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Point of Care Testing Policy

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. Point of Care (POC) laboratory testing refers to analytical patient testing performed outside the physical facilities of the clinical laboratory, at or near the bedside by non-laboratory staff to improve or facilitate patient care. POC testing may be performed under the Clinical Laboratory Improvement Amendment (CLIA) license held by the laboratory and/or an external CLIA license for limited services provided outside of a hospital. The POC laboratory is responsible for oversight of POC testing performed at each site listed under its site-specific CLIA license(s). This document is only applicable to areas that are approved for testing under one one of the laboratory's CLIA certificates.

B. Point of Care Testing involves the quality processes of producing and managing analytical test systems which provide rapid delivery of patient results for immediate clinical use. CLIA determines regulatory requirements for the POC tests based on their respective categories of waived or moderate complexity (non-waived).

C. Not all items/instruments in this policy will apply at each testing site. See site-specific testing menu to determine applicability.

II. POLICY STATEMENT:

A. POC testing procedures must meet testing requirements as defined by the Clinical Laboratory Improvement Amendment of 1988 (CLIA 88), the College of American Pathologists (CAP), Centers for Medicare & Medicaid Services (CMS), and The Joint Commission (TJC).

III. APPROVAL FOR POC TESTING:

A. Prior to the purchase of test systems, the Medical Director, Manager, or designee of any

department or nursing unit may petition to perform POC laboratory testing through the Point of Care Testing Approval Process. The department, or clinical unit, petitioning will agree to follow regulatory requirements for POC testing pertaining to (but not limited to):

1. Patient testing procedures
2. Labeling and storage of test reagents
3. Instrument operation and maintenance
4. Quality control (QC) testing at the frequency outlined in the procedure
5. Documentation of personnel qualifications
6. Training and competency assessment at defined intervals of all personnel performing the test
7. Proficiency testing

B. Only test systems that are Food & Drug Administration (FDA) approved/cleared will be considered.

C. Requests are reviewed at the monthly POC Best Practice Committee meetings.

D. The System Medical Director of POC will review and provide final approval or denial of all requests.

E. If a request is approved, the site-specific POC department(s) will coordinate instrument/test validation, test procedures, training, competency assessment, proficiency testing, and on-going quality assurance (QA) measures.

F. POC testing should only be performed on patients with an appropriate written or electronic order from an authorized person.

1. Note: In extenuating circumstances, a POC glucose may be performed on a non-patient (i.e. visitor, ill employee) if the individual is experiencing symptoms that correlate with a critical glucose value. The test will be performed using a provisional barcode (999999999) for the patient ID so that POC personnel may later enter the result into the chart, should the individual be admitted. In an emergency situation, a written or electronic order from an authorized requester is still required and must be completed in Epic.

IV. DELEGATION OF RESPONSIBILITIES:

A. The System POC Medical Director is responsible for all aspects of POC laboratory operations and administration. The medical and technical responsibilities of POC may be delegated to other qualified personnel, as appropriate, but the Medical Director remains responsible for the overall operation and administration of the POC department to assure that quality patient services are provided. According to the CLIA personnel categories, the following individuals have been delegated the following specific responsibilities in addition to the responsibilities outlined in the CLIA personnel category:

1. System POC Medical Director has the responsibility for POC testing including but not limited to the approval of new testing methods/equipment, establishment or verification of laboratory test performance specifications, approval of lab bulletins and lab test directory (LTD) entries, procedures, proficiency testing, quality

assurance, clinical expertise, and guidance/consultation.

2. Site-specific Laboratory Medical Directors oversee the site-specific CLIA license(s) and have the responsibility for POC testing under that license, including but not limited to the approval of new testing methods/equipment, approval of lab bulletins/ LTD entries, procedures, review of report content and format, proficiency testing, quality assurance, clinical expertise, and guidance/consultation.
3. System POC Technical Director/Clinical Consultant has the responsibility of approval of new testing methods/equipment, establishment or verification of laboratory test performance specifications, approval of lab bulletins/LTD entries, procedures, review of report content and format, Individualized Quality Control Plan (IQCP) policies, quality assurance, clinical expertise, and guidance/consultation.
4. System POC Manager chairs the POC Best Practice Committee and manages POC testing on a system level. Responsible for troubleshooting and managing repairs, training and competency assessment, daily result review, monitoring the POC databases, assisting with validation studies, reviewing and approving validations for additional/replacement waived instruments (initial validations must be approved by a MD), verifying that the quality control (QC) is performed at set frequencies, reviewing monthly QC/maintenance logs and other forms as designated in approval section of the form, writing/revising and reviewing POC policies, procedures, lab bulletins, and LTD entries, submitting proficiency testing (PT) survey results including evaluation reports, alternate PT assessment and corrective action, monitoring staff certification in POC databases including following up with management and testing personnel regarding deviations, other duties that comprise the POC quality assurance program, scheduling and maintaining compliance with regulatory and accreditation requirements. The Manager will conduct annual performance reviews of staff.
5. Lab Managers are responsible for troubleshooting and managing repairs, training and competency assessment, daily result review, monitoring the POC databases, assisting with validation studies, reviewing and approving validations for additional/ replacement waived instruments (initial validations must be approved by a MD), verifying that the QC is performed at set frequencies, reviewing monthly QC/ maintenance logs and other forms as designated in approval section of the form, writing/revising and reviewing policies, procedures, lab bulletins, and LTD entries, submitting PT survey results including evaluation reports, alternate PT assessment and corrective action, monitoring staff certification in POC database including following up with management and testing personnel regarding deviations, other duties that comprise the POC quality assurance program, scheduling, and maintaining compliance with regulatory and accreditation requirements. Responsibilities also include assignment and performance of function checks such as patient comparisons, calibration verification checks, and various maintenance functions as applicable for the POC instruments/methods.
6. POC Supervisors are responsible for troubleshooting and managing repairs, training and competency assessment, daily result review, monitoring the POC databases, assisting with validation studies, reviewing and approving validations for additional/ replacement waived instruments (initial validations must be approved by a MD),

verifying that the QC is performed at set frequencies, reviewing monthly QC/ maintenance logs and other forms as designated in approval section of the form, writing/revising and reviewing policies, procedures, lab bulletins, and LTD entries, submitting PT survey results including evaluation reports, alternate PT assessment and corrective action, monitoring staff certification in POC database including following up with management and testing personnel regarding deviations, other duties that comprise the POC quality assurance program, scheduling, and maintaining compliance with regulatory and accreditation requirements. Responsibilities also include assignment and performance of function checks such as patient comparisons, calibration verification checks, and various maintenance functions as applicable for the POC instruments/methods. The Supervisor will conduct annual performance reviews of staff.

7. Lead Medical Technologists are responsible for troubleshooting and managing repairs, training and competency assessment, daily result review, monitoring the POC databases, assisting with validation studies, verifying that QC is performed at set frequencies, reviewing monthly QC/maintenance logs and other forms as designated in approval section of the form, writing/revising and reviewing policies and procedures, submitting PT survey results including evaluation reports, alternate PT assessment and corrective action, monitoring staff certification in POC database including following up with management and testing personnel regarding deviations, and other duties that comprise the POC quality assurance program. Lead Medical Technologist staff also have the responsibility of verifying proper staffing for the department, scheduling, and verifying compliance with regulatory and accreditation requirements. Responsibilities also include assignment and performance of function checks such as patient comparisons, calibration verification checks, and various maintenance functions as applicable for the POC instruments/methods.
8. Medical Technologists are responsible for troubleshooting and managing repairs, training and competency assessment, daily result review, monitoring the POC database, assisting with validation studies, verifying that QC is performed at set frequencies, reviewing monthly QC/maintenance logs and other forms as designated in approval section of the form, writing/revising and reviewing policies and procedures, submitting PT survey results including evaluation reports, alternate PT assessment and corrective action, monitoring staff certification in POC database including following up with management and testing personnel regarding deviations, and other duties that comprise the POC quality assurance program. Medical Technologist staff assist in verifying compliance with regulatory and accreditation requirements. Responsibilities also include assignment and performance of function checks such as patient comparisons, calibration verification checks, and various maintenance functions as applicable for the POC instruments/methods.
9. Additional laboratory staff, such as Medical Directors, Technical Directors, Managers, quality team, Infectious Disease, and safety department, may be consulted in their area of expertise, as needed.
10. Testing areas authorized to perform POC testing have a designated on-site supervisor to assist and monitor testing personnel during the hours that patient testing is performed. Supervisors are responsible for verifying that testing personnel carry out their duties as required and address any issues with testing personnel that

are recognized by the POC department. POC recognizes the Manager, Assistant Manager, Clinical Specialists, shift supervisors, or the in-charge designee as the responsible on-site supervisor.

B. See the Laboratory Director Operation and Administration Delegated Responsibility Policy for more information.

V. TEST METHOD IMPLEMENTATION:

A. The System Medical Director of POC testing approves POC test systems before implementation. Prior to reporting patient results from POC devices, validation of manufacturer's performance specifications must be performed, documented, and retained on file for the life of each test method and at least 2 years after discontinuation of testing.

