DESCRIPTION/OVERVIEW

- The Point of Care Testing (POCT) program, or near patient testing, is established to ensure regulatory and accreditation compliance of laboratory POCT for quality results; standardization of test methodology, reagents and instrumentation; and cost effective patient care. To meet accreditation standards, it provides: (1) a consistent method for validation and implementation of new POCT or equipment, (2) review of ongoing procedure performance as measured by proficiency testing, quality control, mock surveys and semiannual comparison studies to a reference method, and (3) assistance with employee training, initial and annual competency testing. POCT staff will assess new methods/equipment and recommend preferred choice to the University of New Mexico Hospitals (UNMH) POCT Advisory Committee.

- The POCT program assists department managers at multiple testing sites at the UNMH Hospital, UNM Cancer Centers, University Psychiatric Center, Children’s Psychiatric Center, and the UNMH ambulatory clinics to maintain compliance with the various regulatory and accreditation agencies. This includes but is not limited to the College of American Pathologists (CAP), The Joint Commission (TJC), and Clinical Laboratory Improvement Amendments (CLIA). This involves multiple CLIA certificate and varying levels of test complexity from waived to non-waived, including Provider Performed Microscopy (PPM).

REFERENCES

- CAP All-Common Checklist, July 28, 2015

AREAS OF RESPONSIBILITY
The Point of Care Testing (POCT) Quality Assurance Procedure is applicable to every person and department performing point of care testing.

PROCEDURE

1. Implementation of Point of Care Testing
   1.1. The POCT Advisory Committee consists of representatives of University Hospital administration, pathologist, clinicians, hospital departments and TriCore Point of Care Testing department.
   1.2. The department requesting new POC testing must submit an application to the POCT department and sign the University Hospital’s POCT Compliance Agreement Form before any testing will be considered for approval. Forms are available from the POCT office.

   1.3. Several considerations must be taken into account before a new test method is put in place and may include and not limited to:

      1.3.1. Cost effectiveness;
1.3.2. Effect on patient care and outcomes;  
1.3.3. Appropriateness for given site, test and patients;  
1.3.4. Standardization with current method(s) of analysis;  
1.3.5. How results will be documented, tracked and billed;  
1.3.6. Who will be responsible for assuring compliance with all applicable regulatory and accreditation requirements; and  
1.3.7. Compliance with present or previous testing.  
1.4. Once the department has been approved for testing they will coordinate with the POCT office for validation of the instrument(s), training, quality control logs, and a CLIA license if needed.  

2. Procedure Manual  
2.1. Policies and procedures applicable to POCT users are available on The University of New Mexico Hospitals’ intranet under Policies and Procedures. Each test is listed separately.  
2.2. A complete hardcopy procedure manual is available in the POCT office. The POCT Medical Director/Designee and the UNMH POCT Advisory committee review and approve all new policies and procedures as well as substantial changes to existing procedures.  
2.3. Procedures are written to meet CAP, CLIA, and TJC regulatory requirements.  
2.4. The POCT Director/Designee reviews and approves all policies and procedures bi-annually.  
2.5. If there is a change in Medical Directorship, the new Medical Director ensures (over a reasonable period of time) that POCT procedures are well documented and undergo at least bi-annual review.  
2.6. Each test’s Online Course in Learning Central (LC) contains an acknowledgement for the testing personnel to indicate they have read and understand the appropriate procedure.  
2.7. It is the Department Manager’s responsibility to ensure that their personnel comply with the testing procedures.  
2.8. If a procedure is discontinued, a copy will be maintained for two years in the POCT office. The procedure will contain the date that it was taken out of use.  

