up
- 4.1.7. Method Verification for each test

4.2. The Point of Care department / Laboratory Compliance prepare samples for quality assessments, correlations and linearity's. The samples must meet acceptable specimen criteria for each test.

4.3. The POC team notifies the CLIA/CAP sites involved in the quality assessment. They distribute the samples and process the data accrued during testing.

4.4. The POC team distributes changes in policies and procedures during annual competency assessments, "What's Up In Nursing", mass emails, CBLs, PowerPoints and POC meetings with the testing location.

4.5. The POC team manages the following quality indicators;
- 4.5.1. Quality Indicator Report for each CLIA POC site.
- 4.5.2. Biannual Correlation studies and summary reports: Avox, Creatinine, INR, ACT-LR, ACT +, Blood Gas, EPOC, Piccolo, ROTEM, and Clinitek Status.
- 4.5.3. Quarterly correlation studies for Glucose.
- 4.5.4. Biannual Linearity studies and Summary reports: Avox, Creatinine, Blood Gas analyzers, Piccolo and EPOC.
- 4.5.5. Daily QC and Patient result review
- 4.5.6. Monthly QC summary reports
- 4.5.7. Monthly testing personnel sample errors and rejected samples.
- 4.5.8. Monthly Rounding reports (including: Reagent Labeling)
- 4.5.9. Review of Monthly Maintenance logs
- 4.5.10. Data analysis, establishing and performing corrective action plans
- 4.5.11. Method performance evaluation reports on repaired instruments

5. DEFINITIONS:

5.1. Also refer to the current CAP Checklist for a more comprehensive list of definitions

5.2. Proficiency testing – a program in which specimens of unknown sample material are periodically sent to members of a group of laboratories for analysis, with each laboratory's results compared with those of its peers

5.3. Correlation/Comparability - Monitoring the agreement between patient results obtained for an analyte using the Point of Care device and a laboratory analyzer. The number and acceptable criteria is determined by the Medical director or designee who meets the CAP qualifications for each test. A range of values are used to assess the devices upper and lower limits or around clinical decision point. EP Evaluator comparison program can help assess the data.

5.4. Calibration- The set of operations that establish, under specified conditions, the relations between reagent system/instrument response and the corresponding concentration. Activity values of an analyte.

5.5. Linearity/Calibration verification -The process to confirm that an assay system continues to correctly recover the concentration or activity of the analyte over the AMR

5.6. Quality Assessment - Mechanism used to mimic the PT process of utilizing a previously analyzed specimen for reviewing laboratory processes

5.7. Biannual - Twice a year

6. QUALITY MECHANISMS

6.1. Quality Control
- 6.1.1. Quality control is performed and documented per each manufactures' guidelines.
- 6.1.2. Quality control is performed in the same manner as patient specimens and by testing personnel.
- 6.1.3. Quality control is reviewed for acceptability by testing personnel before patient results are reported.
- 6.1.4. Quality control is monitored daily by the POC coordinators in Telcor/QML, if applicable.
- 6.1.5. Corrective action is documented and patient results reviewed.
- 6.1.6. The manager and division director, or designee, review quality control reports monthly.
- 6.1.7. Each new lot of quality control for moderate complex testing is verified by the point of care coordinators by testing before use.
- 6.1.8. All unacceptable quality control is reviewed.
- 6.1.9. All quality control results exceeding 3 SD are excluded from the data summary report.
- 6.1.10. Data is stored on the L Drive.
- 6.1.11. Monthly Quality control report to include:
  - 6.1.11.1. Number of instruments, analytes.
  - 6.1.11.2. Define acceptable quality control criteria.
  - 6.1.11.3. New lot of QC or reagent acceptability confirmation criteria.
  - 6.1.11.4. A summary of unacceptable errors is included in the monthly report.
  - 6.1.11.5. Internal and External quality control data

6.2. IQCP -Individual Quality Control Plan
- 6.2.1. Point of Care instruments with an IQCP; East –Avox & Signature Elite (ACT).
  UH-ROTEM, Avox, Signature Elite (ACT&INR)
  CPE, MMH Pulmonology/ RT-Siemens 500.
- 6.2.2. The IQCP has three required areas: Risk Assessment, Quality Control Plan, and Quality Control Assessment Monitoring.
- 6.2.3. The Risk Assessment:

6.2.3.1. A process to identify the sources of potential failures and errors, QC study and historical data review
6.2.3.2. The Risk Assessment includes pre-analytical, analytical and post-analytical phases of each test
6.2.4. The Quality Control Plan:
6.2.4.1. Defines all aspects monitored based on the potential errors identified in the risk assessment phase.
6.2.5. Quality Control Assessment Monitoring:
6.2.5.1. The POC department performs ongoing monitoring of the quality assessments, see monthly reports.
6.2.5.2. If problems are identified, evaluation of corrective action is performed, the IQCP will be re-assessed.
6.2.5.3. If there are any changes in the pre-analytical, analytical or post analytical phases of the test, the IQCP will be re-assessed.

6.3. Linearity/Calibration Verification
6.3.1. The manufacturer's approved materials used for calibration verification include low, midpoint, and high values that are near the AMR.
6.3.2. Refer to the Lab Admin Policy Method Performance Verification and specific POCT documents for guidelines and criteria for linearity/calibration verification studies.
6.3.3. Linearity/Calibration Verification is performed on applicable instruments every 6 months: Avox, Creatinine, Epoc, ABL90 and Piccolo. No outliers may exist and must be investigated (see below). The outlier must be removed from the calculation of the linearity curve.
6.3.4. If any level fails, troubleshoot and repeat testing.
6.3.4.1. Obtain another linearity kit and repeat this process with fresh solutions.
6.3.4.2. Before repeating any linearity, troubleshoot the cause of the outliers and follow these steps:
6.3.4.2.1. Verify ranges listed with each kit of linearity.
6.3.4.2.2. Make sure the correct level is being tested and matches the level on the analyzer.
6.3.4.2.3. Ensure that the linearity ranges entered onto the statistical graph match the linearity kit ranges or master test list technical range.
6.3.4.2.4. Make sure that the linearity kit has not expired.
6.3.4.2.5. Ensure no bubbles were present.
6.3.4.2.6. Ensure sufficient sample volume was used.
6.3.4.2.7. Repeat linearity using a fresh kit.
6.3.4.2.8. If linearity data points are unacceptable upon repeated testing, remove the instrument from service.
6.3.4.2.9. Acceptable values are listed in the package insert.
6.3.5. Data is stored on the L Drive.

6.4. Calibration
6.4.1. Calibrations follow manufacturer's instructions
6.4.1.1. Blood Gases: See specific procedure for frequency and material.

6.5. Quality Assessment (blind sample)
6.5.1. A previously analyzed specimen is given to a testing employee and results are compared for acceptability.
6.5.2. Performed on waived testing in locations where primary instrument already exists. See Table below.

6.6. Proficiency Testing
6.6.1. Proficiency testing is performed on primary instruments/methods. Refer to Lab Admin Policy Proficiency Testing for guidelines and regulatory standards.
6.6.2. See Table below "Proficiency Testing"

6.7. Correlation
6.7.1. If more than one non-waived instrument exists for tests, the instruments are correlated to the primary location biannually. Refer to the Lab Admin Policy Method Performance Verification for guidelines and criteria for correlation.
6.7.2. Correlation studies are performed as a method of quality assessment.
6.7.3. Correlation Criteria:

6.7.3.1. Criteria for acceptability are method dependent and medical directors or designee who meets the CAP qualifications will determine what is considered acceptable. As a general rule the following statistics are generally met: Slope = 0.80-1.20, r = > 0.90, and total allowable error. The acceptable criteria are documented on the data summary report.
6.7.3.2. If the data summary is unacceptable, troubleshooting and repeat testing must be performed.
6.7.3.3. If the correlation continues to be unacceptable, contact technical support.
6.7.4. Data analysis:
6.7.4.1. The data is reviewed for identifiable, procedural, analytical, clerical and specimen handling errors.
6.7.4.2. Discrepant results and outliers are investigated.
6.7.4.3. Sample Rejection Criteria
6.7.4.3.1. Specimens may be rejected due to specimen integrity issues.
6.7.4.3.2. If a specimen is rejected for a single analyte for test systems with multiple analytes, the sample must be rejected for all the analytes.
6.7.5. The manager and division director reviews the correlation report.
6.7.6. A summary of unacceptable errors is included in the report.
6.7.7. The correlation raw data is stored on the L Drive.

6.8. Communication
6.8.1. The point of care staff round at each moderate complex outpatient site quarterly. This is tracked on a monthly schedule and documented on rounding forms.
6.8.2. The point of care staff round to the moderate complex testing sites at UH Main/ East on a rotating schedule. Each site is rounded at least annually.
6.8.3. The point of care manager also rounds with nursing managers as needed, as well as leaders of other testing locations.
6.8.4. Testing locations submit issues to the Point of Care email address path.glucose@osumc.edu.

6.9. Education
6.9.1. The point of care department develops yearly competency assessments.
6.9.2. The department also assists with training / education days as needed.
6.9.3. Point of care employees are required to take yearly continuing education.
6.9.4. Point of care employees look for educational opportunities, especially with POCT instrumentation.
6.9.5. The Point of Care department works with nursing education to develop and distribute education.

6.10. Temperature Monitoring
6.10.1. Refrigerator and room temperatures are recorded on each day of testing. The thermometer records the minimum and maximum temperatures.
6.10.2. If temperatures are out of range corrective action is taken, reagents are moved to a location with appropriate temperature monitoring, if needed.
6.10.3. If the minimum and or maximum temperatures are out of range, corrective action is taken; the reagents are discarded, if needed.
6.10.4. All thermometers must be replaced before expiration of the calibration.

7. POINT OF CARE QUALITY DOCUMENTATION:

7.1. Quality Indicator Report
7.1.1. Reports are completed monthly or quarterly and reviewed by the medical director. All unacceptable results are reviewed and corrective action documented.
7.1.2. Indicators: Pre-analytical, analytical and post-analytical phases of testing are monitored.
7.1.3. Quality Indicators are reviewed annually and evaluated for effectiveness.

7.2. OSUWMC Scorecard
7.2.1. Process: Point of Care Testing Manager and/or Coordinators complete the scorecard.

7.2.2. The data is shared with the CSR Steering committees for the James, OSUMC nurse managers CNS, and directors, radiology directors, nursing quality webpage and on the nursing share point site.
7.2.3. Indicators: Glucose critical result notification documentation, glucose quality control remedial action documentation, reagent handling, rounding, glucose sample errors and rejected samples.

7.3. Monthly Survey Readiness
7.3.1. Process: Evaluate a specific POC test for adherence to specific CAP guidelines.
7.3.2. Indicators to include: reference range verification, quality control documentation, patient identification, documentation of personnel training and education, instrument function checks, accuracy of procedure/process, and documentation in medical record.
7.3.3. Personnel file audits
7.3.3.1. POC audits testing personnel files for diplomas and documentation of initial training and competency.

7.4. Error detection and result review
7.4.1. All INR results >3.0 are reviewed to ensure repeat testing or a lab draw specimen confirmed the result.
7.4.2. The POC department performs an EMR review for POC/Lab GFR value that spans a GFR at 40; the clinical decision point.
7.4.3. The POC middleware exception que is monitored for unusual results and clerical errors.

7.5 Quality Action plans for testing unit
7.5.1 The POC department works with testing locations to develop corrective action plans and improve processes to be compliant with laboratory regulations.

8. QUALITY ASSESSMENT (QA) TABLES

8.1. Summary for quality assessment samples for Waived Testing

8.1.1. For QA sample types that differ from patient sample types, the testing personnel are given instructions on sample processing.

Test	Quality Assessment Samples	Manufacturer	Location of Instruments/Kits
Urine hCG	2	Alere	UH, East, Morehouse, CPE Radiology and Stefanie Spielman Comprehensive Breast Center (SSCBC)
Whole blood glucose (WBG)	3	Nova	UH, East, James, Morehouse, CPE, CPG, CPLC, Stoneridge II, SSCBC
Hemocue Hgb	2	HemoCue	UH
DCA Vantage	2	Siemens	UH/BSH

8.2. Summary for Proficiency Testing for Point of Care:

8.2.1. For PT sample types that differ from patient sample types, the testing personnel are given instructions on sample processing.
8.2.2. Testing personnel and POC coordinator must sign the green sticker on the survey to indicate the instructions have been reviewed.

Test	Instrument Name	Survey Name	Locations	Primary Instrument/kit
ROTEM	ROTEM	CAP-TEG	Ross OR, Perfusion	ROTEM SN 2605,
ACT+	Hemochron Signature Elite	CAP-CT3	UH – Ross OR, Perfusion	Loaner: SE7640
ACT-LR	Hemochron Signature Elite	CAP-CT2	UH – all locations other than Ross OR	Loaner: SE7640
ACT-LR	Hemochron Signature Elite	CAP-CT2	East – Cath Labs	SE7394
Whole Blood Creatinine	Nova StatSensor	CAP-WBCR	Imaging -Gahanna, Lewis Center, Stoneridge II and CPE	One instrument at Gahanna, Lewis Center and Stoneridge II CPE : CPE #2 meter is primary
hCG, Urine, waived	Kit –Alere Urine	CAP-CM UhCG	PT performed at: Imaging Gahanna, Lewis Center, Stoneridge II	Kit testing
pH, pCO_2, pO_2,	Siemens 500	CAP-AQ	Respiratory Therapy-CarePoint East, MMH	1 instrument at each location
Rapid Malaria Ag	BinaxNow kit	RAML	UH	Kit testing

9. **Correlation studies: Quality Mechanism**
   9.1. EP evaluator or other OSU approved correlation templates are used to help assess data and calculate statistics on applicable studies.
   9.2. See Quality Mechanism, correlation section for correlation guidelines; acceptable /reportable criteria

   9.3. **Avoximeter East (3 units) and Ross (7 units)** -O2 Saturation and Hgb
      9.3.1. O2 Saturation and Hgb are performed on the Avoximeter 1000E and are correlated biannually with the blood gas instrument.
      9.3.2. East-10 patient samples are run on each of the 3 Avoximeters and the blood gas instrument in Respiratory Therapy at East.
      9.3.3. UH Ross-10 patient samples are run on each of the 7 Avoximeters and the blood gas instrument in CCL.
      9.3.4. Analytes correlated are Hgb and O2 saturation.
      9.3.5. Patient samples must be processed immediately due to specimen stability.

   9.4. **Nova StatSensor** – Creatinine
      9.4.1. Meters are correlated to the primary site:
         9.4.1.1. 2 meters at East are correlated biannually against the chemistry instrument in the Rapid Response Lab, 5 patient samples each.
         9.4.1.2. 13 meters at UH are correlated biannually against the chemistry instrument in the Critical Care Laboratory, 5 patient samples each.
         9.4.1.3. 2 meters at SSCBC are correlated biannually against the chemistry instrument in the SSCBC lab, 5 patient samples each.
         9.4.1.4. 2 meters at Martha Morehouse is correlated biannually against the chemistry instrument at the MMMP laboratory, 5 patient samples each.

9.4.1.5. 1 meter at CarePoint Lewis Center is correlated biannually against the chemistry instrument in the Critical Care Laboratory or Rapid Response Laboratory, 5 patient samples each.
9.4.1.6. 1 meter at CarePoint Gahanna Center is correlated biannually against the chemistry instrument in the Critical Care Laboratory or Rapid Response Laboratory, 5 patient samples each.
9.4.1.7. 1 meter at Stoneridge is correlated biannually against the chemistry instrument in the Critical Care Laboratory or Rapid Response Laboratory, 5 patient samples.
9.4.1.8. 2 meters at CarePoint East are correlated biannually against the chemistry instrument in the Critical Care Laboratory or Rapid Response Laboratory, 5 patient samples each.

9.5. **ABL90** Blood gas analyzers are correlated biannually against the blood gas instrument in CCL.
9.5.1. **James OR/PACU/Ross Perfusion ABL90**
9.5.1.1. 20 patient samples are run on each of the analyzers and the blood gas instrument in CCL.
9.5.1.2. The analytes correlated are pH, PO2, PCO2, Hbg, O2 Sat, Sodium, Potassium, Glucose, Ionized calcium, and Lactate

9.6. **Hemochron Signature Elite** -INR testing is correlated biannually.
9.6.1. 10-15 patient samples are correlated against the coagulation instrumentation in CCL

9.7. **Hemochron Signature Elite** -ACT testing is correlated biannually
9.7.1. CAP 3 cross check samples and 2 levels of quality control are used to perform biannual correlations.

9.8. **Nova StatStrip-** Glucose
9.8.1.1. Quality control data stored in Telcor is retrieved quarterly to evaluate one week of data points throughout the OSUMC system. Data is partitioned by quality control lot number for each level with the most data points across multiple meters and locations being selected for evaluation of mean, SD and for director approved TAe. Each quarter the distribution of meters within a given lot will change across the system allowing for a dynamic comparison of different devices.
9.8.1.2. Values above 3SD are documented, but excluded from the data analysis.
9.8.1.3. Acceptability is determined and reviewed by the manufactures' package insert, manager and division director.
9.8.1.4. CAP cross check samples are analyzed on 30 glucometers twice a year. The CAP cross check samples are submitted to CAP for peer analysis.

9.9. **Epoc UH**
9.9.1. **20** patient samples are correlated biannually; UH EPOC with UH Critical Care Laboratory
9.9.2. Analytes performed on each Epoc are pH, PO2, PCO2, O2 saturation, Sodium, Potassium, Glucose, lactate, bicarb, creatinine, Hgb and Iodized Calcium.

9.10. **Piccolo**
9.10.1. 10 patient samples are correlated biannually against the chemistry instrument in the Critical Care Laboratory
9.10.2. Analytes performed on the Piccolo are ALB, BUN, CA, CL, GLU, K+, LAC, MG, NA, PHOS.

9.11. **Clinitek Urinalysis**
9.11.1. 2 samples are correlated biannually; 2 Cliniteks in the James 300 GU Clinic and Neuro Clinic, with the UH Critical Care Laboratory Clinitek.

9.12. **ROTEM**
9.12.1. 10 patient samples are correlated biannually; 2 ROTEM instruments in Ross OR Perfusion.

10. **REFERENCE DOCUMENTS**

10.1. College of American Pathologist, accreditation program, regulations. 2015

11. **RELATED DOCUMENTS**
    11.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms