Keywords: moderately complex, point of care testing, quality assessment

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Appendix A: Organizational Chart for Point-of-Care Testing
Appendix B: Competency Assessment
Appendix C: CAP Proficiency Schedule
Appendix D: Annual Appraisal Form
Appendix E: Trainer training and competency
I. PURPOSE

The intent of this Quality Assessment (QA) plan is to formalize and standardize the quality assurance practices at all Point-of-Care Testing (POCT) sites performing Moderately Complex assays under the oversight of The Johns Hopkins Medical Institutions Department of Pathology Point-of-Care Testing program.

Quality assurance practices refer to planned, on-going, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, mistakes are found and corrected, and areas for improvement are identified and investigated.

II. GOALS

The goal of this QA plan is to achieve excellence in clinical testing and performance by addressing the following objectives related to the pre-analytic, analytic and post-analytic processes.

<table>
<thead>
<tr>
<th>Pre-analytic</th>
<th>-Ensure sample integrity, identity and quality.</th>
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<tr>
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<td>-Ensure accurate and precise performance of the meter.</td>
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<td>-Provide training and resources to maintain and improve the skills of the staff operators.</td>
</tr>
<tr>
<td>Analytic</td>
<td>-Rapidly identify and correct problems encountered while following written procedure</td>
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<td></td>
<td>-Provide the staff with cost-efficient procedures, reagents and equipment needed to perform testing and to implement this QA plan and to meet all applicable federal, state and accreditation requirements.</td>
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<tr>
<td>Post-Analytic</td>
<td>-Ensure that records are maintained that permit the evaluation of the quality and reliability of the data produced.</td>
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<td>-Ensure the accurate transmittal of test results to the provider or associated staff performing a procedure.</td>
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<td></td>
<td>-Create mechanisms for communication of QA issues to and from the POCT office for testing personnel.</td>
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III. SCOPE

The scope of this QA plan will cover all the inpatient and outpatient areas of the JHMI that perform POC Moderately Complex testing as required by the unit’s protocol.

IV. DEFINITIONS

**Point-of-Care Testing:** Laboratory testing or services are performed outside the physical facilities of the main clinical laboratory at or near where the patient is located and do not require permanent dedicated space. It is also referred to as near patient testing, ancillary testing or bedside testing.

**Moderate Complex Testing:** CLIA-88 classifies tests according to complexity into waived and nonwaived categories. The non-waived category is further subdivided into tests of moderate and high complexity. Each specific laboratory test system, assay, and examination is graded for level of complexity by assigning scores of 1, 2, or 3 for each of seven criteria. See the following website for specific categorization information.
Testing Personnel: Staff with at least a high school diploma or certificate of equivalency and being deemed competent to perform the testing after training by the Unit Trainer.

Unit Trainer/Liaison: Is appointed by the Site Medical Director, who has responsibility over the authorized testing personnel and the testing. Should have clinical experience and understanding of the technical aspects of clinical relevance of the point-of-care test and the educational equivalence of a Technical Consultant, which is a Bachelor's degree. Ambulatory sites under their own CLIA license should have a back-up or second person with such training.

Site Medical Director: A physician (MD, DO) with a current Maryland medical license who is the Director of the Service/Unit performing point-of-care testing or designee who has supervisory authority over the Site Coordinator.

Point-of-Care Coordinator: A fully qualified Medical Technologist/Clinical Laboratory Scientist with at least 4 years experience in the discipline of laboratory testing.

V. RESPONSIBILITIES

Testing Personnel:

• Responsible for specimen processing, test performance, result reporting according to laboratory guidelines and procedure.
• Have completed the defined training requirements and can demonstrate competence.
• Have at least a high school diploma or equivalency.

Point-of-Care Coordinator

• Responsible for the technical oversight of all testing performed at the point-of-care.
• Establishes a quality control program appropriate for the tests performed.
• Establishes a training and competency program appropriate for the tests performed and the staff performing testing.
• Responsible for writing the test procedure and developing any needed logsheets, keeping the procedures and logsheets up-to-date and acquiring director’s approval and review as required.
• Resolves technical problems and ensures that remedial actions are taken whenever test systems deviate from established specifications.
• Ensures that patient results are not reported until corrective action has been taken and the test system is functioning properly.
• Evaluates the competency of the Unit Trainer/Liaison and assures that all Testing Personnel maintain their competency to perform test procedures and test results promptly and accurately. Competency is assessed using the same requirements as testing personnel in addition to the Trainer Competency Checklist. See Appendix E.
• Ensures enrollment and participation in a proficiency testing program commensurate with the testing services provided, and oversees necessary remedial action when necessary.
• Ensures that all point-of-care testing sites are performing testing according to written procedures, and are in compliance with all federal, state, and accreditation requirements.

