Every patient deserves the GOLD STANDARD ...

Point-of-Care-Testing Checklist

CAP Accreditation Program

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07.28.2015
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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-LAB Solutions. They are available in different checklist types and formatting options, including:

- **Master** — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- **Custom** — customized based on the laboratory’s activity (test) menu; available in PDF, Word/XML or Excel formats
- **Changes Only** — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

### SUMMARY OF CHECKLIST EDITION CHANGES

**Point-of-Care-Testing Checklist**  
**07/28/2015 Edition**

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. **New**
2. **Revised:**
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. **Deleted/Moved/Merged:**
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

*NOTE: The listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.*

#### NEW Checklist Requirements

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#### REVISED Checklist Requirements

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INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a point-of-care testing laboratory section or department.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

DEFINITION OF POINT-OF-CARE TESTING

Point-of-Care Testing (POCT) is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at the site (e.g., capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space; these are covered under the Limited Service Laboratory Checklist.

APPLICABILITY

This checklist must always be accompanied by the Laboratory General, All Common, and Team Leader checklists, as these checklists apply to all laboratory activities, whether occurring in dedicated space or not.

This checklist covers tests that are classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests). It may also be used to inspect FDA-cleared/approved point-of-care tests that are modified by the laboratory. Modified FDA-cleared/approved tests are subject to the nonwaived checklist requirements and high complexity personnel qualifications.

The requirements in this checklist for quality control and calibration are different for waived testing, as compared to nonwaived testing; please refer to the relevant individual checklist sections for further details. Checklist requirements for quality management, results reporting, instruments and equipment, and safety are the same for both waived and moderately complex tests.

Tests and instruments that are NOT covered by the POC checklist include all tests classified under CLIA as high complexity, as well as legal drug testing, multichannel blood cell counters, bacterial cultures, and tests that use instruments requiring high levels of maintenance or technical skill. The CAP central office may be contacted for information about whether a specific test or instrument may be inspected using the POC Checklist.

If a POCT site has a scope of service in a particular laboratory discipline that exceeds those addressed in this checklist, then a section-specific checklist (e.g. Hematology, Microbiology) may be required.

This checklist does not cover patient self-testing. The CAP Laboratory Accreditation Program does not inspect or accredit patient self-testing.

PRINCIPLES OF POCT OPERATIONS
To be accredited, all analytes being measured under the POCT program/site must be included in the on-site inspection. POCT programs may be inspected as sections of the central laboratory if they are registered under the same CLIA number. In this circumstance, they are included in the Laboratory General and Team Leader checklists used for the central laboratory. If the POCT sites are registered under separate CLIA numbers, separate Laboratory General and Team Leader checklists must be completed for each POCT program. The POCT program may be centrally coordinated, with designated qualified personnel who review testing procedures and quality control, and conduct training of the testing personnel, although this is not a requirement.

When records are maintained centrally by a designated coordinator or POCT Director, only one copy of this Point-of-Care Testing Checklist need be completed. The Inspector will review all centrally maintained records and visit at least a sampling of the testing sites in order to evaluate compliance with the Standards. If records are not maintained centrally, the Inspector must visit each POCT site, and a separate Checklist must be completed for each location. In the latter case, each POCT site will be inspected as an additional laboratory section.

Inspector Instructions:

- Discuss test sites with the POCT coordinator to identify the scope of testing performed at each site. Visit a representative sampling of POCT test sites and observe patient testing, if possible. Sampling should include:
  - Sites with high and low test volume
  - Sites that are representative of all tests performed and instruments used
  - Sites with different types of testing personnel (e.g. nursing, ABG personnel, surgery)
- Interview testing personnel on procedures for proper patient identification, specimen labeling, test procedure performance, quality control, instrument maintenance, patient result reporting, and safety practices
- Observe proper disposal of sharps and test device disinfection after use
- Determine if practice matches related policies and procedures

QUALITY MANAGEMENT

All quality management (QM) requirements in the Laboratory General Checklist pertain to POCT.

Inspector Instructions:

- Organizational chart
- What is your course of action when testing problems are encountered during the night shift?
Follow an incident identified on the incident/error log and follow actions including notification and resolution.

POC.03550 Organizational Chart Phase II

The POCT program has a written organizational system/chart setting forth levels of authority, responsibility and accountability.

NOTE: The organization must define responsibility and accountability for persons who perform or supervise POCT testing. This may include an organizational chart, a policy defining personnel designated to perform various tasks (QC reviews, competency assessment, PT review, etc.) and/or a set of policies defining responsibilities of POCT users. These elements may be combined in one document or included in laboratory policies on delegation of responsibilities and in individual POCT policies.