B. The Biomedical department performs electronic, mechanical, and operational checks prior to implementation.

C. Validation studies for waived testing will include quality control testing and other validation steps as requested by POC Medical or Technical Directors. Additionally, calibration verification may be performed when calibration materials are commercially available.

D. Validation studies for non-waived instruments/kits will include accuracy, precision, reportable range, and reference range studies.

1. Method comparison between the POC method and the corresponding clinical laboratory method, if within acceptable limits, establishes analytical accuracy and allows the use of laboratory-established reference ranges. For FDA approved methods, which are the only methods approved for testing at the POC, data provided by the manufacturer may be used for specificity assessment information which documents interfering substances. Any interferences and necessary interventions will be listed in each individual procedure. For non-waived devices with internal/electronic QC, validation studies must include studies of internal and external quality controls. When there are multiple identical devices, the POC Medical Director will determine the extent of the validation studies for all devices while verifying performance specifications for each instrument or device. Correlation results are subjected to statistical analysis using linear regression analysis. Results are graphed with the evaluation method on the y axis versus the reference method on the x axis. Proportional bias may be estimated from the slope of the line and constant bias, from the intercept. A general guide for acceptability of the correlation coefficient R is that R squared should not be less than 0.85 (R=0.92). R depends greatly on the range of the data, however, and in some cases a lower value may still be acceptable. Medical and Technical Directors are consulted to determine if it is necessary to add additional samples to firmly establish the relationship between the two methods. Accuracy may be further assessed by running QC, standards of a known concentration, left over proficiency testing specimens, vendor-approved material or surrogate material approved by a Pathologist or Technical Director. Results are assessed by Medical or Technical Director who evaluate whether accuracy is acceptable within allowable error. Exceptions may occur in cases where very low levels of the analyte are measured.

2. Allowable error for a given analyte may be used as a guideline for determining the

acceptability of method comparisons between a POC method and main lab method, comparison between POC instruments of the same model, linearity and analytical measuring range verification, lot-to-lot evaluation of reagents and reagent cartridges, and carryover studies. Medical or Technical Directors evaluate allowable error guidelines as needed and should be consulted when these values are exceeded in the quality assurance studies. These guidelines are not to be used for QC ranges. Current allowable error limits for non-waived methods are given below:

a. pH +/- 0.04
b. pCO_2 (partial pressure of carbon dioxide) +/- 8% or 5 mmHg
c. pO_2 (partial pressure of oxygen) +/- 8% or 4 mmHg
d. Hemoglobin +/- 4% or 0.5 g/dL
e. Hematocrit +/- 4%
f. O2Hb (% oxyhemoglobin) +/- 3 percent units
g. COHb (% carboxyhemoglobin) +/- 3 percent units
h. MetHb (% methemoglobin) +/- 2 percent units
i. Na+ (sodium) +/- 4 mmol/L
j. K+ (potassium) +/- 0.3 mmol/L
k. Cl- (chloride) +/- 5% or 4 mmol/L
l. Ca++ (ionized calcium) +/- 4% or 0.4 mg/dL
m. Glucose +/- 8% or 6 mg/dL
n. Lactic Acid +/- 7% or 0.4 mmol/L
o. Bilirubin +/- 20% or 0.4 mg/dL
p. HCO_3 (bicarbonate) +/- 20% or 4 mmol/L
q. BUN (blood urea nitrogen) +/- 9% or 2 mg/dL
r. Creatinine +/- 10% or 0.2 mg/dL
s. INR (international normalized ratio) +/- 15%
t. Albumin +/- 8%
u. ALP (alkaline phosphatase) +/- 20% or 10 U/L
v. ALT (alanine aminotransferase) +/- 15% or 6 U/L
w. AST (aspartate aminotransferase) +/- 15% or 6 U/L
x. Total Protein +/- 8% or 0.4 g/dL

3. Precision is established by repeat measurement of QC material for both within-run and between-run time frames, as directed by Medical or Technical Director. Methods that require an IQCP will need additional QC testing to gather data sufficient to justify the intended time frame between external QC testing, as outlined in the approved IQCP for a given test system.
4. Reportable range is established by linearity/calibration verification consistent with

literature from the vendor. The range of the linearity of the method establishes the analytical measurement range (AMR) of the procedure using commercial standards, QC material, or material that is approved by the Pathologist or Technical Director. Linearity data is plotted as observed with the y axis versus the expected x axis. Points which deviate more than 10% from the expected value should be considered by the Medical or Technical Director for each analyte and the expected value for the material tested. AMR is defined and approved by the Pathologist or Technical Director according to clinical standards.

5. Validation data is reviewed and signed by the POC Medical Director, Technical Director, and/or site-specific Medical Director prior to test implementation.
6. Reference intervals are verified by transference for POC methods that correlate with tests performed in the laboratory. Reference intervals from the manufacturer or from the literature may also be verified by using samples from at least 20 individuals that meet criteria for a reference sample population.

E. Validation data is to be made available to clients in POC testing areas upon request. The information provided may, include, where applicable, a summary of analytical performance specifications, analytical accuracy, precision, analytical sensitivity, test method interferences, reference interval, and reportable ranges. Clients must treat data as confidential.

F. Test validation documentation is maintained in the site-specific POC department for the life of the instrument/test plus 2 years.

G. Interfaces are verified to confirm that results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to the electronic health record (EHR). Verification is performed prior to implementation of an interface and whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results. All interface validation studies should review all applicable report elements such as individual results, group results, units of measure, reference intervals, abnormal flags, and comments.

VI. INTERMITTENT TESTING:

A. If tests are taken out of production or testing is suspended, evaluation is required before resuming patient testing. This does not apply to situations where testing is not performed due to a short-term situation such as testing supply availability issues or instrument down-times.

1. Intermittent testing is subjected to a method performance verification within 30 days prior to restarting patient testing.
2. Proficiency testing or an alternate assessment will be performed within 30 days prior to resuming patient testing.
3. Competency assessment will be performed for operators within 12 months prior to restarting patient testing.

VII. EQUIPMENT:

A. Equipment managed by POC must have documentation of activity/problems for the life of the device in the POC data management system Telcor QML (QML) or equipment log.

B. The Biomedical Engineering department performs electrical, mechanical, and operational

checks prior to implementation. They also troubleshoot and perform minimal repair on equipment upon request.

C. POC staff review manufacturer's recommendations and establish, if applicable, procedures for documentation of maintenance or function checks. Maintenance and function checks are assessed by POC staff and reviewed monthly. Ongoing instrument function checks or maintenance are documented in QML or on equipment logs, the monthly QC logs, or site-specific task checklists, as applicable.

D. Instruments must be returned to the manufacturer for either repair or replacement if QC results are not in range and cannot be linked to defective reagents, if linearity or calibration verification fails, if patient comparisons with main lab are not within acceptable limits, if instruments malfunction, or if error codes appear that cannot be resolved.

E. Non-waived devices that undergo repair or replacement of critical components of the instrument should be verified by QC testing and calibration verification prior to resuming patient testing. Instrument comparisons may be performed in place of calibration verification for non-waived devices for which no calibration verification material is commercially available (e.g., Hemochron Signature Elite and GEM Hemochron 100 where 2-3 patient comparisons are performed on each approved cuvette/cartridge type after major maintenance). Instruments that use probes (e.g., ABL80, ABL90) must undergo a carryover study after major maintenance or repair.

F. Loaner instruments will be distributed, if available, while a primary instrument is out of service for maintenance and/or repair.

G. POC instruments/test kits must not be moved between units and/or CLIA sites without the written permission of POC staff. Should an instrument relocation be approved by POC, validation studies may be needed prior to permitting use for patient testing.

VIII. MANUFACTURER'S INSTRUCTIONS AND NOTIFICATIONS:

A. Manufacturers' recommendations for handling and storing reagents, performance of QC (both internal and external), and patient testing are adhered to for all POC tests. POC staff are responsible for reviewing the operating manual and package inserts for reagents, QC, linearity, and calibration verification material. If revisions are noted, the current revision is reviewed to confirm manufacturers' instructions are followed and procedures are updated accordingly. Current instructions are retained with one prior version.

B. If a manufacturer issues a recall or notification regarding reagents, supplies, instruments, equipment or software, the POC staff will review the notification upon receipt and determine what actions are needed.

IX. PROCEDURE MANUALS:

A. Procedure manuals are written by POC staff and are derived from manufacturer's instructions, operator manuals, vendor training session recommendations, package inserts, along with any site-specific instructions without deviating from manufacturer's recommendations. Guidelines from the College of American Pathologists (CAP) checklists will be followed, including initial

date of use documentation. The POC Medical Director and/or site Medical Director reviews and approves all new policies and procedures before implementation and at least biennially thereafter. Procedure manuals will be reviewed when there is a change in directorship within a reasonable time and when substantial changes are made to the policy, procedure, or methodology. Minor changes to the policy or procedure, not affecting patient testing procedure, are conveyed to testing personnel by e-mail communication to department management and unit trainers. Updates to clinicians regarding changes in the analytic methodology and updates that impact workflow will take place via laboratory bulletins. If education or re-training is necessary, POC staff will coordinate with unit management and education staff to determine the method of education/re-training and the schedule to do so.