Unit Trainer/Liaison

• Ensures functional communication between the Point-of-Care Testing Coordinator, Testing Personnel and Site Medical Director.
• Ensures Testing Personnel’s adherence to laboratory procedures.
• Maintains his/her annual competency by meeting with the POCC.
• Provides the hands-on and direct observation portion of the Testing Personnel competency. Provides copies of all training and competency materials for retention in the POCT office and maintains copies in the unit as well.
• Meets and/or communicates periodically with the Point-of-Care Coordinator to address any quality assurance or patient safety issues.
• Provides to the POCT office Laboratory Personnel Qualification sheets and education documents for all Testing Personnel.
• Ensures that all equipment is maintained and operable.
• Communicates inventory needs to the POCT office.
• At ambulatory sites under their own CLIA license, they take responsibility for ensuring the prompt analysis of samples and submission of CAP proficiency testing results before the deadline.

Site Medical Director:

• Ensures competent Testing Personnel with appropriate credentials.
• Provides consultation as to the appropriateness of the testing ordered and the interpretation of results. Is aware of all the limitations of the assay.
• Appoints a Unit Trainer/Liaison.
• Ensures functional communication with Unit Trainer/Liaison and the Point-of-Care Testing office and Directors.
• Performs an on-site annual visit to off site laboratories, providing records and minutes of activities of this visit.

VI. COMMUNICATION OF PROCEDURE CHANGES
Minor changes in operating procedures will be disseminated from the Point-of-Care Coordinator to the Unit Liaison and, in turn, to the testing personnel. The Unit Liaison will ensure that all testing personnel are aware and carry out these changes in procedure.

Major changes will result in documented retraining initiated by the Point-of-Care testing office.

The classification of change type, major or minor, will be determined by the Point-of-Care Testing office.

All testing personnel are required to attest to reading the current procedure at the time of their annual competency assessment and acknowledge responsibility for the contents of the procedure.

VII. EQUIPMENT AND CONSUMABLES
The instruments used for various Point-of-Care assays are selected after a thorough evaluation process including correlation studies with the Core Laboratory, precision and accuracy. The instruments are monitored for Quality Assurance by daily Quality Control, periodic correlations and semi-annual linearity or calibration verification testing. Quality Control records are retained for seven years. Other performance check records are retained in the POCT office for the life of the meter.

The meters will be regularly cleaned by testing personnel as per manufacturer’s instructions.

In addition to the meter, consumables may be required, such as reagents, sensors, control solutions and linearity kits.

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If the current labeling of these consumables indicates the need for refrigeration before and/or after opening, areas where the inventory is stored require a lab grade refrigerator capable of maintaining a temperature of 2-8 °C. Refrigerators are monitored by a remote monitoring system contracted by the hospital.

All new lot numbers and shipments of consumables will be checked in by the POCT office before being issued to the units for use except for the ABL 90. In the case of the ABL 90, the reagents are tracked by device and only require quality control when first installed.

Refer to the Department of Pathology policy for recording manufacturer’s updates and recalls, OPER002 Laboratory Equipment Management and Adverse Reporting:

https://hpo.johnshopkins.edu/hopkins/policies/68/4263/policy_4263.pdf?_=0.900153726995

Refer to the Department of Pathology policy for record retention, ADM005 Record and Material Retention Guidelines:

https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/39386/policy_39386.pdf?_=0.879320563195?_=0.137979030055

VIII. SUPPLY RECALL
Refer to Pathology Quality Management System QM003

http://pathology.jhu.edu/department/staff/generalpolicy.cfm

IX. PURCHASING AND INVENTORY
Inventory of most consumables is managed by the POCT office. Coagulation supplies are ordered and stored in the POCT office. Creatinine supplies are ordered and stored in the hospital Central Stores location. ABL 90 consummables inventory is managed by the users.

X. SITE REQUIREMENTS
Each unit to perform Moderate Complex testing should have a location with a cleared horizontal surface with access to electrical power and an active network jack, if needed to transmit data. In most cases, the Point-of-Care meter is hand held and can be carried to the patient’s location if needed.

XI. TRAINING AND COMPETENCY
Testing personnel will be trained by the Site Coordinator as specified by the Point-of-Care Testing office. The Unit Trainer is trained by the Point-of-Care Testing office staff. As per CLIA’88, training and competency occurs twice during the first year and annually thereafter.