REFERENCES

POC.03700 Unusual Laboratory Results Phase II

There is a written procedure for the detection and correction of significant clerical and analytical errors, and unusual or unexpected test results, in a timely manner.

NOTE: This system may need to include feedback from clinicians, with subsequent investigation and monitoring of patient results for unusual patterns (e.g. a series of unexplained hypoglycemic values) suggesting analytic error. Where POCT personnel are also the individuals who will act upon test results (e.g. by altering insulin dosage in response to whole blood glucose results, or altering heparin dosage in response to activated clotting time or aPTT), there should be defined criteria for correlating unexpected test results with other clinical findings to confirm such results whenever possible.

The intent of this requirement is NOT to require confirmation of all results outside the reference (normal) range.

Evidence of Compliance:
✓ Records of review of results OR records of consistent implementation of the error detection system(s) defined in the procedure AND
✓ Records of timely corrective action of identified errors

POC.03800 Troubleshooting Responsibilities Phase II

There is a system in place to ensure that difficulties with methodology or other unusual problems can be promptly resolved on any shift.

NOTE: The intent is to ensure that resources are available to quickly assist with unusual problems to minimize any adverse impact on patient care. Adequate support may require a backup testing procedure (i.e. sending the sample to a central laboratory), retesting by a different method/device, or having a suitably trained individual from the laboratory, nursing service, or medical staff available on all shifts to assist with troubleshooting.

**REVISED** 07/28/2015

POC.03810 Manufacturer Instructions Phase II
The POCT program follows manufacturer instructions for all test systems or provides validation records if the test has been modified.

NOTE: Changes in the specimen type, collection device, or intended medical use are examples of common modifications (see "modification of manufacturer's instructions" in the Definition of Terms as found in the All Common Checklist).

If the laboratory modifies the manufacturer's instructions for an FDA-cleared/approved test, the modifications to the test must be validated by the laboratory. In addition, the test becomes subject to checklist requirements for high complexity testing, including personnel qualifications, competency assessment, method performance specifications, proficiency testing (nonwaived program enrollment), comparability of instruments/methods, quality control, reagents, instrument maintenance and function checks, and calibration and analytic measurement range verification. Requirements in the "Nonwaived" sections of the Point-of-Care Testing Checklist and All Common Checklist apply.

RESULTS REPORTING

Additional requirements for result reporting found in the All Common and Laboratory General Checklists are applicable to POC testing.

Inspector Instructions:

- Sampling of reporting policies and procedures
- Information to clinicians regarding urine screening tests for drugs of abuse
- Select a point-of-care test result and identify the individual who performed the test

POC.04400 Results in Medical Record

There is a written procedure for entering POC test results into the permanent patient record.

NOTE: To ensure patient safety and prevent medical error, health care workers should not make management decisions based on POC test results unless those results are entered into patient records. POC test results may be uploaded into the electronic medical record after decision making.

If test results are hand-written in the medical record, the results are legible.

REFERENCES
1) Friedman BA, Mitchell W. Integrating information from decentralized laboratory testing sites. The creation of a value-added network. Am J Clin Pathol. 1993;99:637-642
3) Jones JB. The importance of integrating POCT data into an organized database. Advance/Lab. 1999;8(9):8-10
POC.04537  Urine Drugs of Abuse  Phase II

The following information is available to clinicians regarding urine screening tests for drugs of abuse.

1. Substances or classes of substances analyzed as part of the drug test
2. Specimen type
3. Cut-off concentration for a positive result for each drug
4. Report status for positive results (e.g. unconfirmed or pending confirmation)
5. A statement that unconfirmed results are to be used only for medical (i.e. treatment) purposes. Unconfirmed screening results must not be used for non-medical purposes (e.g. employment testing, legal testing).

NOTE: It is important that the treating physician be aware of the above information. This information may be provided on the patient report or elsewhere in the medical record, or in a written memorandum to clinicians. However, it is specifically recommended that the substances analyzed be included in the patient report.

Note that the POC checklist may be used to inspect drug screening for medical purposes only. For legal drug testing, the Chemistry checklist must be used.

POC.04575  Group A Streptococcus Direct Antigen Detection  Phase I

If group A Streptococcus direct antigen testing is performed, confirmatory testing is performed as appropriate on negative samples.

NOTE 1: Policies should be established for the use of cultures or other additional tests on specimens that test negative, as appropriate. These policies should take into account the sensitivity of the assay in use, the age and clinical presentation of the patient, and other factors.

NOTE 2: Direct antigen tests should be performed and reported in a timely fashion, since their principal advantage (compared to more sensitive methods such as culture) is rapid turn-around time.

REFERENCES

POC.04700  Testing Personnel Identification  Phase II

Records indicate (by initials, signature, etc.) who performed each test.