B. Electronic procedure manuals for POC tests are available on the laboratory shared network drive, the Corewell Health intranet, and Corewell Health's corporate document control system. Testing personnel review new and revised POC procedures on the approved corporate document control system, and this review is documented on their POC competency assessment forms. If the shared network drive and/or employee website are down, printed copies of the procedures may be found in each POC laboratory.

C. All electronic and paper copies of procedure manuals are subject to document control and will be updated accordingly to reflect revisions and biennial reviews. Previous revisions must be archived. Retired procedures are marked with the retirement date and are retained by POC for a minimum of 2 years after discontinuation.

D. Biennial procedure review includes but is not limited to reviewing operator manuals and package inserts from all products, updating electronic and printed procedures, reviewing and updating if necessary reference and critical ranges in the laboratory information system (LIS), and printing LIS screens as a record of interface validations. The site Medical Director/ designee will review and sign the EHR patient reports for content acceptability.

X. PATIENT IDENTIFICATION:

A. Patients must be identified at the POC using a minimum of 2 identifiers, neither of which is the room number (Joint Commission) before POC testing begins. In addition, testing personnel are instructed to use scanning capabilities whenever possible.

B. Refer to the Patient Wristband Identification document for wristband placement and information correction.

XI. SPECIMEN COLLECTION AND LABELING:

A. Refer to the individual testing procedures for specific specimen collection requirements and policies that pertain to specimen collection.

B. POC only allows using specimen types/collection devices that are recommended by the manufacturer and validated by the laboratory during test implementation.

C. Specimen collection supplies should not be expired.

D. POC testing will be performed at the patient's bedside or specimens must be labeled with 2 patient identifiers if specimen is taken to another location to perform testing.

XII. PATIENT TESTING:

A. Patient testing will be performed as recommended by the manufacturer by personnel trained to perform a specific POC test. Operators are required to follow steps outlined in the instrument procedure manual to assure accuracy of patient test results. Refer to individual test procedures for detailed instructions.

XIII. UNEXPECTED RESULTS:

A. As with all diagnostic tests, results should be scrutinized in light of a patient's specific condition. Any result exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data.

B. Clinicians/testing personnel must notify the site-specific POC department if unusual patterns in patient results are seen that may indicate an instrument problem. POC personnel will investigate the issue by performing troubleshooting actions that may include any of the following: electronic QC, liquid QC, patient comparisons between POC instrument and lab instrument and/or calibration verification as warranted by the investigation. Unusual lab results will be compared to other laboratory tests and clinician notes will be reviewed to verify that POC values are appropriate.

C. QML is configured to trap results associated with errors or instrument flags and send them to an exception queue before questionable results transfer to the EHR. Such results are reviewed by POC staff and communicated to testing personnel to confirm that repeat POC testing is done or subsequent lab testing takes place, if deemed necessary by the clinician.

D. Testing personnel are instructed to utilize an alternate test method if interfering substances are present. A list of known interferences is given in each POC procedure and are available in the manufacturer-supplied literature.

E. Errors in manual entry of POC results must be reported to the site-specific POC department in order to correct the result in the LIS and EHR. Clinicians should already have received the correct POC test results for medical decision-making in real time.

F. Also refer to the Critical Values section below.

XIV. REPORTABLE RANGES:

A. The reportable range of a test or analyte is established by the linearity of the method and the validated AMR. The reportable range may be extended below or beyond the limits of available linearity material, according to the College of American Pathologists (CAP) guidelines and direction from the Medical Director, for parameters for which there is no commercially available material or patient samples that are viable to extend the reportable range, such as with certain blood gas parameters.

B. The reportable range of a test or analyte is determined during evaluation of the method, but may be further modified by the calibration verification and analytical measurement range verification. Analytic sensitivity is derived from manufacturer's published detection limits. When performing method validations for non-waived testing, reportable range is approved by the POC Medical Director or Technical Director. Results falling outside the reportable range are reported as < or > than the range limits in the patient EHR. Refer to individual procedure

manuals for protocols for reflexing certain testing to the core laboratory at the clinician's discretion when results fall outside the reportable range.

XV. REFERENCE RANGES:

A. Patient test results reported in the hospital information system (HIS) are associated with reference ranges. Normal ranges are established and verified by laboratory Medical and Technical Directors. Documentation of this evaluation is located in the respective areas within each clinical laboratory. POC tests utilize the corresponding main laboratory reference ranges by establishing acceptable patient correlations between POC instruments and the lab instruments at initial instrument validation and continuous method comparisons semiannually for non-waived analytes. POC tests that do not have an equivalent laboratory test will establish/store the reference range studies in the site-specific POC department. Tests for which results are reported as a part of a treatment protocol monitored by clinicians may not include laboratory reference intervals, such as with platelet mapping by thromboelastography (TEG).

XVI. CRITICAL VALUES:

A. Critical values approved for a given analyte are defined in the procedure. Critical values may be confirmed in the main laboratory or by the bedside instrument. When a critical value is obtained, the required steps to follow (e.g., reporting, lab draw, provider notification) are summarized in each individual test procedure. Critical results are a part of the patient's EHR.

B. Critical result notification and documentation are reviewed daily by POC staff. When documentation of critical value notification is lacking, POC staff will complete the Point of Care Testing Follow-up form and will submit the form to the department manager.

    1. Note: Documentation of an appropriate action taken (e.g. glucose administration, insulin administration, blood transfusion, etc.) for the critical value is acceptable in lieu of notification documentation (Documenting Critical Values at the Point of Care | AACC.org).

C. Staff that are licensed care givers (i.e. clinical nurses, CRNAs, Perfusion staff, etc.) may follow department protocols for critical result notification and documentation. See the following policies for more information:

    1. Communicating Critical Laboratory Results
    2. Communicating Laboratory Critical and Courtesy Alert Values
    3. Guidelines for Management of Diabetic Ketoacidosis (DKA) in Pediatric Patients (<18 years)
    4. Blood Glucose Monitoring in Term or Late Preterm Infants
    5. Adult Hypoglycemia Management Protocol / Standing Order (BG < 70 mg/dL)
    6. Critical Tests - Reporting Results/Values

XVII. RESULT DOCUMENTATION:

A. Interfaced and manually entered POC results are found in the patient's EHR and include the

date, time, reference ranges, and testing personnel. Results are entered and reviewed by authorized personnel who verify the accuracy of the result before final acceptance into the EHR. POC test results that require manual entry into the WebMRE system or Nova Meter Test Entry (MTE) are documented/reviewed at the patient bedside at the time of analysis.

B. When manual entry of patient results is delayed, testing personnel will utilize a patient result log to record patient results before they are entered into the EHR. In this case, POC staff will perform a monthly clerical audit on manually entered results to confirm that they were correctly entered into the EHR.

C. When a new device or location is implemented with data management, POC staff will verify that the results are transmitting accurately from the POC device to the POC data management system and into the HIS before allowing automatic transfer of patient results.

D. All valid POC results must be documented in the patient's EHR for clinicians to make medical decisions based on POC results.

    1. Exceptions may exist with TEG assays. Refer to TEG procedures for more information.

XVIII. USER AUTHENTICATION AND AUTHORIZATION PRIVILEGES:

A. POC staff members grant access to Aqure, HemoCue DM, TEG Analytical Software/TEG Manager, and QML (WebMRE).

B. Only authorized users may access these software systems. User names and passwords are not shared with unauthorized personnel.

C. POC staff establishes the user access roles. User rights are limited to only the level needed to execute assigned responsibilities.

XIX. INFORMATION SYSTEM DOWNTIME:

A. During a computer system downtime, POC testing performed on nursing units is handled in the following manner:

    1. The nurse caring for the patient will communicate the results directly to the clinician, as needed, from the POC device.
    2. Once the system is restored, devices that normally upload results automatically will upload into the computer system.
    3. During a WebMRE downtime, test results that would normally be manually documented into WebMRE will be recorded on the POC Downtime Form accurately reflecting the date and time that testing was performed. Once the WebMRE system has recovered, testing personnel will enter results from POC Downtime Form into the WebMRE system and will send the form to the site-specific POC department review and auditing.
    4. Staff may look up results on the POC instrument during system downtimes.

B. After a partial or complete downtime, POC staff members will verify patient results are

correctly flowing to patient charts. A subset of patient results will be reviewed over all tests systems to confirm recovery was achieved.