Elements of competency assessment, outlined in Appendix B, include but not limited to:

- Direct observation of routine test performance, function checks and maintenance
- Review of records of test results
- Review of worksheets, QC records, PT records and maintenance records
• Problem-solving skills
• Knowledge of the procedure
• Assessment of performance through blind samples or PT samples
Testing personnel shall be required to provide a copy of either their diploma or transcript of their highest academic achievement prior to being allowed access to the test system for which they are being trained. Additionally, any potential testing personnel who have a foreign (outside of the U.S.) diploma will be required to provide a copy of the report verifying U.S. equivalency of their education prior to being allowed access to the test system for which they are being trained.

If the trainer deems that any portion of the competency assessment is performed unsatisfactorily, a correction action plan, such as retraining, must be carried out. The operator must achieve a subsequent satisfactory performance before being allowed to continue testing.

XII. HANDLING REAGENTS AND CONTROLS
To assure the quality of test results produced by the Point-of-Care meters, the following guidelines are to be followed unless tracked electronically by the device:

• All consummables shall be marked with date of receipt
• All consummables shall be marked with the date opened.
• Expired consummables may never be used for patient testing.
• All consummables shall be labeled with expiration date.
• All new lot numbers or shipments of test strips and controls are to be validated prior to being placed into service for patient testing.
• All consummables shall be properly stored according to manufacturer’s instructions.
• Material Safety Data Sheets can be found on the POCT website, http://pathology.jhu.edu/department/staff/POCT/index.cfm

XIII. PROCEDURES
Procedures or step-by-step written instructions must be made available to all staff performing testing. This will ensure that personnel know how to perform specific tasks, and testing success is not left to chance.

All Moderately Complex Test procedures are electronically available on the Department of Pathology POCT Program’s website. http://pathology.jhu.edu/department/staff/POCT/index.cfm

All Moderately Complex tests performed by the Department of Pathology POCT program are FDA approved/cleared. The manufacturer’s instructions are followed without modification.

All testing will be accomplished according to a written procedure selected, developed and optimized for each situation in advance of the actual work. Procedures will be equivalent to or exceed requirements recognized by existing state and federal regulations and will include the following criteria as applicable:

• Specimen collection, Handling and Rejection criteria
• Specimen storage criteria
• Safety
• Quality Control and Calibration requirements
• Failed Quality Control corrective action guidelines

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Subject
Quality Assessment Plan for Moderately Complex Point-of-Care Testing

• Patient test procedure
• Interpretation of results
• Limitations of test method
• Back-up method
• Criteria for referral of specimens
• References

Procedures are approved, dated and signed for use by the Laboratory Director.

All significant changes in the procedures must also be approved, signed and dated by the Laboratory Director.

Procedures must be re-approved, signed and dated if the directorship of the POCT program changes.

When a test procedure is discontinued, a copy of the procedure with the dates of initial use and discontinuance must be retained for two years.

XIV. SPECIMEN INTEGRITY
Analysis of specimens for diagnostic, therapeutic or clinical management requires that the specimen must always be unequivocally identifiable, adequate and reflective of the clinical condition in question. If a specimen does not meet such criteria, it should not be tested as the data is misleading and may result in inappropriate treatment or management of the patient.

The patient needs to be properly identified using a minimum of two identifiers (neither to be the room location) prior to collecting the specimen. The identification should be actively identified instead of passively, i.e. ask the patient to state his/her name and birth date. Accompanying requisitions and paperwork are verified for correct patient information.

The specimen must be collected in a manner specified by the test procedure.

XV. ANALYTICAL METHOD
The analytical methods utilized in point-of-care testing have been validated through the process of method verification. Method verification is a series of exercises that the laboratory undertakes to ensure a document that a method is working properly in its laboratory setting and enables the laboratory to make decisions on how to manage the method. The laboratory verifies the manufacturer’s performance specifications and any other relevant claims before initiating patient testing in the following applicable characteristics:

• Accuracy
• Precision
• Analytical sensitivity
• Analytical specificity
• Reportable range of patient results
• Reference range
• Calibration and control procedures

The Laboratory Director reviews the validation studies and approves each test for clinical use. This review and approval is documented by the director’s signature on a summary statement kept on file with the validation studies.

Where the manufacturer provides documentation of analytical interferences, those references are included in the test procedure.
XVI. QUALITY CONTROL

Each testing site will run the Quality Control as described in the specific Quality Control procedures.

All control results and remedial actions must be recorded and records kept on site for a minimum of two years and a total of seven years in long-term storage.