3. Competency  
3.1. Only competent operators are permitted to perform POCT.  
3.2. Competency will involve a training session with an identified trainer, which will include the completion of the appropriate online course in Learning Central with a written exam and proper skills demonstration recorded into Learning Central.  
3.2.1. Testing personnel performing non-waived testing are required to be trained initially and have competencies completed during the first year (semi-annual) and annually thereafter.  
3.2.2. Testing personnel performing waived testing are required to be trained initially and have competency assessed annually thereafter.  
3.3. Trainers will include:  
3.3.1. POCT Coordinator or POCT Staff  
3.3.2. Unit based educator (UBE).  
3.3.2. Manufacturer technical personnel.  
3.3.3. Trained hospital staff.  
3.3.4. Trainers observing nonwaived skills must qualify as Technical Consultants under CLIA 88; they must have a Bachelor’s degree in a biological, chemical or physical science and 2 years relevant experience.  
3.4. For those testing personnel performing nonwaived testing, a diploma of their highest level of education must be kept in their file (HR and/or testing unit). A high school diploma or equivalent is the minimum qualification. Submission of diploma must be recorded in Learning Central (LC) before the relevant LC test program can be assigned.
3.5. Testing personnel will be assigned the Initial course and skills for each test they are trained for by the POCT staff when attending a scheduled new hire training class.
3.5.1. POCT staff will record the initial skills in Learning Central (LC).
3.5.2. Each department will be responsible to assign online POC course(s) and assess and record the annual skills in LC when due.

3.6. Each department will be responsible for assigning the online course (with exam), training, assessing, and recording the observed skills in LC for any additional POC testing not included in the initial new hire orientation.
3.7. Each department will be responsible for assigning the annual online course with exam, assessing skills and recording them in LC for all POC tests performed as appropriate for the testing performed.
3.8. Provider Performed Testing
   3.8.1. When a LIP (licensed independent practitioner) performs waived testing that does not involve an instrument and the test falls within his or her specialty, they document evidence of training and competency through the credentialing and privileging process.
   3.8.2. During the credentialing and privileging process the provider will identify the microscopic tests that they perform, if any.
   3.8.2.1. The provider will be assigned to the University of Washington’s Medical Training Solutions (MTS) online competency assessment program for microscopic tests they perform. They will be assigned competencies twice a year.
   3.8.3. Providers performing testing that involve an instrument will be required to complete training and competencies as stated in 3.2.

4. Patient and Specimen Management
   4.1. Patient Identification
      4.1.1. Proper patient identification is essential to labeling and testing of specimens and documentation of results to the correct individual’s medical record.
      4.1.2. Identification of patients will be in compliance with University Hospital Patient Identification Procedure.
   4.2. Patient Preparation
      4.2.1. Criteria for the preparation of patients depend on the type of testing to be performed. This information is outlined in the individual procedure.
   4.3. Specimen Collection and Labeling
      4.3.1. Standard Precautions apply to collection of specimen and testing for all point of care tests.
      4.3.2. Appropriate personal protective devices must be worn when collecting specimens and performing tests.
      4.3.3. Specimens should be collected per hospital protocol. Special considerations are outlined further within the individual procedures.
      4.3.4. Each POCT test that is implemented will be reviewed to assure that the minimum amount of blood is taken from patients for that test.
      4.3.5. In the event that POCT is not performed at the patient’s bedside, the specimen must be labeled according to the University Hospital Specimen Labeling Procedure.
      4.3.6. Only auto-disabling single-use lancet devices are used for capillary collection for POC testing.

5. Quality Control
   5.1. Quality Control (QC) is utilized to assure that:
5.1.1. Equipment is functioning accurately and precisely;
5.1.2. Operators are capable of using the equipment to produce accurate patient results; and
5.1.3. Reagents used are valid and produce acceptable patient results for each analyte.
5.2. Regulations require that control specimens are to be tested in the same manner and by the same personnel as would test patient samples.
5.3. The frequency and type of controls are outlined in the individual procedures and can include both electronic and liquid quality control materials.
   5.3.1. All QC must be properly documented, including procedural, electronic, or liquid QC by testing personnel. Depending on the test method, QC will either be stored electronically or manually.
   5.3.2. QC results are verified for acceptability by testing personnel before reporting patient results.
5.4. The acceptable range for liquid QC will be established or verified by POCT office where those limits are statistically valid.
5.5. If QC results exceed the acceptable range, the testing personnel will investigate. Immediate actions include (but not limited to):
   5.5.1. Ensure the procedure was performed correctly,
   5.5.2. Reagents and quality control were not expired, and
   5.5.3. Instrument is clean.
   5.5.4. Document corrective action on the QC log or instrument. Repeat quality control testing. If the controls are within the acceptable range, proceed with patient testing. If the controls are out of acceptable range, contact the POCT department for further assistance and troubleshooting.