C. Refer to the Point of Care Downtime Result Recording, Reporting, and Recovery procedure.

D. Cyber attack

    1. In the event of a cyber attack that impairs POC resulting, the downtime plan described above will be used.

    2. Areas utilizing POC testing will be directed to to send all non-critical testing to the main laboratory.

XX. TEMPERATURE MONITORING:

A. For optimal performance of tests systems, proper environmental and storage conditions must be maintained. Manufacturer's instructions are followed for the handling and storage of all reagents. The CAP does not require records of room temperature/humidity monitoring in areas where a small working supply of reagents are kept. However, centralized reagent storage areas, even those outside of the laboratory, must be monitored for temperature and/or humidity acceptability.

    1. Do not store reagents or QC in refrigerators containing medications per the Medication Refrigerator and Freezer policy.

B. Daily refrigerator temperatures will be recorded on the corresponding log for refrigerators that store reagents or controls (where applicable). Testing areas that are connected to an electronic monitoring system for refrigerator temperature monitoring need not manually record the temperatures. However, if the electronic monitoring system becomes non-operational, the temperatures must be monitored and recorded manually daily until the electronic monitoring system becomes operational. POC will retrieve the temperature reports monthly. All temperature reports and logs will be reviewed monthly by a POC staff member. Out-of-range temperatures will require corrective action documentation and follow up with the unit management and will be the responsibility of the POC staff member reviewing the log(s).

    1. Note: Areas not staffed 7 days a week may utilize and record minimum and maximum temperatures. On the first day that an area is open (i.e. Mondays, day after holiday, etc.), both the minimum and maximum temperature and/or humidity will be recorded for the day(s) the area was closed. The temperature/humidity monitor must be reset prior to the recording period (i.e. Fridays, before holiday, etc.).

C. POC staff will determine when or if it is necessary to move items from one storage area to another when the temperature is out-of-range by considering the following items:

    1. The reason the temperature was out-of-range (i.e. refrigerator door left ajar, recently added reagents, etc.).

    2. Whether the temperature is trending toward the acceptable range.

    3. Whether the observed temperature has returned to the acceptable range.

    4. The immediate availability of an alternate storage location.

    5. The kinds of items in storage (i.e. patient testing reagents versus training/research supplies).

D. Thermometric monitoring devices are replaced prior to the date of expiration of the guarantee of calibration. Only certified thermometers will be used to monitor temperatures where POC testing reagents are stored. Exceptions exist where Temp Trak sensors are placed on refrigerators/freezers and no certificates of calibration are available for the sensors. Temp Trak temperature sensors are verified against a National Institute of Standards and Technology (NIST) calibrated thermometer before initial use and annually thereafter.

E. Each thermometer is visually inspected for damage and general functionality each time the temperature is recorded. This may be periodically recorded on the temperature logs (e.g. in the comment section) to satisfy inspection criteria.

F. Temperature reports are printed and reviewed monthly. Reagents that have been in an out-of-range area for greater than 4 hours must be evaluated for acceptability of QC.

G. The following POC devices have internal function checks that prevent the instrument from performing patient testing if the device is not within vendor specified temperature/humidity range: HemoCue, Nova StatStrip, GEM Hemochron 100, Hemochron Signature Elite, ABL80, ABL90, TEG, Piccolo, i-STAT, Liat, and CoaguChek XS.

XXI. REAGENTS AND CONTROL SOLUTIONS:

A. Where applicable, each shipment and each lot number of reagents (including controls, test strips, and kits) are verified to be within acceptable limits (manufacturer assay range) before distribution by running a minimum of two levels of external liquid control material. Corrective action will be taken and documented when QC validations fail (e.g. product or analyzer returned to the manufacturer).

    1. See the individual procedures and manufacturer literature for more information.

B. New reagent lots and/or shipments for non-waived tests must be validated to verify that there is no significant change in patient or QC results from the currently used lot/shipment. This is accomplished by performing liquid control measurements on the current lot of reagents as well as the new lot/shipment of reagents. Results are reviewed for acceptability before lots are placed in service. QC results run on the new lot of reagents are compared to QC results run on the current lot of reagents and acceptable criteria are similar to the limits established for patient comparisons for each analyte tested.

C. When storage temperatures or open vial stability of a reagent or control product changes the expiration date, the new expiration date must be clearly recorded on product and used within the new expiration date or the manufacturer's expiration date, whichever comes first.

D. Reagents must not be used beyond their expiration date. POC staff will remove reagents that are not labeled with the new room temperature expiration date, and notify the unit management team. POC staff will randomly conduct internal inspections on nursing units and testing areas and confirm that all products are used within appropriate dates. See the POC Internal Inspection procedure. If an expired product is found, QC will be performed on the expired product to verify the reagent/consumable is yielding acceptable results and patient results were not compromised. Further follow-up studies will be performed and patient results will be evaluated if the initial QC study produces unacceptable results. All additional studies will be evaluated on a case-by-case basis.

E. Components of a kit are not interchangeable with different lots unless otherwise specified by

the manufacturer. Refer to the specific procedure manual and QC section for additional instructions or handling and storage requirements.

XXII. MAINTENANCE AND TROUBLESHOOTING:

A. Maintenance and troubleshooting requirements vary with each device. Refer to individual test procedure (troubleshooting section) for a detailed description and recommendations for back-up testing. Maintenance and function checks requirements are set forth based on manufacturer's recommendations. Function checks may include QC testing, calibration verification, and if applicable, instrument comparisons and must be within specified limits before patient testing is allowed. Maintenance logs, where applicable, are reviewed monthly by POC.

B. Preventative maintenance on instrumentation is performed as suggested by the manufacturer.

C. Instrument/test problems/concerns are reported by the testing area to the site-specific POC department immediately, or on any shift via the the site-specific POC department pager or by using the laboratory phone tree to obtain support from trained POC staff. The Information Technology (IT) Help Desk can be notified with computer related issues. If issues persist and a loaner instrument is not available, specimens can be sent to the main laboratory for analysis. All problems and corrective action are documented in QML or on the instrument equipment log in order to monitor instrument problems or trends.

XXIII. QUALITY CONTROL (QC):

A. QC testing provides assurance that the test system is performing as expected. Controls must be run as indicated by the manufacturer and/or IQCP (see below), prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate. Departments authorized for POC testing will actively participate in appropriate QC programs developed and monitored by POC. Testing personnel will review QC results to verify acceptability prior to patient testing. QC results must be documented either electronically, or on a log sheet provided by POC.

    1. QC log sheets will include the reagent log numbers, instrument identification, date, operator, test result, and corrective action.

B. Waived testing QC is performed at a frequency that is recommended by the manufacturer. See individual procedures for more details.

C. For non-waived testing, POC either follows the minimum daily requirements as defined by CLIA and CAP, or follows an IQCP. In order to reduce the frequency of running daily external liquid controls on non-waived devices that employ an internal QC process, the stability of each test system is verified according to the CAP IQCP guidelines and recommendations regarding QC testing as explained below. Documentation of validation studies are retained in POC. See the site-specific Point of Care Individualized Quality Control Plans and individual procedures for more detail.

    1. New non-waived instruments under an IQCP must demonstrate acceptable QC over a period of 30 days with external controls and built-in controls. Then, the non-waived instrument's external QC may be performed according to the manufacturer's

instructions or every 31 days, whichever is more frequent.

D. Non-waived test system internal/electronic QC, if applicable, is performed daily with the exception of coagulation testing instruments that run QC every 8 hours and blood gas instruments require a minimum of 1 level of QC every 8 hours of operation.

E. Each new lot of QC material is run upon receipt to verify the acceptable control ranges provided by the manufacturer. The data is transcribed on a procedure-specific lot to lot verification form and reviewed by POC staff. See individual procedures for additional information and documentation forms.

    1. Tolerance limits are established by utilizing the manufacturer's ranges.

F. Control specimens are tested in the same manner, if applicable, as patient testing and by the same personnel who perform patient testing. Where available, two levels of QC at two different concentrations are used for all lots of reagents in use. To detect device or process failure, operators performing QC testing must verify that controls are not outside the acceptable range and document the results prior to patient testing. The procedure will specify type and frequency of control testing. POC performs external liquid controls on each new analyzer before placing into use, with each shipment of reagents and each lot of reagents, after major system maintenance, after replacement of a critical part that may affect test performance, and after software upgrades, if recommended by the vendor.

G. Out-of-range QC results are directly transmitted into the POC data management system (QML) or into the analyzer's database and are immediately flagged. Corrective action must be initiated, documented, and POC notified if the operator is unable to resolve the problem. Operators are not to proceed with patient testing if QC results fall outside the acceptable range. Refer to the troubleshooting section in the procedure for appropriate corrective action recommendations. Most POC devices employ the QC lock-out feature which prevents testing personnel from performing patient testing until QC testing has been performed successfully. QC lockout is in place for ABL80, ABL90, GEM Hemochron 100, Hemochron Signature Elite, HemoCue, Liat, Nova StatStrip, and TEG 6s instruments. Patient samples will not be tested until QC issues are resolved, where QC lock-out is not available.