NOTE: It is not necessary to have this information in the chartable patient report, but an audit trail must be kept.

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section must be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- Records of instrument/equipment approval
Instrument/Equipment Approval

The instruments and equipment in use are approved by the laboratory director or designee.

REFERENCES

PERSONNEL

There must be educational credentials and training records for all personnel performing point-of-care testing. Records demonstrating educational qualifications for nonwaived testing personnel (i.e. diploma or transcript) must be available in the employee’s personnel file and demonstrate compliance with the qualifications defined in the Personnel section of the Laboratory General Checklist based on the complexity of testing performed. Licenses, registrations, and certifications are not acceptable records of educational credentials. Copies of diplomas or transcripts are acceptable records of educational qualifications.

Inspector Instructions:
- Section director’s qualifications
- Sampling of initial training records
- Sampling of competency assessments
- Listing of POCT personnel
- Diplomas or transcripts for nonwaived testing personnel

- How do you ensure that each individual performing POCT is competent? Do you have a specific example of an employee who demonstrated unacceptable competency assessments? What were the corrective actions?

Section Director Qualifications

The section director of the POCT program is a physician (preferably a pathologist) or a doctoral scientist.

NOTE: The section director is responsible for medical, technical, and scientific oversight of testing in the POCT program.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field

Authorized POCT Personnel

There is a current list of POCT personnel that delineates the specific tests and methods that each individual is authorized to perform.

REFERENCES

**REVISED** 04/21/2014

Initial Training
There are records demonstrating that all staff have satisfactorily completed initial training on all instruments/methods and specimen collection techniques applicable to the point-of-care testing that they perform.

NOTE: The records must show that training specifically applies to the testing performed by each individual.

Retraining must occur when problems are identified with employee performance.

Evidence of Compliance:
✓ Written procedure for initial training of POCT personnel AND
✓ Records of training in personnel file (e.g. training certificate of completion)

POC.06875 Competency Assessment - Waived Testing

There is a written program to ensure that each person performing waived testing maintains satisfactory levels of competence.

NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in POC.06850. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of employee competency must occur when problems are identified with employee performance.

For waived test systems, it is not necessary to assess all six elements listed below at each assessment event: the POCT program may select which elements to assess. Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks, as applicable
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills

Evidence of Compliance:
✓ Written policy defining the method and frequency for assessing competency AND
✓ Record of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation required and performed at defined frequency

REFERENCES

POC.06910 Competency Assessment - Nonwaived Testing

There is a written program to ensure that each person performing nonwaived testing maintains satisfactory levels of competence.
NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in POC.06850. Thereafter, during the first year of an individual’s duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of employee competency must occur when problems are identified with employee performance.

For nonwaived test systems, competency using all six elements described below must be assessed for each individual on each test system during annual and semiannual assessments, unless an element is not applicable to the test system. Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks, as applicable
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills

The laboratory must identify the test systems that an employee uses to generate patient results. Competency must be evaluated and recorded for all testing personnel for each test system. A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment, or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte. In many situations, tests performed on the same analyzer may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform (e.g. pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure staff are performing those aspects correctly.

Many of the elements of competency assessment are performed during routine review of an employee throughout the year. Records of these elements, including observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed by routine review, the competency policy must outline how this routine review is used to evaluate competency. Competency assessment by routine review may be recorded with a checklist. The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience as defined in the regulatory requirements associated with the complexity of the testing.

Evidence of Compliance:
✓ Written policy defining the method and frequency for assessing competency AND
✓ Record of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation required and performance at defined frequency

REFERENCES
QUALITY CONTROL

QUALITY CONTROL – WAIVED TESTS

Inspector Instructions:

- Sampling of quality control policies and procedures
- Sampling of QC records

- How do you determine when QC is unacceptable and when corrective actions are needed?

- Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

POC.07037 Documented QC Results - Waived Tests

The laboratory follows manufacturer instructions for quality control, reviews results, and records acceptability prior to reporting patient results.

**NOTE:** Quality control must be performed according to manufacturer instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run prior to reporting patient results. The laboratory director or designee must review QC data at least monthly or more frequently if specified in the laboratory QC policy.

With respect to internal controls, acceptable control results must be recorded, at a minimum, once per day of patient testing for each device.*

*Acceptable internal control results need not be recorded, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results.

Evidence of Compliance:
- Written procedure consistent with manufacturer instructions for each waived test **AND**
- Records showing confirmation of acceptable QC results

POC.07124 QC Corrective Action - Waived Tests

There is a record of corrective action when control results exceed defined acceptability limits.
QUALITY CONTROL – NONWAIVED TESTS

Inspector Instructions:

- Sampling of quality control policies and procedures
- Sampling of QC records, including staining QC and external and internal quality control processes

- How does your laboratory verify or establish acceptable QC ranges for POCT?
- How do you determine when quality control is unacceptable and when corrective actions are needed?

- Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the POCT procedure for corrective action
- Use QC data to identify tests that utilize internal quality control processes to confirm that any individualized quality control plan (IQCP) is used as approved by the laboratory director

**REVISED** 07/28/2015
POC.07300 Daily QC - Nonwaived Tests

Controls are run at least daily, or more frequently if specified in manufacturer’s instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.

Controls must be run prior to reporting patient results, after a change of analytically critical reagents, major preventive maintenance, or change of a critical instrument component. Daily quality control must be run as follows:

1. Quantitative tests - two controls at different concentrations at least daily, except for coagulation tests (two controls every eight hours), or unless otherwise required elsewhere in this checklist
2. Qualitative tests - a negative control and a positive control (when applicable) at least daily

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.

If an internal quality control process (e.g. electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.
Evidence of Compliance:
✓ Records of QC results including external and internal control processes AND
✓ Written quality control procedures AND
✓ Manufacturer product insert or manual

REFERENCES

POC.07456 Acceptable Limits - Controls

Acceptable limits are defined for control procedures.

NOTE: The POCT program must verify the acceptable limits for control materials that have numeric limits established by the manufacturer. For unassayed control materials, a valid acceptable range must be established by repetitive analysis in runs that include previously tested control material.

Evidence of Compliance:
✓ Records of verification of acceptable limits for control range of each lot

REFERENCES

**REVISED** 07/28/2015

POC.07484 QC Corrective Action

There are records of corrective action when control results exceed defined acceptability limits.

NOTE: Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results.

The corrective action for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (e.g. trending for repeat failures, etc.).

POC.07512 QC Handling

Control specimens are tested in the same manner and by the same personnel as patient samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient testing. This does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysis participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled, recognizing that pre-analytic and post-analytic processes may differ from those encountered with patients.

Evidence of Compliance:
✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES
POC.07540  QC Confirmation of Acceptability  Phase II

The results of controls are reviewed for acceptability before reporting results.

NOTE: It is implicit in quality control that patient test results will not be reported when controls yield unacceptable results.

Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Evidence of corrective action taken when QC results are not acceptable

REFERENCES

POC.07550  Monthly QC Review  Phase II

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.).

Evidence of Compliance:
✓ Records of QC review including follow-up for outliers, trends, or omissions

POC.07600  QC Stain Reactivity  Phase II

If applicable, all stains (except Gram stains) are checked for intended reactivity each day of use.

NOTE: Gram stains must be checked at least weekly, and with each new batch of stains, using known gram-positive and gram-negative organisms.

Evidence of Compliance:
✓ Records of QC for stain reactivity at defined frequency

REFERENCES
CALIBRATION OF QUANTITATIVE SYSTEMS

CALIBRATION – WAIVED TESTS

Inspector Instructions:

| READ | • Sampling of calibration policies and procedures  
|      | • Sampling of calibration/calibration verification records |
| ASK  | • How do you ensure that instruments are calibrated or have calibration verification at the defined frequency?  
|      | • What steps are taken if calibration/calibration verification fails? |
| DISCOVER | • Further evaluate the responses, corrective actions and resolutions for unacceptable calibration/calibration verification |

POC.08050 Calibration, Calibration/Verification - Waived Tests  

For waived tests, the POCT program follows manufacturer instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

- Written procedure consistent with the manufacturer’s instructions for each waived test AND
- Records for calibration/calibration verification-related functions as required by the manufacturer AND
- Records of recalibration or other appropriate corrective action when calibration verification is unacceptable

CALIBRATION – NONWAIVED TESTS

Inspector Instructions:

| READ | • Sampling of calibration AMR policies and procedures  
|      | • Sampling of calibration/calibration verification records  
|      | • Sampling of AMR verification records |
| ASK  | • What is your course of action if calibration/calibration verification is unacceptable?  
|      | • When was the last time you performed a calibration procedure and how did you verify the calibration?  
|      | • What is your course of action when results fall outside the AMR? |
Further evaluate the responses, corrective actions and resolutions for unacceptable calibration, unacceptable calibration verification, and results outside the AMR.

The remaining requirements in the CALIBRATION OF QUANTITATIVE SYSTEMS section do not apply to waived tests.

Definitions:

CALIBRATION: The set of operations that establish, under specified conditions, the relationship between reagent system/instrument response and the corresponding concentration/activity values of an analyte. Calibration procedures are typically specified in the manufacturer's instructions, but may also be established by the laboratory.

CALIBRATION VERIFICATION: The process of confirming that the current calibration settings for each analyte remain valid for a test system.