6. Quality Management
   6.1. The POCT department is responsible for the review of monthly QC records and they are retained for two years in the POCT office.
   6.2. For POC testing that cannot be programmed to stop patient testing when QC has not been performed or has failed, written QC logs will be graded. This grading will include successful and complete QC performance at required intervals with all required elements of QC testing documented on the log.
   6.3. QC compliance reports will be submitted to the University Hospital POCT Advisory Committee, UH Quality department, and TriCore RRL Quality Division.
   6.4. When any POCT site performs below the 94% threshold as established by the POCT Advisory Committee for QC compliance, the department manager is notified of the problem by the POCT Coordinator, with the intent that early notification will lead to an early return to compliance.
   6.5. If compliance falls within any of the following criteria, the department manager is notified that a written action plan be submitted to the UH POCT Advisory Committee:
      6.5.1. 1 month at or below 75%;
      6.5.2. 2 months out of 6 months below 85% compliance;
      6.5.3. 3 months out of 6 months below the 94% compliance standard; or
      6.5.4. QC result is out of accepted range and no trouble-shooting occurred before patient testing.
      6.5.5. QC not performed when required.
   6.6. The written action plan must be submitted to the POC Advisory Committee within two weeks of receipt of notification. The action plan must outline how the error will be corrected. It must be of sufficient detail that the UH POCT Committee can assume it will work.
6.7. A representative of the department is invited to present the written action plan at the next POCT Advisory Committee meeting.

6.8. If no written action plan is submitted to POCT, this could indicate that the department no longer desires to perform POC testing. The POCT Advisory Committee will recommend to the Hospital Administration that the area be disallowed from performing testing.

6.9. If compliance remains below 94% on subsequent evaluations the POCT Advisory Committee will take action up to and including recommendation to the Hospital Administration that the area be disallowed from performing testing.

6.10. If the testing site requires a second Action Plan within 6 months of a previous Action Plan request, the site will be placed on probation for 1 month.

6.10.1. QC will be reviewed by the POCT staff closely through the probation period.

6.10.2. At the end of one month the POCT Advisory Committee will review data and decide to reinstate the site to normal operating status or recommend to the Hospital Administration that the area be disallowed from performing testing.

6.10.3. Testing may be reinstated for a second probationary period if the site petitions the Committee with an approved Action plan.

7. **Mock Surveys**

7.1. When appropriate, POCT staff performs mock inspections with tracers in the hospital units and clinics. The mock inspections are based on TJC, CAP, and CLIA standards.

7.2. POCT staff interview testing personnel concerning how testing is performed and charted. Reagents are inspected for storage and expiration dates requirements. Employee competencies are reviewed for completeness.

7.3. Chart audits are conducted for review of accuracy and that results are accompanied by normal reference ranges.

7.4. Summaries of the tracer are emailed to the unit director or clinic manager with recommendations and action items.

7.5. The written action plan must be submitted to the POC Advisory Committee within two weeks of receipt of the notification.

7.6. If no written action plan is submitted this could indicate that the department no longer desires to perform point of care testing.

8. **Proficiency Testing**

8.1. All POCT that is recognized under the Tricore University Hospital Rapid Response Laboratory’s CLIA certificate and CAP accreditation must participate in proficiency testing if that testing is considered the primary method for that test.

8.2. This program involves running unknown samples by testing personnel that are obtained from a CAP-approved proficiency testing provider multiple times per year. The POCT office will coordinate the Proficiency Testing and track performance of the testing sites.

8.2.1. Alternative testing material or chart review may be used to establish proficiency if testing material is not commercially available.

8.3. Testing personnel are randomly selected to participate in each challenge.

8.4. Proficiency testing specimens are to be integrated into the routine workload, analyzed by personnel who routinely test patient samples, and use the same primary method system as for patient samples.