H. Patient/client test results obtained after QC have failed and after the last acceptable QC were run (if impacted by the instrument failure that caused the QC to be out of range) will be re-evaluated via chart review by POC staff and/or clinicians to determine if there is a significant clinical difference in the result. POC personnel will determine if re-testing patient samples is needed. If it is determined that unacceptable results are present in the patient's chart, the manager of the unit will be notified and the course of action will include removing unacceptable results from the EHR and notifying the appropriate clinicians of the error.

I. QC data is reviewed daily in QML by POC staff to detect trends or problems. The POC Medical Director designates that POC staff review the monthly QC Levey Jennings to verify that cumulative QC data for POC devices are within 2 SD, coefficient of variation (CV)s are <10% (<14% for the Hemochron), unless otherwise stated, and to detect any problems or trends. The monthly Radiometer Peer Comparison Reports are reviewed to verify that QC data for ABL devices are within 3 SD and the CV is <10%. POC staff check that all out-of-range QC results have documented corrective action and/or proper troubleshooting before any patient testing is performed, or that the instrument was removed from use.

J. Departments required to fill out QC and/or maintenance logs must submit completed logs on a

monthly basis to be reviewed by POC staff. Whenever deficiencies are present, a POC Quality Assurance Monthly Report is sent to department management to initiate process improvement.

K. Departments with low patient volume are to perform QC only on the days that patients will be tested, so long as manufacturer/IQCP requirements are met.

XXIV. INSTRUMENT COMPARISONS:

A. Instrument comparisons are performed twice per year, approximately every 6 months, on all non-waived POC tests under the same CAP/CLIA number, unless otherwise specified. See individual procedures for test requirements.

    1. For devices/methods that do not have a comparable laboratory equivalent (i.e. Hemochron), a reference instrument may be designated to be used for comparison. For more detailed information and acceptable limits, refer to the specific procedure.
    2. For devices/methods that do not have a comparable instrument under the same CAP/CLIA number, a reference instrument may be designated to be used for comparison, if available. If no other comparable instrument is available within the same CAP/CLIA site, comparison studies are not required.

B. Periodic instrument/patient comparisons are not required on waived tests but can be performed when troubleshooting device problems, when investigating complaints from clinicians, or if specified in the waived POC test procedure.

C. Where applicable, fresh human samples and/or QC/calibrators/linearity standards are used to verify correlation between the laboratory analyzers and the POC devices and to verify continuous appropriateness of POC reference ranges. The percent difference will be calculated, and data is reviewed for acceptability by a POC staff member according to criteria set by POC Medical Director or Technical Director or site Medical Director.

XXV. LINEARITY/CALIBRATION VERIFICATION/ AMR:

A. Linearity (including calibration verification and AMR verification) will be performed, where applicable, on all newly implemented POC devices. Linearity is performed on waived instruments as indicated in manufacturer instructions. Linearity will be performed twice per year, approximately every 6 months, on all non-waived devices, after major maintenance or repairs, after software upgrades (when required by vendor), when QC reflects unusual trends, or when QC is consistently outside the laboratory's acceptable limits. Refer to individual test procedures. When multiple devices are in use, a subset may be validated on a rotational basis with different devices each time, so that all devices are checked. The subset should include each lot of reagents that are in use at the time the AMR is performed. AMR is inferred by quality control review for devices that are not sampled on a given rotation.

    1. Note: Linearities are not required on clot-based testing.

B. Calibrators and calibration verification materials are required for the ABL80 and ABL90 instruments. Calibration materials are procured from the vendors to confirm matrix-

appropriate target values. The vendors provide defined target values for the samples. Manufacturer's instructions are followed for calibration and calibration verification procedures. Calibrations and calibration verifications that fail the established acceptability criteria must be repeated and pass. If test systems fail to meet established criteria during the calibration verification process, the manufacturer is contacted for troubleshooting. Instruments are not used for patient testing until successful calibration verification is obtained.

C. Acceptable linearity for calibration verification of a given analyte verifies the analytical measurement range (AMR). Patient results that fall outside of the linearity range are reviewed and re-assayed, if deemed appropriate by the clinician. They are reported as < the lower limit of acceptability or > than the upper limit of acceptability respectively, for all analytes performed. AMR parameters are programmed in the QML system for appropriate reporting of > or < results.

D. Linearity materials are obtained from the manufacturer or manufactuer-recommended supplier. Linearity materials must have the appropriate matrix when compared to patient samples. Some examples of linearity materials that may be used in the absence of vendor materials are previously tested patient samples that have been spiked with known amounts of the analyte to be tested, QC materials that span the AMR and have method-specific target values, or reference materials with matrix characteristics and target values appropriate for the method.

E. Manufacturer's instructions are followed and high quality materials with method and matrix-appropriate target values, that include low, midpoint, and high values near the AMR, are used for calibration and calibration verification/AMR, where applicable. When applicable, devices are sent back to the manufacturer for recalibration. Refer to the test procedure manual, package inserts, and equipment logs for detailed instructions.

XXVI. CARRYOVER:

A. Carryover occurs when a portion of a leading sample is transferred into the following sample. Carryover may be quantified as percent interaction by testing a low concentration sample (1), followed by a high concentration sample, followed by the same low concentration sample (2). The percent interaction is calculated using the formula

1. $$\% \text{ Interaction} = \frac{[\text{Low Result (2)} - \text{Low Result (1)}]}{\text{High Result}} \times 100$$

B. Depending on the analyte and clinical use of a given test, varying amounts of percent interaction may be acceptable, but if percent interaction exceeds 1%, clinically significant carryover may be present and should be further investigated by follow up carryover testing. The absolute or percent differences between the two low samples should be well within allowable error for a given analyte, as determined by the POC Medical Director.

C. Non-waived test systems which pipette or aspirate sample (e.g., ABL80, ABL90) should be checked for carryover prior to being put into service, unless they use disposable tips. If the instrument has more than one sample probe, each should be checked. These initial carryover studies are evaluated and approved by site-specific Medical Director and/or POC Medical or Technical Director as a part of test validation.

D. Evaluation for carryover should also be performed after major instrument repair (including

annual preventative maintenance) or after probe replacement. These ongoing carryover studies are evaluated and approved by a site-specific POC Manager or Supervisor using allowable error criteria determined by the POC Medical or Technical Director for each test.

XXVII. PIPETTE ACCURACY:

A. Pipettes used for quantitative dispensing are checked at least annually for accuracy. Fixed and adjustable volume pipettes are checked by a photometric method (e.g. the Artel system or equivalent).

B. The accuracy of pipettes integrated into automated analyzers is checked each day of QC testing, with approved QC ranges determining acceptability. Precision of integrated pipettor systems is checked with QC statistics evaluated monthly.

C. Manufacturer instructions should be followed for monitoring and maintaining pipettor accuracy and precision.

XXVIII. QUALITY ASSURANCE:

A. The POC Medical Director designates POC staff the task of routinely reviewing QC logs and databases for possible errors, shifts, and trends. Whenever deficiencies are present, a POC Quality Assurance Monthly Report, POC Testing Follow-Up form, or Quality Safety Report (QSR) is sent to department management informing them of compliance issues and guiding them with process improvements.

B. POC Quality Assurance Monthly Report ratings below Good/90% for two consecutive months will require an action plan from the department Manager detailing process for improvement(s). Follow up with the Manager will be the responsibility of the POC staff sending the report(s). At the end of each year, a cumulative summary report is also sent to each department Manager for review.

C. POC staff visit and inspect equipment and reagents in POC testing areas.

XXIX. QUALITY ASSURANCE (QA) MONITORS:

A. QA monitors are carried out to evaluate the pre-analytical, analytical, and post analytical phases of testing. Monitors are used to detect problems and identify opportunities for process improvement.

B. POC staff will investigate reports of unusual results obtained while using POC testing. Corrective action will be documented in QML or the respective equipment log. POC staff perform daily review of patient results in QML to monitor for unusual patterns which may suggest system errors. QML is capable of sorting results to allow the POC staff to determine whether trends are related to a patient condition or if they are due to an instrument's analytical error.

C. A POC Testing Follow-Up form is sent out to notify unit Managers of problems relating to patient identification, clerical error, lack of critical value notification documentation, or misuse of the equipment in order to educate and alert testing personnel, and correct problems.

D. Results are trapped in QML if associated with flags or error codes. QML is monitored throughout the day to provide timely correction of errors. ADT (admission, discharge, transfer)

registration problems are investigated by POC staff prior to releasing results. A RL Solution report may be generated to facilitate error correction depending on the circumstances and degree of the problem found.

E. Specific QA monitors vary by site. QA monitor targets for all monitors are 100% compliance.

XXX. PROFICIENCY TESTING (PT):

A. Proficiency testing promotes patient care by identifying significant differences between test results obtained by a single laboratory and reference analytical values or results obtained by laboratories performing similar analytical methods. POC subscribes to CAP and American Proficiency Institute (API) external proficiency testing, which is performed a minimum of 2 times per year per analyte depending on the product used. Refer to the proficiency instructions for handling/storage that are received with each proficiency shipment.