ANALYTICAL MEASUREMENT RANGE (AMR): The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.

Further discussion of the above concepts may be found in the Chemistry and Toxicology checklist.

**REVISED** 07/28/2015

POC.08100 Calibration Procedures Phase II

Calibration procedures for each test system are appropriate, and the calibration records are reviewed for acceptability.

NOTE: Calibration must be performed following manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials and criteria for acceptable performance.

REFERENCES


POC.08300 Calibration Verification Criteria Phase II

Criteria are established for calibration verification, and compliance is recorded.

NOTE: Criteria typically include:

1. At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient test results and the range used to report patient test data, or the control value
2. If QC materials reflect an unusual trend or shift or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem
3. After major maintenance or service
4. As recommended by the manufacturer
5. At least every six months

Evidence of Compliance:
✓ Written policy defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system AND
✓ Records of calibration verification at defined frequency

REFERENCES

**REVISED** 07/28/2015
POC.08400 Recalibration

Test systems are recalibrated when calibration verification fails to meet the established criteria of the POCT program and records maintained.

REFERENCES

**REVISED** 07/28/2015
POC.08450 AMR Limits Defined

Upper and lower limits of all quantitative reportable parameters on the point-of-care testing instrument are defined, and results that fall outside these limits are reported properly.

NOTE: Apparent analyte concentrations that are lower or higher than the AMR do not routinely require repeat analysis if the result is reported as less than the lower limit, or greater than the upper limit, respectively, and the laboratory has evidence that the low result is not due to sampling/dilution errors, immunologic "hook effects," etc.

If there is a need to report an actual value, a patient sample should be referred to a laboratory that either has a method with a wider verified analytical measurement range (AMR), or that can perform sample dilutions or concentrations so that the analyte concentration is brought into the AMR of an analytical method.

The AMR does not apply to clot-based coagulation tests.

Evidence of Compliance:
✓ Written policy defining AMR by analyte AND
✓ Records of actions taken when results fall outside defined limits

REFERENCES

POC.08500 AMR Verification

Verification of the analytic measurement range (AMR) is performed with matrix-appropriate materials of known analyte value appropriate to the AMR of the instrument.

NOTE: If the materials used for calibration or for calibration verification include low, midpoint, and high values that are near the AMR, and if calibration verification data are within the user's acceptance criteria, the AMR has been verified; no additional procedures are required. If the
calibration and/or calibration verification materials do not include the full AMR, the AMR must be verified by assaying additional materials reasonably near the lowest and highest values of the AMR.

Single-use devices are a special case in which a large number of devices may be in use at any time within an institution. The AMR must be verified for each device when placed in service, and following maintenance or repair. However, it may not be practical to perform the semiannual verification of the AMR using a special set of specimens for all devices, and verification may be performed on a sample of devices, provided that such a sampling procedure does not conflict with manufacturer instructions. (If different types of instruments and different lots of reagent strips/cartridges are in use, a sample of each instrument type and each lot of strips/cartridges must be included in this subset.) For the devices not sampled, verification of the AMR may be inferred by other approaches. Examples include: 1) review of external QC results to ensure acceptability; 2) comparison of POCT results with near-simultaneously collected specimens analyzed in the main laboratory. (This type of comparison is facilitated when the POCT results are downloaded to a central data management computer.) Other approaches may be satisfactory. Manufacturer's instructions for calibration verification/AMR verification must be followed. The sample of devices on which reverification is performed should be rotated so that over time all devices are directly verified.

Evidence of Compliance:
✓ Written policy for AMR verification defining the types of materials used, frequency and acceptability criteria consistent with manufacturer’s instructions

REFERENCES

POC.08600 AMR Verification Criteria Phase II

Criteria are established for verifying the analytical measurement range (AMR), and compliance is recorded.

NOTE: The AMR must be verified every six months, and when any of the following criteria are met:

1. A change in major test system components
2. A change in lots of chemically or physically active reagents (unless the laboratory can show that changing lots does not affect the range used to report patient results)

Evidence of Compliance:
✓ Written policy defining the frequency and acceptability criteria for AMR verification

REFERENCES

**NEW** 07/28/2015

POC.08625 Neonatal Bilirubin Testing Phase II

Neonatal bilirubin results in the range of 5 to 25 mg/dL are accurate and suitable for use with standardized clinical practice interpretive guidelines, with accuracy verified at least annually.

NOTE: Each laboratory must assess the accuracy of its instrument/test system over the range of bilirubin values appropriate for the clinical guidelines (5-25 mg/dL). In many cases, acceptable performance can be verified using proficiency testing materials with assigned reference values. In other cases, the laboratory can meet the objective by using patient samples to perform
correlation studies against (1) a reference method; OR (2) an alternate method that consistently demonstrates good performance in a proficiency testing program (based on the method mean value as compared to the reference value). In all cases, such comparisons should include at least one or two samples annually in the target clinical range of 5-25 mg/dL.


