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.

Goals

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

| Pre-analytic | - Ensure sample integrity, identity and quality.  
| - Ensure accurate and precise performance of the meter.  
| - Provide training and resources to maintain and improve the skills of the staff operators.  

| Analytic | - Rapidly identify and correct problems encountered while following written procedure  
| - 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.  

| Post-Analytic | - Ensure that records are maintained that permit the evaluation of the quality and reliability of the data produced.  
| - Ensure the accurate transmittal of test results to the provider or associated staff performing a procedure.  
| - Create mechanisms of communication of QA issues to and from POCT office to testing personnel.  

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.

Definitions

**Point-of-Care Testing**
Laboratory testing or services that 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.
http://www.fda.gov/cdrh/clia/categorization.html/
Testing Personnel
Staff with at least a high school diploma or certificate of equivalency and been deemed competent to perform the testing after training by the Unit Trainer.

Unit Trainer/Liaison
Is appointed by the Site Medical Director, 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.

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 disciplines of laboratory testing.

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.
- 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 training and competency for all Testing Personnel. Provides copies of all training and competency materials for retention in the POCT office and maintains copies in the unit as well.
- Maintains a current and up-to-date organizational chart which lists the current Site Medical Director, Unit Trainer/Liaison and all currently trained and competent Testing Personnel.
- Meets and/or communicates periodically with the Point-of-Care Coordinator to address any quality assurance issues.
- Provides to the POCT office Laboratory Personnel Qualification sheets for all Testing Personnel.
- Ensures that all equipment is maintained and operable.
- Communicates inventory needs to the POCT office.

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.

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.

Equipment and Consummables

The instrument used for various Point-of-Care assays are selected after thorough evaluation process including correlation studies with the Core Laboratory, precision and accuracy. The instruments are monitored for Quality Assurance daily by two levels of
Quality Control, monthly 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 Test strips or cuvettes, Control Solutions and linearity kits

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 temperature at 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 issued to the units for use.

**Supply recall**
Refer to Pathology Quality Management System QM003

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

**Purchasing and Inventory**
Inventory of the 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.

**Site requirements**
Each unit to perform Moderate Complex testing should have a location with a cleared horizontal surface with access to electrical power. In most cases, the Point-of-Care meter is hand held and can be carried to the patient’s location if needed.

**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 include but not limited to:

- Direct observation of routine test performance
- 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

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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:

• All consummable 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://pathology2/pointofcare/poct/](http://pathology2/pointofcare/poct/)

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://pathology2/pointofcare/poct/](http://pathology2/pointofcare/poct/)

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
• 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 at least annually by the Director of the Point-of-Care Testing Program or designee.

All changes in the procedures must also be approved, signed and dated by the Director of the Point-of-Care Testing Program or designee.

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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.

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.

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 an 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

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.

**Internal Assessments**

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<tr>
<th>QA Activity</th>
<th>Description</th>
<th>Follow-up</th>
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<tr>
<td>Site visit</td>
<td>On a regular basis, at least twice per week, 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 POC3-215 Daily Review of Moderate Complex Sites procedure.</td>
<td>The Unit Trainer/Liaison is notified if any corrective measures are warranted. This review identifies opportunities for improvement for the testing site.</td>
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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>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>
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<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>
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External Assessments

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<td>Proficiency Testing</td>
<td>Each testing site 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. Refer to <a href="http://pathology.jhu.edu/department/General-Policy/PT-Policy.pdf">http://pathology.jhu.edu/departmen...</a></td>
<td>Corrective action is taken for any unacceptable results.</td>
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<tr>
<td>CAP Accreditation Surveys</td>
<td>Moderate Complex Point-of-Care Testing is reviewed every two years beginning 2009 as part of the CAP Laboratory Accreditation Survey. Each testing site has the potential for an on-site review. These surveys are unannounced.</td>
<td>Corrective action plans must be submitted if any deficiencies are identified.</td>
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<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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</table>

Performance Improvement

Performance Improvement initiatives are implemented when potential problems or areas of improvement are identified by assessment activities or by user or physician complaint. An on-going mechanism is developed to monitor, assess and correct the identified issue.

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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.

Communications  Whenever an error or problem occurs that needs to be communicated to POCT Site Coordinator, the issue should be documented in the Communication and Problem Log. Information should include the problem, personnel involved and resolution. In addition, POCT personnel may be reached by telephone at 5-2645 or by e-mail POCTGroup@jhmi.edu.