B. When PT materials are not available commercially, or when the main laboratory already tests similar PT materials from the same PT program, proficiency testing requirements are satisfied by alternative assessments. These may include assayed controls, completed CAP proficiency surveys (only after results are posted), or other in-house methods approved by the POC Medical Director or Technical Director, such as semiannual method comparisons with the main lab method. Alternate performance assessments are completed semi-annually.

C. Trained operators from units performing POC testing will analyze proficiency samples in the same manner that patient testing is performed. PT will be rotated among all devices or test kits in use and among personnel who routinely test patient specimens. Proficiency testing is integrated within the routine testing workload. After obtaining PT results, further testing of the same PT survey material may only be performed after the due date for submitting results to the PT provider.

D. Proficiency results are reviewed by POC staff and the POC Medical Director, Technical Director, or designee, and then submitted to the proficiency provider for evaluation. Attestation statements are signed by POC Medical Director, Technical Director, or designee along with the individual performing the PT testing. The CAP Participant Summary Report is returned indicating performance relative to other laboratories using the same method and is reviewed by the POC department and Medical Director within a month of receiving the Participant Summary Report in the mail.

E. POC staff evaluates samples chosen for alternative assessments, and tolerance limits are established by the POC Medical Director or Technical Director. Data is then submitted to the POC Medical Director, Technical Director, or designee for final approval.

F. Graded, ungraded, and alternate PT results may be reviewed by the System Manager, Manager, POC Supervisor, Lead Medical Technologist, or Medical Technologist. PT records must show that results are evaluated for acceptable performance.

    1. Alternate PT is used for the pHydrion assay as no commercially available PT material is available.

G. Corrective action is initiated within one month when proficiency results are determined to be “unacceptable,” when challenges are not graded for any reason, when there are submission errors or lack of consensus, or when proficiency results, although acceptable, show a bias or trend (e.g., standard deviation index (SDI) exceeding +/-3.0). Corrective action may include

consulting with the instrument vendor, performing QC testing, method comparisons, or repeating proficiency testing if material is still available. Self-evaluation is performed on all ungraded and educational challenges. The evaluations must be completed within 60 days of the receipt of the results. Exceptions may be necessary if feedback is pending from the manufacturer. Investigations should include the following:

1. Detailed investigation of the problem.
2. Conclusion as to the cause of the incident.
3. Specific corrective action taken to prevent recurrence of the incident.
4. Evidence that the corrective action resolved the problem.
5. Supporting documentation.

H. POC will follow CAP's direction to cease patient testing due to repeated unsuccessful proficiency testing in accordance to all conditions outlined in the Cease Patient Testing Notification.

I. POC staff will advise testing personnel that all proficiency samples should be treated as blind and independent and, therefore, are prohibited from inter-laboratory communications (referral or acceptance) about the samples before the deadline for submission of the data for evaluation. In order to make the results inaccessible to personnel from other affiliated laboratories, a "dummy" number (such as 111111111 or 999999999) is used to identify the PT samples in the LIS. Testing personnel perform PT within their routine workload and are prohibited from performing duplicate analysis unless they note an error in testing for which they would routinely repeat patient testing under similar circumstances, such as cuvette/test strip not completely filling with sample. Proficiency samples are never referred to another test site with a different CLIA number. POC lab staff explain to testing personnel the purpose of PT and the guidelines pertaining to prohibiting inter-lab communication until after the deadline for submission of the data. These guidelines include not sending or receiving PT samples to/from the main lab if unable to obtain a result via the POC method.

XXXI. SAFETY:

A. Patient and QC testing will be carried out in accordance with the Standard Precautions and Hand Hygiene policies.

B. Syringes, lancets, needles, blood specimens and test equipment will be disposed of in designated biohazard puncture-resistant containers. Corewell Health provides properly labeled biohazard containers in all patient care areas for discarding contaminated waste and sharps.

C. Testing personnel must wear gloves and follow hand hygiene before and after performing patient testing. Hands must be cleaned by using a hospital approved disinfectant/ antimicrobial method. Gloves are changed between patients and not washed, disinfected, or reused. Gloves must be replaced immediately when torn or contaminated. Testing personnel are instructed on personal protective equipment (PPE) use during training and competency assessments for POC testing.

1. The Wayne Special Pathogens Lab (SPL) may have additional requirements. See the current Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing document provided by the Centers for Disease Control and Prevention

(CDC). Only employees with the appropriate personal protective equipment (PPE) donning and doffing training should participate in SPL testing.

D. Corewell Health provides testing areas with auto-disabling single-use retractable blade fingerstick devices for POC testing. Testing personnel should only use single-use lancet pens on one patient. Personnel are instructed to not recap, bend, break, or manipulate needles, or remove them from disposable syringes.

E. Plastic capillary tubes are available for capillary blood gas testing. The use of glass capillary tubes should be avoided.

F. Operators are instructed to identify patients with 2 independent identifiers.

G. Specimens should be collected using safe handling techniques that should include but are not limited to verifying a tight seal on collection containers, avoiding specimen spills, and wearing PPE.

H. Hand-held POC devices that come in contact with patients should be cleaned and disinfected with a hospital approved disinfectant or bleach wipe after each patient use in order to prevent transmission of infections. Bench-top analyzers should be cleaned and disinfected when contaminated with patient samples. See individual procedures for more information. All hospital-approved wipes have been approved for use in decontaminating instruments exposed to COVID-19.

    1. In the event that an Ebola patient is tested on one of the SPL instruments, contact technical support for that specific instrument for decontamination and/or disposal guidance.

I. Operator lock-out is employed with various POC instruments in order to confirm that only trained testing personnel have access to POC devices for patient testing. Operators are not permitted to let other staff members use their identification (ID) or password. Where possible, POC results are electronically downloaded from the instrument to the EHR to reduce human error. POC personnel review all results daily and corrective action is taken when errors are detected. Most POC devices allow scanning of patient wristbands, and the WebMRE system offers positive patient identification (PPID) when manually resulting POC results.

J. Instruments are selected that use a minimum amount of specimen.

K. Secondary specimens and aliquots are not used at the POC.

L. All critical care area instruments have battery back-up that last a minimum of 45 minutes. During an extended power outage, testing personnel may choose to relocate POC instruments and utilize a red emergency power outlet.

M. Safety Data Sheets (SDS) may be located on MSDSonline.

N. See the Laboratory Safety Manual for more information:

    1. Laboratory Chemical Hygiene Plan
    2. Laboratory Employee Incident Investigation and Root Cause Analysis
    3. Procedure for Laboratory Employees to Communicate Concerns Regarding Test Quality and Laboratory Safety
    4. Laboratory Education - New Hire Orientation : Laboratory New Employee Safety Training Checklist

5. Phlebotomy Safety Guidelines
6. Laboratory Personal Protective Measures
7. Laboratory Infection Control
8. Laboratory Spill Response
9. Laboratory Waste Disposal
10. Laboratory Noise Protection Guidelines
11. Laboratory Ergonomics
12. Laboratory Fire Safety
13. Laboratory Electrical Safety Related Work Practices
14. Laboratory Policy for Compliance with Applicable Federal, State and Local Laws and Regulations

O. Emails containing patient information will only be sent to internal email addresses to confirm proper security and patient privacy. Emails sent to an external email account, must have all patient information obliterated.

XXXII. POC EMERGENCY STAFFING PLAN:

A. In the event of an unexpected system failure (e.g. heating, ventilation, air conditioning (HVAC), water, communication, computer system), power failure, natural disasters (e.g. tornado, fire, flood), emerging public health threats, cyber-attacks, terrorist events, or workplace violence, every effort will be made to continue to monitor POC testing equipment and patient results.

B. POC staff will refer to the site-specific Emergency Management Quick Reference Guide that is posted in every laboratory section. In the event that an evacuation is necessary, site-specific evacuation route(s) are posted in the Emergency Management Quick Reference Guide.

C. At least one POC staff member is available at all times to handle emergent situations by phone tree for each testing site.

XXXIII. PROVIDER PERFORMED TESTING AND PROVIDER PERFORMED MICROSCOPY:

A. Provider Performed Testing (PPT) and provider performed microscopy testing (PPM) is testing that is personally performed by a physician or mid-level practitioner in conjunction with the physical examination or treatment of a patient. The PPT tests include fecal occult blood, AmniSure, pH testing for chemical spills to the eye, and pH testing of pooled vaginal fluid for checking premature rupture of membranes and bacterial vaginosis. PPM testing includes Fern Testing of pooled vaginal fluid for checking premature rupture of membranes and wet mounts to determine if yeast, Clue Cells and/or *Trichomonas vaginalis* are present.

B. Results are documented by the clinician who performed the test in the HIS and include the test, result, QC result (if applicable), name of testing personnel, and date/time. Fecal Occult Blood testing result documentation should also be associated with a note indicating that the internal quality control performance monitor area results are acceptable (QC OK). For areas

resulting the test in the LIS, the reagent lot number, expiration date, and internal QC documentation will be documented.