Evidence of Compliance:
✓ Written assessment, at least annually, by the laboratory director or designee, indicating that agreement with target values in the range of the clinical guidelines is adequate for clinical purposes

REFERENCES

BLOOD GAS ANALYSIS

Inspector Instructions:
• Sampling of blood gas analysis policies and procedures
• Sampling of records of collateral circulation tests performed
• Sampling of blood gas calibration records
• Sampling of blood gas QC records

• How are personnel that perform arterial punctures made aware of possible complications?

• Select a blood gas result and follow the entire process from specimen collection to final result reporting

POC.08705 Knowledgeable - Arterial Punctures

Personnel performing arterial punctures are knowledgeable about the more significant complications of this procedure compared with venipuncture.

Evidence of Compliance:
✓ Records of training in personnel files

REFERENCES
POC.08760  Collateral Circulation  Phase II

For radial artery sampling, a test for collateral circulation is performed and recorded before arterial puncture, as applicable.

NOTE: The various technologies available have been evaluated in the published literature. Consensus should be established between the point-of-care program and involved clinicians to define in which patients and under what circumstances such a test is medically useful in averting potential patient injury. The site from where the sample was obtained should be recorded.

Evidence of Compliance:
✓ Written collection procedure defining situations that require testing for collateral circulation to include preferred technique(s)
✓ Records of collection site and results of applicable collateral circulation testing

REFERENCES

POC.08815  Ambient Air Contamination  Phase II

There is a procedure to prevent ambient air contamination of blood gas samples before analysis.

Evidence of Compliance:
✓ Written procedure for prevention of ambient air contamination

REFERENCES

POC.08870  Instrument Operation  Phase II

There are written procedures for operation and calibration of all blood gas instruments.

POC.08925  Calibration Materials  Phase II

The materials used for calibration of the pH, CO₂, and O₂ sensors are either in conformance with the instrument manufacturer's specifications or traceable to NIST Standard Reference Materials.
**NOTE:** Calibration materials, either liquid or gas, must be traceable to appropriate reference standards. In the case of single-use devices, the calibration material is often contained within the test cartridge.

**REFERENCES**


**POC.08980** Calibration - Blood Gas Instruments

**Phase II**

Blood gas instruments are calibrated according to manufacturer's specifications and at least as frequently as recommended by the manufacturer.

**NOTE:** Instruments used infrequently must be recalibrated each time of use. Some instruments have built in calibration that is performed automatically by the instrument; however, there must be some defined procedure for verifying the reliability of this process. If appropriate, the calibration must compensate for the influence of barometric pressure.

**Evidence of Compliance:**

✓ Written calibration procedure, including defined frequency **AND**

✓ Records for calibration at defined frequency

**REFERENCES**

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24);3709 [42CFR493.1267(a)]


**REVISED** **07/28/2015**

**POC.09035** Daily QC - Blood Gas Instruments

**Phase II**

A minimum of one level of quality control for pH, pCO₂ and pO₂ is analyzed at least every eight hours of operation when patient specimens are tested, or more frequently if specified in the manufacturer's instructions or laboratory procedure.

**NOTE:** The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed. Controls must be run prior to reporting patient results after a change of analytically critical reagents, major preventive maintenance, or change of a critical instrument component.

If an internal quality control process (e.g. electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

**Evidence of Compliance:**

✓ Written quality control procedures **AND**

✓ Records of QC results including external and internal control processes **AND**

✓ Manufacturer product insert or manual

**REFERENCES**

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24) [42CFR493.1267(b)]

**REVISED** 07/28/2015  
POC.09090  Daily QC - Blood Gas Instruments  

**Phase II**

The control materials for pH, pCO₂ and pO₂ represent both high and low values on each day of patient testing.

**NOTE:** If using internal controls (e.g. electronic simulators), the controls should challenge at high and low values.

**Evidence of Compliance:**
- ✓ Written policy defining QC requirements AND
- ✓ QC records reflecting the appropriate use of controls

**REFERENCES**
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register, 2003(Jan 24) [42CFR493.1267(b)]

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**REVISED** 07/28/2015  
POC.09145  QC - Blood Gas Instruments  

**Phase II**

At least one level of quality control for pH, pCO₂ and pO₂ is included each time patient specimens are tested, except for automated instruments that internally calibrate at least once every 30 minutes of use.

**NOTE:** An internal quality control process (e.g. electronic/procedural/built-in) may be used to meet this requirement if an individualized quality control plan (IQCP) approved by the laboratory director addresses the use of the alternative control system

**Evidence of Compliance:**
- ✓ Written policy defining QC requirements AND
- ✓ QC results OR record of internal calibrator

**REFERENCES**
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register, 2003(Jan 24): 3709 [42CFR493.1267(c)]

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**D-DIMER STUDIES**

**Inspector Instructions:**
- • Sampling of D-dimer policies and procedures
- • Sampling of patient records

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**NEW/REVISED** 07/28/2015  
POC.09150  D-dimer Unit Results  

**Phase II**

If the unit type (e.g. FEU or D-DU) and unit of magnitude (e.g. ng/mL) reported with the patient results are different from the units generated directly by the D-dimer method, the laboratory verifies the correct conversion of the units.
**NEW/REVISED** 07/28/2015

POC.09153  D-dimer - Evaluation of VTE  Phase II

If a quantitative D-dimer method is used in the evaluation of venous thromboembolism (VTE), the method is valid for this purpose.

**NOTE:** D-dimer methods intended for evaluation of VTE may be used, along with pretest probability, if a method specific cut-off value is available. Cut-off values are not universal, so method specific data regarding the negative predictive value and the sensitivity should be available. For cut-off data acquired from the literature, the CLSI (H59-A) recommends a negative predictive value of ≥98% (lower limit of CI ≥95%) and a sensitivity of ≥97% (lower limit of CI ≥90%) for non-high pretest probability of VTE.

For D-dimer methods that are FDA-cleared/approved for exclusion of VTE, the package insert includes the cut-off value and this value should be provided in the report. It is not feasible for most laboratories to perform a sufficient clinical validation of a D-dimer cut-off for use in the evaluation of VTE (i.e. either exclusion or aid in diagnosis), including separate validation of the cut-off for deep vein thrombosis and pulmonary embolism. Therefore using the cutoff supplied from the manufacturer is strongly recommended.

If a laboratory or group of laboratories determine a cut-off (not published in literature or the package insert), a summary of data including the NPV, sensitivity, and power of determination must be available. The CLSI Guideline H59-A recommends correlation with imaging studies and follow-up after three months on a minimum of 200 cases to establish the threshold for VTE exclusion.

**Evidence of Compliance:**
- Package insert stating an Intended Use for the exclusion of VTE or aid in the diagnosis of VTE AND
- A method specific cut-off for the evaluation of VTE from the package insert, literature, or an extensive clinical validation study

**REFERENCES**
7) Gould MK. Review: of the various D-dimer assays, negative ELISA results are most useful for excluding a diagnosis of deep venous thrombosis or pulmonary embolism. ACP J Club. 2004 Nov-Dec;141(3):77

**NEW/REVISED** 07/28/2015
POC.09156 D-dimer Reporting

If a D-dimer test is used for evaluation of venous thromboembolism (VTE), the laboratory reports both the cut-off value and reference range.

**Evidence of Compliance:**
✓ Patient reports including both the reference range and the cut-off value for VTE evaluation

**NEW/REVISED** 07/28/2015
POC.09160 Sensitivity of D-dimer Test - Evaluation of VTE

If a D-dimer test is insufficiently sensitive to exclude venous thromboembolism, the laboratory informs clinicians that the test must not be used for this purpose.

**SAFETY**

The inspector should review relevant requirements from the Safety section of the Laboratory General checklist, to assure that the POCT program is in compliance. Please elaborate upon the details of each deficiency in the Inspector’s Summation Report.
### Inspector Instructions:

<table>
<thead>
<tr>
<th>READ</th>
<th>OBSERVE</th>
<th>ASK</th>
</tr>
</thead>
</table>
| • Sampling of POCT safety policies and procedures | • Patient specimen collection and testing  
• Glove use and proper hand hygiene practices  
• Single use fingerstick devices  
• Disinfection of portable or hand-held test devices | • Do you ever feel that your safety or your patient’s safety is compromised while performing laboratory testing?  
• What types of measures are being used during POC testing to reduce the transmission of infections from patient to patient |

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**POC.09172 Safety Manual**

**Phase II**

The POCT program has a program to assure the safety of patients and health care personnel commensurate with the scope of its activities.

**POC.09180 Standard Precautions - Hand Hygiene**

**Phase II**

**Standard precautions are used for point-of-care testing by testing personnel.**

**NOTE:** Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions.

**Evidence of Compliance:**

✓ Written procedure detailing proper hand/glove hygiene when testing patients using point-of-care devices

**REFERENCES**


**POC.09185 Single-Use Devices - Fingerstick**

**Phase II**

**Only auto-disabling single-use fingerstick devices are used for assisted monitoring of blood glucose and other point-of-care testing.**

**NOTE:** These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. All waste sharps are discarded in compliance with the Laboratory General Checklist in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

**Evidence of Compliance:**

✓ Written policy detailing requirement of limitation of single-use devices to one patient

**REFERENCES**

1) [http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html accessed 1/30/2012](http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html)  
2) [http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm accessed 1/30/2012](http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm)  
POC.09190  Testing Devices - Disinfection

There is an infection control policy in effect to prevent transmission of infection via portable or handheld testing devices.

NOTE: Compliance with the manufacturer's guidelines when provided is required. Handheld or portable testing devices must be disinfected after each patient use.

REFERENCES

PROVIDER-PERFORMED TESTING

IMPORTANT INFORMATION FOR LABORATORIES AND INSPECTORS

The following section applies to all point-of-care test sites performing provider-performed testing (PPT), unless a separate CLIA number is obtained to exclude it from CAP inspection. PPT is defined by the College of American Pathologists as testing that is personally performed by a physician or midlevel practitioner (e.g., physician assistants, nurse practitioners, certified nurse midwives) in conjunction with the physical examination or treatment of a patient, and is limited to the following provider-performed microscopy (PPM) procedures and waived tests.

1. pH, body fluids, waived*
2. Vaginal pool fluid smears for ferning
3. Fecal leukocytes
4. Gastric biopsy urease, waived*
5. Nasal smears for eosinophils
6. Occult blood, fecal and gastric, waived*
7. Pinworm examination
8. Post-coital mucus examination
9. Potassium hydroxide (KOH) preparations
10. Semen analysis, qualitative
11. Urine dipstick, waived*
12. Urine sediment microscopy
13. Wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements

* If nonwaived methods are used for these tests, other sections of the Point-of-Care Testing Checklist and the All Common Checklist are required. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analytestwaived.cfm.

The Provider-Performed Testing section is used alone to inspect the tests listed above when performed by a qualified provider, the other sections of the Point-of-Care Testing Checklist and the All Common Checklist do NOT apply. The performance of tests, other than those tests listed above, are subject to inspection with the other sections of the Point-of-Care Testing and All Common Checklists and/or other discipline-specific checklists, as appropriate.
**REVISED** 04/21/2014

POC.09200  PPT Scope of Testing  Phase II

**There is a written policy outlining the nature of laboratory testing that may be personally performed by providers within their scope of clinical practice.**

**NOTE:** The policy should include training requirements, specimen collection, the use of personal protective equipment, reporting policies, competency assessment, and quality management.

**REVISED** 04/21/2014

POC.09300  PPT Procedure Manual  Phase II

**There is a written PPT procedure for each test, including specimen handling information.**

REFERENCES

**REVISED** 04/21/2014

POC.09400  PPT QM Program  Phase II

**A quality management program, appropriate for the nature of the testing performed, exists and includes the following items, as applicable.**

1. Quality control of stains and reagents
2. Storage of reagents (including test kits) and controls
3. Corrective action for unacceptable QC
4. Instrument maintenance and function checks (centrifuges, microscopes, refrigerators, etc.)
5. System to detect and correct reporting errors
6. Assurance that manufacturer instructions are followed
7. Proficiency testing (external or alternative)

REFERENCES

**REVISED** 04/21/2014
POC.09500  PPT Training  Phase II

There are records demonstrating that all providers have satisfactorily completed initial training on the performance of the specific tests performed.

NOTE: Medical staff credentialing is not an acceptable record of training.

**REVISED** 04/21/2014

POC.09600  PPT Competency Assessment - Nonwaived Testing  Phase II

There is a written program to ensure that all providers performing nonwaived PPT maintain satisfactory levels of competence.

NOTE: During the first year of nonwaived testing, competency must be assessed at least semiannually. After a provider has performed nonwaived testing duties for one year, competency must be assessed annually. Retraining and reassessment of provider competency must occur when problems are identified with test performance.

Competency assessment must include all six elements described below for each test system during each assessment period, unless an element is not applicable to the test system. Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting of critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks, as applicable
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples of external proficiency testing samples; and
6. Evaluation of problem-solving skills

Competency may be assessed by the director of the POCT program or delegated to an individual meeting the technical consultant qualifications for moderate complexity testing.

This requirement does not apply to waived PPT. The laboratory director may determine how competency is determined.

Evidence of Compliance:
✓ Written policy defining the method and frequency for assessing competency for nonwaived PPT AND
✓ Record of competency assessment for new and existing providers reflecting the specific skills assessed and the method of evaluation

REFERENCES

POC.09700  PPT Reporting  Phase I

The system for reporting PPT results is adequate.

NOTE: The following elements are the usual components of a chartable result:

1. Patient identifier
2. Test ordered/performed and physician's name/identifier
3. Date/time of specimen collection
4. Test result
5. Reference interval or interpretive notes, as appropriate