8.5. The POCT Department will manage the distribution of proficiency samples, the submission of completed proficiency testing, and record retention of completed worksheets.

8.6. The Medical Director for POC Testing or designee will review and sign-off on all survey results and alternative performance assessment results.

8.6.1. The POCT office will investigate any unacceptable results and document problem resolution.
9. **Equipment**
   9.1. Only equipment and reagents that have been approved by the POCT Advisory Committee may be used to perform any POCT.
   9.2. All POCT instruments and testing supplies are to be purchased through vendors approved by the UNMH Product & Standards Committee.
   9.3. Prior to implementation, each POCT method must be validated using established laboratory protocols.
   9.4. If an instrument is malfunctioning, call the POCT. **Do not use the instrument for patient testing until the issue has been resolved.**
   9.5. When an instrument is removed due to malfunction, the POCT department or University Hospital Clinical Engineering department will keep a log of all repairs.

10. **Reagents**
   10.1. The individual procedure guidelines will outline the appropriate reagents to be used with the test system. No substitutions may occur unless authorized by the POCT department.
   10.2. The storage requirements will be based on the manufacturer’s guidelines listed on the package insert.
   10.3. All reagents will be used within the valid expiration date.
   10.4. Multiple components of a reagent kit are to be used only within the same kit lot unless otherwise specified by the manufacturer.

11. **Results**
   11.1. All patient results must be recorded in the patient’s medical record with the testing personnel’s name or initials and date and time of the test.
   11.2. Results that do not automatically electronically chart need to be entered in the patient electronic medical record by Ad Hoc/I View or by scanning in paper testing logs.
   11.3. The person recording the result is to double check for clerical errors. Any results that are not consistent with the patient’s presentation must be documented by testing personnel. Any pattern of inconsistency should be discussed in a timely manner with the TriCore POCT Department. Corrective action will be taken and documentation of all incidents will be retained.
   11.4. All results that are outside of the expected or normal range are immediately reported to the nurse and/or physician caring for the patient. If unexpected results are obtained the testing personnel should repeat testing or send a specimen to the lab.
   11.5. The treating provider has discretion to choose if critical values should be repeated by the laboratory reference method. Normal ranges are posted within the individual procedures.
   11.6. Reference intervals for each analyte tested have been established or verified for the population being tested, when applicable.
   11.7. Critical limits are established for the results of certain tests and are listed in the critical range section of each individual procedure.
   11.8. All critical values must be reported immediately by testing personnel to the physician or clinical personnel responsible for the care of the patient. Documentation should be placed directly in the patient’s chart. The information should contain the result, date and time of the test, operator identification, patient medical record number, personnel notified, and any corrective action.
   11.9. Periodic random chart audits will be performed by POCT staff on selected POC tests to review results for analytical or obvious clerical errors. When possible, chart results will be compared to internal instrument records or worksheets for each audit. Any discrepant audit results will be reported to the unit director.
   11.10. Common interferences for all analytes are included within each individual procedure.

12. **Record Retention**
12.1. All documentation is centrally maintained in the POCT Office.
12.2. All records are kept for a minimum of two years.

13. **Contact Information**

13.1. The POC Department is available on all shifts to assist with troubleshooting or other unusual situations. Contact information is available on the hospital intranet or in the glucose carrying cases.

14. **Safety**

14.1. All personnel are trained in safety during their orientation and on an annual basis thereafter.
14.2. Material Safety Data Sheets are available online to all employees for all POCT reagents.
14.3. Safety Manuals are available online for all employees.

**SUMMARY OF CHANGES**
Replaces POCT Quality Assurance Program, 5/12/14.
Global changes for updated regulatory verbiage; colorblindness testing deleted; Proficiency Testing changed to include only POC tests that are considered as “primary instruments or methods” in the hospital; added Learning Central course to document diplomas on file for nonwaived testing staff; deleted the requirement for the Local Designee form; deleted the 6 month competency requirement for Waived Testing; added Technical Consultant definition and requirement for nonwaived test trainers; made specific references more generic as they are subject to change without impacting the policy.

**RESOURCES/TRAINING**

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**DOCUMENT APPROVAL & TRACKING**

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