C. The laboratory director has determined that PPT waived testing only requires an initial training and competency assessment. The fecal occult blood test, pHydrion test, and pHizatest are waived tests for which providers will be trained initially on the performance of the test.

D. AmnioTest, AmniSure, wet mount, and Fern test are non-waived tests that follow the same training and competency requirements of non-waived tests. See the Training/Competency Assessment section below.

E. Clinicians are responsible for verifying correct result entry into the patient's EHR and will contact POC staff if any issues are noted with the results not correlating with the patient's clinical presentation. Staff must follow standard precautions when performing any testing.

XXXIV. VISUAL COLOR DISCRIMINATION:

A. All patient care employees are tested for visual color discrimination during their pre-employment physical by the Employee Health Services (EHS) department. Results of colorblindness testing are retained in the employee's chart at EHS. Employees that have failed or have difficulty with visual color discrimination are prohibited from performing the POC tests that require color determination. EHS will contact the department Manager to notify them of the limited responsibilities pertaining to tasks/lab testing requiring color discrimination for these employees.

B. POC staff may refer to the Color-Blindness Testing for Laboratory Employees procedure.

C. Functional color blindness assessments are also included as part of the competency assessments for applicable assays.

XXXV. TESTING PERSONNEL:

A. A complete list of authorized operators responsible for performing POC testing is housed in the QML, Aqure, HemoCue, HealthStream, and Workday databases.

   1. POC staff are authorized to perform patient testing for testing systems with current competency assessments on file, but do not routinely do so.
   2. Only Corewell Health employees and approved contractors (i.e. Comprehensive Care Services, NorthStar Anesthesia, agency staff, etc.) will be granted POC testing privileges.

B. Non-waived testing personnel must also provide documentation of qualifications (diploma, transcript, degree, or Primary Source Verification (PSV)). Personnel performing moderate complexity testing must, at a minimum, have earned a high school diploma or equivalent. The CAP Laboratory Personnel Evaluation Roster is electronically signed annually by the Medical Director for each CLIA laboratory.

C. Testing personnel are responsible for the following: performing QC testing and documenting corrective action, if applicable, following all policies and procedures set forth by the POC department, performing routine maintenance and troubleshooting and reporting problems to the site-specific POC department, participating in performance of proficiency testing and performing in the same manner as patient testing, and completing the required training/

competency assessments.

D. Trained testing personnel are authorized to perform the POC test as long as their certification/ competency is up-to-date and do not require supervision. Supervisory review is not required prior to reporting point of care test results or during test performance. Testing personnel are only allowed device access and/or access to the WebMRE system for tests that they are trained/approved to perform.

XXXVI. TRAINING/COMPETENCY ASSESSMENT (CERTIFICATION/RE-CERTIFICATION):

A. Only personnel who have successfully completed the initial comprehensive training program and yearly training and competency assessment (re-certification), conducted by POC staff or its designate, are authorized to perform POC testing. Personnel performing moderate complexity tests during the first year must be re-assessed semiannually (within 7 months from initiation of testing) and have the second assessment no later that 12 months from the start of testing during the first year. Operators will be locked out of devices, where the capability exists, prohibiting testing via QML or Aqure (for the ABL instruments) until the semiannual and subsequent assessments are completed. Competency assessments for non-waived tests require assessment of all 6 CLIA elements, as applicable, of competency listed in the respective POC's competency assessment form and below:

    1. Direct observation of patient testing
    2. Result review and critical value documentation
    3. Reviewing QC results
    4. Direct observation of maintenance
    5. Assessment of test performance using known samples
    6. Evaluation of problem-solving skills

B. The database of authorized personnel is maintained by POC staff. This includes updating staff access/certification records in the QML database or inactivating testing personnel who no longer use POC instruments. Daily result review in the QML database verifies that approved testing personnel are using POC devices. Nurse Managers and designees receive a POC authorization list from the site-specific POC department and will make updates to the employee lists as needed.

    1. Competency and training records are shared, if requested, for waived assays with other POC sites within Corewell Health East.
    2. Competency assessments must be completed at each CLIA license site for non-waived assays.

C. A training guide and competency assessment form are distributed and used to assist the instructor/trainer in providing a uniform training program, which includes lecture and review of hospital policy. There are not variations in testing at different testing sites, as all testing and workflows have been standardized. Furthermore, training sessions include the following

elements: direct observation of patient identification, PPE requirements, preparation, specimen collection/handling and processing, patient and QC testing procedures, QC records (if available for the POC test), reporting of patient results including critical values, preventative maintenance logs (if applicable for the POC test), instrument maintenance and function checks, limitations, and troubleshooting skills. Staff must complete initial training including specimen collection before they are able to perform patient testing. Training and competency assessment forms indicate the elements of competency assessment needed for each POC test. The trainer also demonstrates how to properly use the equipment and then assesses the trainee's competence. Authorized trainers are indicated in the QML software with a T and the instrument's acronym on the "Title" line or on a site-specific spreadsheet. Additionally, each trainee is required to successfully complete a knowledge based exam which is a part of their training and competency assessment checklist document. POC staff provides unknown samples that have been previously analyzed and with known target results for training sessions to be tested.

1. Alternately, selected waived testing may utilize an on-line module, quiz, and QC performance review for ongoing competency assessment. POC staff will monitor on-line module performance.
2. Paper competency forms are updated periodically. Staff are instructed to utilize the current version of the form from the on-line policy management system. Should a previous version of a competency form be received in the POC lab, POC staff will verify that there has not been any training content and/or question content revisions that vary from current testing processes/procedures and current version of the form. Should only minor revisions exist between the versions (e.g. testing site changes (header), typo correction, contact/submission edits, formatting, etc.), the POC personnel will note on the form that the test content on the form is current prior to extending/granting access to the POC testing operator. POC staff will contact the trainer requesting that future competencies be submitted using the current version found on-line. If major revisions to the testing-related content exist between the submitted version and current version, POC staff will not extend/grant access for POC testing and will request a new competency assessment to be completed.

D. Training must occur prior to starting patient testing and reporting patient results and then annually thereafter for waived testing. Moderate complexity testing requires training prior to starting patient testing and reporting patient results, assessment of competency during the first year at least semiannually (approximately 6 months), then annually thereafter.
    1. For instruments that utilize different cassette types but have no variation in sample preparation or patient/QC testing procedure, training and competency assessment may be performed on any cassette type.

E. Trainers are re-certified annually and have been designated by POC staff as competent to assess staff knowledge and use of instrument/test after attending an in-depth train-the-trainer session.

F. Retraining will take place when POC lab personnel identify problems with operators' performance of POC tests. Individuals or clinical units that fail to perform required quality assurance procedures, require 3 or more attempts to pass an on-line module (passing scores are ≥80%), or who fail to perform patient testing according to approved procedures will have their POC testing privileges revoked. After re-education and training, if the employee passes

the competency assessment, testing privileges will be reinstated. Competency assessment forms will be reviewed for legibility and completeness prior to granting instrument access. Where applicable, on-line module completion, passing quiz score and successful QC performance will be reviewed by POC staff. Instrument access will be revoked due to lack of completion or failed competency assessment.

G. To verify that the trainers, and therefore, individuals responsible for competency assessment, are qualified, only certain job titles are permitted to be designated as trainers. The POC System Manager, Laboratory Manager, Supervisor, Lead Medical Technologist, and Medical Technologist meet personnel requirements as trainers/competency assessors for all POC test systems. Additional job titles listed below also meet minimum personnel requirements to perform training and competency assessment for POC testing. For non-waived methods, trainers must have a 4 year college degree (bachelor's degree in chemical, physical, biological, clinical laboratory science, or medical technology with at least 2 years training).