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 Patient Safety Net (PSN) 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 the PSN system. These reported events are investigated. The responses are subsequently documented in the PSN system.

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

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.”

- 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.
- Areas that generate electronic data print a daily report of patient data that is reviewed by POCT staff. Similar retention times apply to electronic data.
• 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.
• Records pertaining to laboratory testing are to be retained on-site for a minimum of two years.
• Long-term storage of records is up to seven years and handled by the Iron Mountain Company. Stored records can be retrieved within 24 – 48 hours.
• The POCT Coordinator is responsible for reviewing records each day of testing to determine that the expected outcomes/results were obtained and detect and identify problems with the procedure.

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.

Information Management
The information management system in use for the transmission of INR results has been developed by the Pathology Data Systems group and is under their purview for quality management and compliance with HIPAA. 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

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.

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

Appendix
Appendix A: Organizational Chart for Point-of-Care Testing
Appendix B: Competency assessment
Appendix C: Completion dates
Appendix D: Annual Appraisal form
Organizational Chart for Point-of-Care Testing

Director/Department Chair
Dr. Brooks Jackson

Deputy Director Clinical Affairs
Dr. Michael Borowitz

Assistant Director
Continuous Quality Improvement
Barbara Parsons

Division Clinical Director
Core Lab
Dr. Daniel Chan
Dr. Thomas Kickler

Associate Clinical Director
William Clarke, PhD

Point-of-Care Testing

Appendix A
## Competency Assessment Tools
### For Moderately Complex Testing

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<th>CLIA 88 Competency Element</th>
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<td>1 – Direct observation of patient testing</td>
<td>Annual competency checklist performed with the unit trainer</td>
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<td>2 – Monitor the recording of test results, CAV’s</td>
<td>Rounds</td>
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<td>Random chart reviews</td>
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<td>3- Monitor of intermediate test results; QC, wkshts, PT, maintenance</td>
<td>Rounds</td>
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<td>4 – Direct observation of maintenance and function checks</td>
<td>Annual competency checklist performed with the unit trainer</td>
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<td>5 – Blind samples</td>
<td>Proficiency testing and correlations</td>
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<td>6- Assessment of problem solving skills</td>
<td>Annual test specific quiz</td>
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Annual Appraisal of the Quality Assessment Plan for Moderately Complex Point-of-Care Testing
POC1-013F1

Date of Appraisal:
Appraisal Team:

QA Initiatives Undertaken since last appraisal:

QA Initiatives Update:

Summary and Trending of Complaints, Incidents, Accidents:

Review of Twelve Elements of QM:

1. Review of Organization – Have there been organizational changes or key admin personnel changes?

2. Review of Personnel Resources – Have there been changes to the employee training and competency programs? Are personnel records up to date?

3. Review of equipment – Have there been any implementation of new instrumentation? Have validation studies been completed and approved?

4. Review of suppliers and customers - Have there been any changes related to inventory control or back-order issues? there Review of Procedures – Are all procedures up to date and reviewed?

5. Review of documents and records – Have there been any problems related to document control?

6. Review of Occurrence Management – Wee there any trends noted in relation to occurrences or non-conformities?

7. Review of Assessments and Audits – Have all assessments and audits been completed according to their specified times?

8. Are there any outliers that need to be addressed?

9. Review of Process Improvements – What process improvements were implemented? Successful?

10. Review of facilities and safety – Were any safety issues or facilities issues identified and corrected?
11. Review of Information Management – Were there any substantial changes to the LIS or patient reporting? Were there any recurring LIS problems?

12. Review of Customer Service and Satisfaction – Has the satisfaction of customers been sampled during the year? Were there any problems or opportunities discovered?

Assessment of QM Monitors/Indicators:

Monitor 1:
Threshold:
%Threshold Met:
Corrective Actions initiated:

Keep Monitor? Yes No
Future actions planned:

Monitor 2:
Threshold:
%Threshold Met:
Corrective Actions initiated:

Keep Monitor? Yes No
Future actions planned:

Changes being made to the QA Plan based on this assessment:

Date QA Plan reviewed by the Laboratory Director:

Appendix D
# Quality Assessment Plan for Moderately Complex Point-of-Care Testing

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<tr>
<th>Name</th>
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<td>Lois Phelan, M.T. (ASCP)</td>
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<td>1/7/2009</td>
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**Approvals:**

- **POCT Director:** William Clarke, PhD

**Issued:**

**Effective:**

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The Johns Hopkins Hospital
Baltimore, Maryland