Quality control is to be performed only by the staff who performs the patient testing and should be rotated among that staff.

Test results can only be released when the quality control results are acceptable.
### XVII. EXTERNAL ASSESSMENTS

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<tr>
<th>QA Activity</th>
<th>Description</th>
<th>Follow-up</th>
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<tbody>
<tr>
<td>Proficiency Testing</td>
<td>Each test system that is not routinely correlated with the Core Laboratory must participate in a CLIA-approved proficiency testing program. If the program consists of testing commercially prepared survey specimens, these samples must be tested with the site’s regular patient workload by personnel who routinely perform the testing, using the site/s routine test method. The results must be submitted to the proficiency testing organization within a defined time period. These results are evaluated by the proficiency testing organization, who determines the acceptability of the results. The Laboratory Medical Director and the POCT Coordinator must review, sign and date the attestation page of the proficiency testing results summary report. The proficiency testing result summary reports and corrective actions are retained for a minimum of 2 years. See Appendix C for the proficiency schedule. Refer to the Proficiency Testing Policy</td>
<td>Corrective action is taken for any unacceptable results.</td>
</tr>
<tr>
<td>CAP Accreditation Surveys</td>
<td>Moderate Complex Point-of-Care Testing is reviewed every two years beginning in 2009 as part of the CAP Laboratory Accreditation Survey. Each testing site has the potential for an on-site review. These surveys are unannounced. Additionally, a self-inspection is performed in the interim year. Results of this inspection are reported to CAP.</td>
<td>Corrective action plans must be submitted if any deficiencies are identified.</td>
</tr>
<tr>
<td>State of Maryland</td>
<td>Unannounced on-site surveys may also be conducted by the State of Maryland when there is a complaint to investigate, to periodically assess compliance with state regulations or for CLIA validation.</td>
<td>Corrective action plans must be submitted if any deficiencies are identified.</td>
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### XVIII. INTERNAL ASSESSMENTS

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<tr>
<th>QA Activity</th>
<th>Description</th>
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### Subject
**Quality Assessment Plan for Moderately Complex Point-of-Care Testing**

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<tr>
<th>Site visit</th>
<th>On a regular basis, a Point-of-Care Coordinator visits each site performing Moderate complex testing to assess its compliance with stated procedures, CAP standards and the State of Maryland regulations. Refer to MODCO 005 Daily Review of Moderate Complex Sites procedure.</th>
<th>The Unit Trainer/Liaison is notified if any corrective measures are warranted. This review identifies opportunities for improvement for the testing site.</th>
</tr>
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<tr>
<td>Patient Correlations</td>
<td>When the same analyte is tested using different methodologies, instruments, or at different sites, the laboratory must have a system in place to evaluate and correlate the relationship between, or among, the results at least once every six months.</td>
<td>The POCT Coordinator identifies meters that are potential outliers, investigates and follows up.</td>
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<tr>
<td>Patient Tracer</td>
<td>Where results are manually entered in to the electronic patient record, periodically randomly selected patient records are traced from their test results on the POCT meter to the permanent record.</td>
<td>The POCT Coordinator identifies clerical or systematic errors, determines the cause and rectifies by making changes in the system or counseling personnel.</td>
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<tr>
<td>Environmental Rounds</td>
<td>Environmental Monitoring Rounds are conducted by the Johns Hopkins Department of Health, Safety and Environment twice a year in clinical areas to assess compliance with the Institution’s safety policies, as well as with federal, state and local safety regulations. These surveys are unannounced.</td>
<td>A corrective action plan is required to be submitted to the Department of Health, Safety and Environment when deficiencies are identified.</td>
</tr>
<tr>
<td>Mock CAP surveys</td>
<td>The Department of Pathology Continuous Quality Improvement Office periodically conducts mock surveys of testing sites to assess compliance with the current CAP standards.</td>
<td>Corrective action plans must be submitted to the CQI Office when areas of improvement have been identified.</td>
</tr>
<tr>
<td>Quality Control Review</td>
<td>Monthly Quality Control results are reviewed and assessed for trends or shifts in the test system's performance.</td>
<td>The POCT Coordinator identifies and addresses test system trends indicated by the QC Performance review.</td>
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</table>
XIX. PERFORMANCE IMPROVEMENT
Performance Improvement initiatives are implemented when potential problems or areas of improvement are identified by assessment activities or by user or physician complaints. An on-going mechanism is developed to monitor, assess and correct the identified issue.

XX. REMOVAL OF TESTING
Testing may be removed from a site, if the site repeatedly fails to take corrective action despite efforts by the POCT Program Office to assist them, and all courses of action have been exhausted.

Testing may also be removed from a site if the site is unsuccessful in proficiency testing performance for the same analyte in two consecutive testing events or two out of three consecutive testing events.

XXI. COMMUNICATIONS
Problems with a device or procedure should be reported to the POCT Site Coordinator. If unable to reach a resolution, contact POCT personnel by telephone at 5-2645 or by e-mail POCTGroup@exchange.johnshopkins.edu during office hours. For unresolvable emergency issues that occur off hours, the POCC on-call can be contacted via the Corus system, POCT Consult. Refer to POCTM028 for details.

XXII. PATIENT SAFETY EVENTS
Each test procedure includes steps to ensure the safety of the patients and operators for which each operator is responsible.

In addition, the POCT office, through the Continuous Quality Improvement division, utilizes the web-based institutional HERO system to monitor and report events related to point-of-care services. All events that involve patient safety, actual or potential, can be reported in this system. These reported events are investigated and addressed.

Patient safety concerns are a standing agenda item on the POCT bi-weekly staff meeting.

XXIII. RECORDS
Records are generated by capturing process or procedure output data on forms. A completed form is a record of activities performed. Records are the heart of any Quality Assessment program because they document every aspect of laboratory activities. The attitude taken by most accrediting and inspecting agencies is that "if you did not document it, then you did not do it."

For manually recorded records:

- Data will be recorded on log sheets using permanent ink. Pencils, correction fluid and tape are not permitted. If an error is made, simply draw a single line through the erroneous data and write the correct data above or beside the mistake along with your initials and the date.
- Dates are to be recorded in the MM/DD/YY format. The year must be included when recording the date because of the length of time for record retention.
- A list identifying staff members who perform laboratory testing is to be maintained that includes their signatures and initials.
- Refrain from using ditto marks or arrows to replicate information; each space is required to be filled in with the requested information.
- Data recorded on log sheets must be legible and complete.
- It is the responsibility of the testing personnel to keep all records current.
• Unauthorized changes to, loss of, or destruction of records is prohibited.
• In view of the possible legal use of some of the data, all records shall be maintained in such a way as to maintain credibility at all times.
• Paper records pertaining to POCT testing are retained in electronic format on the POCT server.
• The POCT Coordinator is responsible for reviewing records regularly and at random to determine that the expected outcomes/results were obtained and detect and identify problems with the procedure.

Electronic records

• Devices that transmit results electronically are supported by the Cloud-based Telcor QML system. This system tracks Quality Control, Linearity, validation as well as patient data.
• The patient data is transmitted from QML via the Core Laboratory data management system to the Epic electronic patient record Lab page.
• The POCT office monitors the QML system to verify successful transmission of data to the patient record.

XXIV. CUSTOMER SERVICE AND SATISFACTION
Once a year a customer satisfaction survey will be designed and distributed among a sampling of POCT operators. Results will be collated and analyzed to identify areas of concern and need for improvement. Topics to be surveyed may include communication, training, result confidence, support.

XXV. INFORMATION MANAGEMENT
The information management system in use for the transmission of POCT results is the Cloud-based Telcor QML system. In addition, the POCT Office performs the following duties:

• Trains new operators and allows access only to those it approves as authorized users.
• Perform a tracer annually to access the integrity and accuracy of data transmission.
• Bi-annually, the director reviews and approves all electronic data reports as outlined in the procedure POC4-502 Laboratory Director Review of Patient Report Formats

XXVI. ANNUAL APPRAISAL
Once a year, the effectiveness of this QA Plan and any associated monitors or indicators will be assessed. The assessment will result in a written report that will be reviewed with staff and management. The need to adjust the plan and monitors will be decided as a result of this assessment and review.

XXVII. RELATED DOCUMENTS
The Johns Hopkins Hospital Interdisciplinary Clinical Practice Manual, The Point-of-Care Testing Policy PAT 056

Johns Hopkins Pathology Department General Policy Manual http://pathology.jhu.edu/department/generalpolicy.cfm

Hopkins Policy Online QM 003
XXVIII. SPONSOR AND DEVELOPER

Sponsor:
Pathology Performance Improvement

Developer:
Point of Care Testing Office

Review Cycle: One (2) year

XXIX. SIGNATURES

Revision History:

- 10/31/19 - Small edits were made to update the appendices.
- 5/24/24 - No edits made to body. Appendix A updated to current Organizational chart.

Reviewed by Laboratory Director:

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<td>William Clarke</td>
<td>09/21/2022</td>
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<td>PhD, Section Director</td>
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