    1. ABL80
        a. Assistant Nurse Manager
        b. Clinical Nurse
        c. Clinical Nurse Manager (CNM)
        d. Clinical Nurse Specialist
        e. Nurse Education Specialist
        f. Nursing Professional Development Generalist
        g. Special Procedure Tech
        h. Special Procedure Tech III
    2. ABL90
        a. Anesthesia Tech Supervisor
        b. Clinical Nurse
        c. CRNA
        d. Perfusion Assistant
        e. Perfusionist
    3. AmniSure
        a. Nurse Education Specialist
    4. AmnioTest
        a. Clinical Nurse
        b. Nurse Education Specialist
    5. CoaguChek
        a. Clinical Nurse
        b. Phlebotomist II
    6. Fern Test

a. Doctor
b. Mid-Level Provider/Advanced Practice Provider
c. Nurse Education Specialist
d. Resident

7. GEM Hemochron 100
    a. Assistant Nurse Manager
    b. Clinical Nurse
    c. Clinical Nurse Manager
    d. Clinical Nurse Specialist
    e. CNM
    f. CRNA
    g. Nurse Education Specialist
    h. Nurse Educator
    i. Nursing Professional Development Generalist
    j. Perfusion Assistant
    k. Perfusionist
    l. Research Nurse Clinician
    m. Special Procedure Tech III
8. Hemoccult SENSA
    a. Mid-Level Provider
    b. Nurse Education Specialist
9. Hemochron Signature Elite
    a. Assistant Nurse Manager
    b. Clinical Nurse
    c. Clinical Nurse Manager
    d. Clinical Nurse Specialist
    e. CNM
    f. CRNA
    g. Nurse Education Specialist
    h. Nurse Educator
    i. Nursing Professional Development Generalist
    j. Perfusion Assistant
    k. Perfusionist
    l. Research Nurse Clinician

m. Special Procedure Tech III

10. HemoCue
    a. Anesthesia Tech
    b. Clinical Nurse
    c. Clinical Nurse Specialist
    d. CRNA
    e. Nurse Educator
    f. Special Procedure Tech
11. i-STAT
    a. Clinical Nurse
    b. Clinical Nurse Manager
    c. CT Tech
    d. CRNA
    e. Lead CT Tech
12. Liat
    a. Assistant Nurse Manager
    b. Associate Nursing Manager
    c. Care Coordinator
    d. Charge Lead Nurse
    e. Clinical Assistant
    f. Clinical Nurse
    g. Clinical Nurse Manager
    h. Clinical Nurse Specialist
    i. CNM
    j. CPR Instructor
    k. Director of Nursing Education Research
    l. Emergency Tech
    m. Graduate Nurse
    n. Nurse Education Specialist
    o. Nurse Educator
    p. Nurse Technician
    q. Nursing Assistant
    r. Nursing Education Manager
    s. Nursing Professional Development Generalist

t. Phlebotomist II
u. Quality Improvement RN
v. Research Nurse Clinician
w. Specialty RN
x. Technical Aide

13. pHizatest
    a. Assistant Nurse Manager
    b. Clinical Nurse Manager
    c. Doctor
    d. Mid-Level Provider/Advanced Practice Provider
    e. Resident

14. Nova StatStrip/Nova Xpress
    a. ACLS PALS Instructor
    b. Anesthesia Tech
    c. Assistant Nurse Manager
    d. Associate Nursing Manager
    e. Care Coordinator
    f. Charge Lead Nurse
    g. Clinical Assistant
    h. Clinical Nurse
    i. Clinical Nurse Manager
    j. Clinical Nurse Specialist
    k. Constant Observation Worker
    l. CPR Instructor
    m. Critical Care Tech
    n. CRNA
    o. CT Technologist
    p. CT Technologist, Lead
    q. Customer Service Coordinator
    r. Director of Nursing Education Research
    s. Emergency Tech
    t. Hemodialysis Tech
    u. Laboratory Support Tech, Senior
    v. Manager of Infusion Center

w. Mental Health Worker
x. Nuclear Medicine Technologist
y. Nurse Education Specialist
z. Nurse Educator
aa. Nurse Prof Dev Specialist
ab. Nurse Technician
ac. Nursing Assistant
ad. Nursing Education Manager
ae. Nursing Professional Development Generalist
af. Opthalmology Technician, Senior
ag. Phlebotomist
ah. Physician Office Staff
ai. Quality Improvement RN
aj. Research Nurse Clinician
ak. Senior Phlebotomist
al. Special Procedure Tech III
am. Specialty RN
an. Technical Aide

15. pHydrion
    a. Doctor
    b. Mid-Level Provider/Advanced Practice Provider
16. Piccolo
    a. Clinical Nurse
    b. CT Technologist
    c. CT Technologist, Lead
    d. MRI Technologist, Senior
    e. Special Procedure Supervisor
17. TEG
    a. Director of Perfusion Services
    b. Perfusion Assistant
    c. Perfusionist
18. Urine Dipstick
    a. ACM
    b. Clinical Nurse

c. Clinical Nurse Manager
d. CNM
e. Nurse Educator
f. Nursing Professional Development Generalist

19. Urine hCG
    a. Assistant Nurse Manager
    b. Associate Nursing Manager
    c. Care Coordinator
    d. Charge Lead Nurse
    e. Clinical Assistant
    f. Clinical Nurse
    g. Clinical Nurse Manager
    h. Clinical Nurse Specialist
    i. CNM
    j. Employee Health Manager
    k. Emergency Tech
    l. Nuclear Medicine Tech, Senior
    m. Nurse Education Specialist
    n. Nurse Educator
    o. Nurse Manager
    p. Nurse Prof Dev Generalist
    q. Nurse Technician
    r. Nursing Assistant
    s. Nursing Education Manager
    t. Nursing Professional Development Generalist
    u. Mid-Level Provider/Advanced Practice Provider
    v. Quality Improvement RN
    w. Research Nurse Clinician
    x. Senior Director of Employee Health and Safety
    y. Specialty RN
    z. Technical Aide

20. Wet Prep
    a. Doctor
    b. Mid-Level Provider/Advanced Practice Provider

c. Resident

XXXVII. POC STAFF COMPETENCY:

A. POC staff will review new procedures and major procedure revisions as a part of competency assessment. POC staff will complete the POC Staff Competency Assessment Record form annually (semi-annually for the first year on non-waived testing) and verify that the 6 CLIA elements of competency assessments are met with a fellow POC assessor that meets the qualifications as stated in CAP checklist item GEN.55510.

1. POC laboratory personnel performing training and competency assessments at multiple CLIA sites must be knowledgeable of the test system being assessed. This entails training and successful competency assessment completion of the test system at the primary work location/CLIA site and/or at each individual CLIA site location. Patient testing may only be performed at site(s)/CLIA locations with current successful competency assessments on file. All POC staff should have their Manager/Supervisor/Site Medical Director approve Form F from the Laboratory Education-Employee Competency Assessment procedure to identify each employee as qualified as a competency assessor.

B. All POC staff are assessed using the competency assessment program and are evaluated annually by performance review to assess competency in non-testing responsibilities as required for individual roles.

C. The laboratory will retrain and reassess employee competency when problems are identified with an employee's performance. If after retraining, the employee is unable to satisfactorily prove competency, further action will be taken which may include supervisory review of work, reassignment of duties, or other actions deemed appropriate by the POC Medical Director and/or site laboratory Medical Director. Documentation of retraining and reassessment of employees who initially fail competency assessment will be available, if applicable.

XXXVIII. PERSONNEL RECORDS:

A. A copy of the academic diploma, degree, diploma, transcript, or PSV must be kept in the laboratory for all operators of non-waived assays. The Testing Personnel Credentialing and Compensation policy and Employment Program discuss the system for reviewing and approval of PSV reports.

XXXIX. RECORD RETENTION:

A. See the Laboratory Document Management and Record Retention Procedure.

XL. REFERENCES:

A. Point of Care Testing Approval Process

B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

C. Beaumont Laboratory Clinical Pathology Carryover Worksheet RC.CH.CSL.ARC.WK.001

D. Beaumont Laboratory Clinical Pathology Quality System Document Management – QS.012
E. Beaumont Laboratory Clinical Pathology Document Management Procedure BHS-FH.QM.PY.002.
F. Beaumont Laboratory Emergency Preparedness Plan OHS.SA.EPP.PR.001
G. Beaumont Laboratory Emergency Preparedness BHS.SA.SM.002
H. Beaumont Laboratory Emergency Preparedness Plan for Minimal Staff During Epidemic RC.OP.PR.031
I. Color-Blindness Testing for Laboratory Employees
J. Laboratory Performance Guidelines for Analytical Methods
K. Laboratory Proficiency Testing
L. Quality Assurance/Quality Control Policy
M. Clinical Pathology Protocol for New Test Introduction RC.CH.LOP.QCQA.PY.004
N. Refer to the Clinical Pathology Safety Manual for more details pertaining to specimen spill cleanup.
O. Lab General Checklist, College of American Pathologists, Northfield, IL, current version.
P. Lab All Common Checklist, College of American Pathologists, Northfield, IL, current version.
Q. Lab Point of Care Checklist, College of American Pathologists, Northfield, IL, current version.
R. Skin Puncture Techniques
S. Medication Refrigerator and Freezer

Attachments

Daily QC Review in QML Reference Guide.pdf

Good Documentation Practices.pdf

Monthly QC Review in Aqure Reference Guide.pdf

Monthly QC Review in QML Reference Guide.pdf

POC Carry-over Worksheet.pdf

POC Personnel Competency Assessment.pdf

POC Quality Assurance Monthly Report.pdf

POC Quality Assurance Summary Report.pdf

POC Temperature and Humidity Log.pdf

POC Temperature Log.pdf

POC Testing Follow-up.pdf

PolicyStat Navigation Reference Guide.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	1/8/2024
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	1/3/2024
CLIA Medical Directors	John Pui: Chief, Pathology	12/26/2023
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	12/26/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	12/19/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	12/19/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	12/19/2023
	Caitlin Schein: Staff Physician	11/22/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	11/1/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	11/1/2023
	Jessica Czinder: Mgr, Division Laboratory	11/1/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne