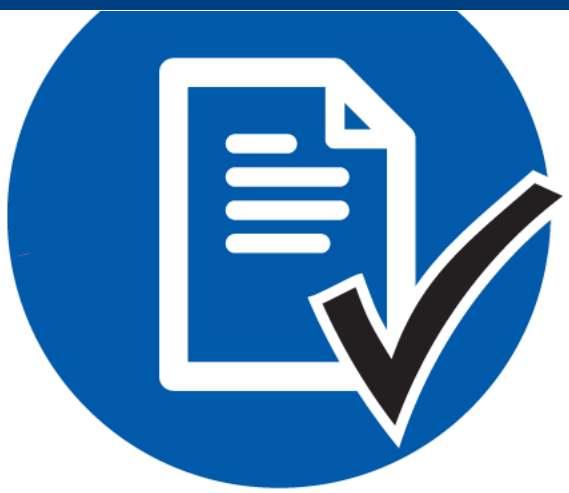
COLLEGE of AMERICAN PATHOLOGISTS

Al Hammadi Hospital Al Suwaidi
Laboratory Department

Point-of-Care-Testing Checklist

CAP Accreditation Program



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Point-of-Care-Testing Checklist

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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. 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.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES
Point-of-Care-Testing Checklist
12/26/2024 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 requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements
None

REVISED Checklist Requirements

Requirement	Effective Date
POC.06875	12/26/2024
POC.06920	12/26/2024
POC.08500	08/24/2023
POC.08600	08/24/2023
POC.08760	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements
None

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.

Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

***Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

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 (eg, capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (eg, 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 Director Assessment 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 or approved point-of-care tests that are modified by the laboratory. Modified FDA-cleared or 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, multichannel blood cell counters, bacterial cultures, and tests that use instruments requiring high levels of maintenance or technical skill. The CAP 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 (eg, 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 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 Director Assessment checklists used for the central laboratory. If the POCT sites are registered under separate CLIA numbers, separate Laboratory General and Director Assessment 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 retained 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 retained records and visit at least a sampling of the testing sites in order to evaluate compliance with the Standards. If records are not retained 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.

QUALITY MANAGEMENT

All quality management system requirements in the Laboratory General Checklist pertain to POCT.

POC.03550 Organizational Chart **Phase II**

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

NOTE: The organization must define responsibility and accountability for persons who perform or supervise POC 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.

POC.03700 Error Detection and Correction **Phase II**

The laboratory has processes to detect and correct significant clerical and analytical errors, and unusual or unexpected test results, in a timely manner.

NOTE: The process may include feedback from clinicians, with subsequent investigation and monitoring of patient results for unusual patterns (eg, a series of unexplained hypoglycemic values) suggesting analytic error. Where POCT personnel are also the individuals who will act upon test results (eg, 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 interval.

Evidence of Compliance:

- ✓ Records of review of results **OR** records of consistent implementation of the error detection processes **AND**
- ✓ Records of timely corrective action of identified errors

POC.03800 Problem Resolution **Phase II**

The laboratory has a system to promptly resolve problems and/or difficulties with point-of-care methods/devices/test systems for all shifts in which point-of-care testing is available.

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 (ie, 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 problem resolution.

POC.03810 Manufacturer's Instructions **Phase II**

The POCT program follows manufacturer's 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, the test is no longer FDA-cleared/approved, and the modification(s) 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.

Evidence of Compliance:

- ✓ Validation records of established performance specifications (accuracy, precision, analytical sensitivity, analytical specificity, interferences, reference interval(s), and reportable range) of any test that has been modified

RESULTS REPORTING

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

POC.04400 Results in Medical Record **Phase II**

The laboratory follows 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 must 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 must be legible.

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.

PERSONNEL

*Personnel performing nonwaived testing must be listed on the Laboratory Personnel Evaluation Roster. Records demonstrating educational qualifications for **nonwaived** testing personnel 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, transcripts, or primary source verification reports are acceptable records of educational qualifications. The training and qualifications of personnel trained outside of the US **must** be evaluated to determine equivalency to an education obtained in the United States, with records of the evaluation available in the personnel file. Equivalency evaluations must be performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (http://www.naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org). Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.*

POC.06800 Authorized POCT Personnel **Phase II**

There are records to identify POCT personnel that are authorized to perform each waived and nonwaived test (eg, roster, process to grant computer system or device privileges).

NOTE: The requirements for testing personnel qualifications (GEN.54750) and personnel records (GEN.54400) are found in the Laboratory General Checklist.

POC.06850 Personnel Training **Phase II**

There are records demonstrating that all POCT personnel have satisfactorily completed training on all instruments, methods, and specimen collection techniques applicable to the point-of-care testing that they perform.

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 demonstration of the skills required for proper test performance of pre-analytic, analytic, and post-analytic phases of testing, as applicable, and their ability to work under the expected level of oversight during routine patient testing. The records must cover all testing performed by each individual.

Training records must be retained for a minimum of two years. After the initial two-year period, records of successful ongoing competency assessment may be used in lieu of training records to demonstrate compliance with this requirement.

Retraining must occur when problems are identified with personnel performance.

***REVISED** 12/26/2024*
POC.06875 Competency Assessment - Waived Testing **Phase II**

The competency of personnel performing waived testing is assessed for each test system at the required frequency.

NOTE: Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results.

Competency must be assessed at the following frequency:

- *After an individual has performed his/her duties for one year and at least annually thereafter. This can be performed throughout the entire year to minimize impact on workload.*
- *When problems are identified with an individual's performance.*

If more stringent state or local regulations are in place for competency assessment of waived testing (eg, California), they must be followed. California regulation CCR Title 17 1036.3 states that a waived laboratory supervisor is responsible for evaluating and documenting competency at least semiannually during the first year an individual tests patient specimens and annually thereafter.

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency must be coordinated with routine practices and procedures. Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. The laboratory director may determine how competency will be assessed for personnel performing waived testing at multiple test sites (same CAP/CLIA number) or laboratories within the healthcare system (different CAP/CLIA numbers). If there are variations on how a test is performed at different test sites or laboratories, those variations must be included in the competency assessment specific to the site or laboratory.

For waived test systems, the laboratory may select which elements to assess. It is not necessary to assess all six elements listed below at each assessment event unless more stringent state and local regulations are in place (eg, California regulation CCR Title 17 1036.3, which includes elements 1, 2, 3, 4, and 6, below). 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 specimens (eg, de-identified patient specimens) or external proficiency testing specimens*
6. *Evaluation of problem-solving skills.*

Competency requirements for waived tests do not apply to physicians and mid-level practitioners (ie, physician assistant, nurse practitioner, nurse midwife, nurse anesthetist, or clinical nurse specialist licensed to practice in the jurisdiction in which the laboratory is located) unless required by state or local regulations.

Evidence of Compliance:

- ✓ Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required frequency

The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

NOTE: Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. The laboratory must identify the test systems that testing personnel use to generate test results, including both primary and back-up methods used for patient testing. If a single test or analyte is performed using different test systems, a separate assessment is required.

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.*
- *It includes instructions, reagents, supplies, equipment and/or instruments required to produce test results.*
- *It may encompass multiple identical analyzers or devices.*
- *It may include multiple tests performed on the same testing platform (eg, analyzer), unless tests have unique aspects, problems, or procedures (eg, pretreatment of specimens prior to analysis. In those situations, competency must be assessed as a separate test system to ensure personnel perform those aspects correctly.*

*The **six required 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*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens) or external proficiency testing specimens*
6. *Evaluation of problem-solving skills.*

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures if they are assessed by an individual qualified to assess competency (POC.06920). Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

The following includes examples of how competency assessment can be coordinated with routine practices and procedures:

- *Assessment of the recording of quality control results and instrument maintenance data in element #3 during the monthly supervisory review process of these records.*
- *Assessment of test performance in element #5 during reviews of proficiency testing or alternative performance assessment records.*
- *Assessment of problem-solving skills in element #6 from monthly reviews of corrective action logs where problems with quality control or instrument function were investigated.*

The CAP provides example competency assessment templates, which can be downloaded from cap.org in e-Lab Solutions Suites - Accreditation Resources - Templates.

Evidence of Compliance:

- ✓ Records of competency assessment reflecting the specific skills assessed for each test system and the method of evaluation

The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

NOTE: Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results.

Competency must be assessed at the following frequency:

- *At least semiannually (first assessment within seven months from the start of testing and second assessment no later than 12 months from the start of testing) during the first year an individual tests patient specimens (new employee)*
- *At least annually after an individual has performed assigned duties for one year**
- *When problems are identified with an individual's performance.*

**The annual assessment of competency can be performed throughout the entire year to minimize impact on workload.*

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. Competency of nonwaived testing personnel must be assessed at the laboratory where testing is performed (CAP/CLIA number). If there are variations on how a test is performed at different test sites, those variations must be included in the competency assessment specific to the site or laboratory.

Evidence of Compliance:

- ✓ Records of competency assessment for new and existing personnel at the required frequency

***REVISED** 12/26/2024*

POC.06920 Competency Assessment - Assessor Qualifications **Phase II**

Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed.

NOTE: The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the assessor vary by the complexity of the testing. The assessor must be knowledgeable about the test systems assessed but is not required to have a completed competency assessment for those test systems unless the assessor is also defined as testing personnel for that test system.

For laboratories subject to US regulations, the following include the minimum qualifications for assessors:

- *High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications (GEN.53400, GEN.53600)*
- *Moderate complexity testing: Technical consultant or individual meeting those qualifications (GEN.53625)**
- *Waived testing: May be determined by the laboratory director*

**If both moderate and high complexity testing is performed, a general supervisor or individual meeting those qualifications may assess the competency for both moderate and high complexity testing.*

Competency of moderate complexity point-of-care and blood gas testing personnel must be assessed by an individual meeting technical consultant qualifications.

Additional information on the qualifications for assessing competency, including additional qualifications for blood gas testing personnel, may be found in the requirements listed above and in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed.

For waived testing performed at laboratories with California laboratory licensure, California regulation CCR Title 17 1036.3 states that a waived laboratory supervisor is responsible for evaluating and documenting competency (refer to GEN.78250).

For laboratories not subject to US regulations, individuals assessing competency must, at minimum, meet the personnel qualifications to perform the test and be knowledgeable on the testing performed.

Evidence of Compliance:
- ✓ Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform competency assessment **AND**
- ✓ Records of competency assessments performed by qualified individuals

POC.06925 Competency Corrective Action **Phase II**

If testing personnel fail to demonstrate satisfactory performance on the competency assessment, the laboratory follows a plan of corrective action to retrain and reassess competency.

NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

Evidence of Compliance:
- ✓ Records of corrective action to include evidence of retraining and reassessment of competency

QUALITY CONTROL

QUALITY CONTROL – WAIVED TESTS

POC.07037 QC - Waived Tests **Phase II**

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

NOTE: Quality control must be performed according to manufacturer's 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:
- ✓ Records showing confirmation of acceptable QC results

POC.07124 QC Corrective Action - Waived Tests **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

QUALITY CONTROL – NONWAIVED TESTS

POC.07300 Daily QC - Nonwaived Tests **Phase II**

The laboratory performs controls for quantitative and qualitative tests each day of testing or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, and when changes occur that may impact patient results.

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 resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate.

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 (eg, 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 defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP 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**
- ✓ Manufacturer product insert or manual

POC.07456 Control Range Establishment or Verification **Phase II**

The laboratory establishes or verifies an acceptable control range for each lot of control material.

NOTE: For unassayed control materials, the laboratory must establish an acceptable control range by repetitive analysis in runs that include previously tested control material. For assayed control materials, the laboratory must verify control ranges supplied by the manufacturer.

Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.

Evidence of Compliance:

- ✓ Records for control range establishment or verification of each lot

POC.07484 QC Corrective Action **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). 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 (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of corrective action for unacceptable control results

POC.07512 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient/client samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

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

POC.07520 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- ✓ Records of alternative control procedures

POC.07540 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient results.

Evidence of Compliance:
- ✓ Records of control result approval

POC.07550 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may 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 (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

CALIBRATION OF QUANTITATIVE SYSTEMS

CALIBRATION AND CALIBRATION VERIFICATION PROCESSES – WAIVED TESTS

POC.08050 Calibration, Calibration/Verification - Waived Tests **Phase II**

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

Evidence of Compliance:
- ✓ 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 AND CALIBRATION VERIFICATION PROCESSES – NONWAIVED TESTS

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

This introduction discusses the processes of calibration, calibration verification, and analytical measurement range (AMR) verification.

CALIBRATION: The process of adjusting an instrument or test system to establish a relationship between the measurement response and the concentration or amount of the analyte that is being measured by the test procedure.

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

Each laboratory must define limits for accepting or rejecting results of the calibration verification process. Calibration verification can be accomplished in several ways. If the manufacturer provides a calibration validation or verification process, it must be followed. Other techniques include (1) assay of the current calibration materials as unknown specimens, and (2) assay of matrix-appropriate materials with target values that are specific for the method.

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 that is not part of the usual assay process.

LINEARITY AND THE AMR
Linearity is a fundamental characteristic of many analytic measurement methods, whereby there is a straight-line relationship between ‘‘true’’ analyte concentrations and measured concentrations. In this context, linearity refers to the relationship between the predicted and observed measurement results and not to the relationship between instrument signal output and analyte concentration. For most assays, this relationship is linear within the AMR.

AMR VERIFICATION
Laboratories are required to verify that the appropriate relationship is maintained over the AMR. Laboratories may verify and use an AMR that is narrower than the range defined by the manufacturer. This may be appropriate when materials available for method validation and/or AMR verification are not available to verify the full range claimed by the manufacturer, or reporting values across the full range defined by the manufacturer is not clinically relevant. For many assays, results beyond the AMR can be reported through dilution or concentration studies (see CHM.13710 & CHM.13720). AMR verification is not required for calculated test results (refer to the Definition of Terms in the All Common Checklist) as long as the individual results contributing to the calculation have AMR verification.

Minimum requirements for AMR verification can be met by using matrix appropriate materials, which include low, mid and high concentration or activity range of the AMR with recovery of results that fall within a defined range of the target value. Records of AMR verification must be available.

CLOSENESS OF SAMPLE CONCENTRATIONS OR ACTIVITIES TO THE UPPER AND LOWER LIMITS OF THE AMR
When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR.

POC.08100 Calibration Procedure **Phase II**

The laboratory calibrates each test system as defined and reviews the calibration records for acceptability.

NOTE: Calibration of FDA-cleared/approved methods must be performed following the manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials, frequency of calibration, and criteria for acceptable performance. Calibration procedures are typically specified in the manufacturer's instructions but may also be established by the laboratory.

POC.08150 Calibration and Calibration Verification Materials **Phase II**

High quality materials with test system and matrix-appropriate target values are used for calibration and calibration verification whenever possible.

NOTE: Calibration and calibration verification must have defined analyte target values and appropriate matrix characteristics for the clinical specimens and specific assay method. Many instrument systems require calibration materials with system-specific target values to produce accurate results for clinical specimens.

Suitable materials for calibration verification include, but are not limited to:

1. *Calibrators used to calibrate the analytical system*
2. *Materials provided by the manufacturer for the purpose of calibration verification*
3. *Previously tested unaltered patient/client specimens*
4. *Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method*
5. *Third party general purpose reference materials that are suitable for verification*

In general, routine control materials and proficiency testing materials are not suitable for calibration verification, except in situations where the material has been shown to be suitable (eg, specifically designated by the method manufacturer) or no other materials are available.

Evidence of Compliance:

✓ Records of calibration and calibration verification

POC.08300 Recalibration/Calibration Verification Criteria **Phase II**

Criteria for the frequency and acceptability of recalibration or calibration verification are defined and followed.

NOTE: Laboratories must either recalibrate or perform calibration verification at least every six months and if any of the following occur:

1. *At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient/client results*
2. *If QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range*
3. *After major maintenance or change of a critical instrument component*
4. *As recommended by the manufacturer*

Single use devices, and other test devices that do not allow user calibration, do not require calibration verification.

Evidence of Compliance:

✓ Records of calibration verification at defined frequency

POC.08400 Recalibration **Phase II**

The test system is recalibrated when calibration verification fails to meet the established criteria of the laboratory.

Evidence of Compliance:

✓ Records of recalibration, if calibration or calibration verification has failed

POC.08450 AMR Limits Defined **Phase II**

The laboratory defines the upper and lower limits of all quantitative reportable parameters on the point-of-care testing instrument, and properly reports results that fall outside these limits.

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 must 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:

✓ Records of actions taken when results fall outside defined limits

***REVISED** 08/24/2023*

POC.08500 AMR Verification Materials **Phase II**

Verification of the analytic measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum include low, mid, and high range of the AMR, and appropriate acceptance criteria are defined.

NOTE: The matrix of the sample (ie, the environment in which the sample is suspended or dissolved) may influence the measurement of the analyte. In many cases, the method manufacturer will recommend suitable materials. Other suitable materials for AMR verification include the following:

1. *Linearity material of appropriate matrix, eg, CAP CVL Survey-based or other suitable linearity verification material*
2. *Previously tested patient/client specimens, that may be altered by admixture with other specimens, dilution, spiking in known amounts of an analyte, or other technique*
3. *Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method*
4. *Patient samples that have reference method assigned target values*
5. *Control materials, if they adequately span the AMR and have method specific target values.*

Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion.

Evidence of Compliance:

✓ Records of AMR verification

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POC.08600 AMR Verification **Phase II**

Verification of the analytical measurement range (AMR) is performed at least every six months and following defined criteria. Records are retained.

NOTE: The AMR must be verified at least every six months after a method is initially placed in service and if any of the following occur:

1. *At changes of reagent lots unless the laboratory can demonstrate that use of different lots does not affect the accuracy of patient/client results, and the range used to report patient/ client test data*
2. *QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range*
3. *After major preventive maintenance or change of a critical instrument component*
4. *When recommended by the manufacturer*

It is not necessary to independently verify the AMR if the calibration of an assay includes calibrators that span the full range of the AMR, with low, midpoint and high values represented (ie, three points) and if the system is calibrated at least every six months. A one-point or two-point calibration does not include all of the necessary points to verify the AMR.

For single-use devices in which a large number of devices may be in use within an institution, the AMR verification may be performed on a sampling of devices, if allowed in the manufacturer's instructions. The sampling procedure must:

- *Include a sample of each instrument type and each lot of strips/cartridges in the subset of devices verified if different types of instruments and different lots of reagent strips/cartridges are in use.*
- *Use an additional approach to infer AMR verification for the devices not sampled, such as: 1) review of external QC results to ensure acceptability; or 2) comparison of POCT results with near-simultaneously collected specimens analyzed in the main laboratory.*
- *Include a rotation of devices on which reverification is directly performed over time.*

AMR verification is not required for clot-based coagulation tests, platelet function tests, and other tests where output is a unit of time or arbitrary reporting unit (rather than measured analyte concentration). AMR verification is not required for calculated test results as long as the individual results contributing to the calculation have AMR verification.

Evidence of Compliance:
✓ Records of AMR verification, as required, at least every six months

BLOOD GAS ANALYSIS

POC.08750 Arterial Puncture Complications **Phase II**

Personnel performing arterial punctures are trained in the recognition and management of possible complications of this procedure.

Evidence of Compliance:
✓ Records of training in personnel files

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POC.08760 Collateral Circulation **Phase II**

For radial artery sampling, a test for collateral circulation is performed before arterial puncture if clinically indicated, with results recorded.

NOTE: Any of the various technologies evaluated in the published literature are acceptable. Consensus should be established between the point-of-care program and involved clinicians to define situations that require testing for collateral circulation, if any, to potentially avert patient injury.

Evidence of Compliance:
✓ Records of collection site and results of applicable collateral circulation testing

POC.08815 Ambient Air Contamination **Phase II**

The laboratory has a process to prevent ambient air contamination of blood gas samples before analysis.

POC.08925 Calibration Materials **Phase II**

The materials used for calibration of the pH, CO_2, and O_2 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.

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: 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:
- ✓ Records for calibration at defined frequency

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

A minimum of one level of quality control for pH, pCO_2 and pO_2 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, and when changes occur that may impact patient results.

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 resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate.

If an internal quality control process (eg, 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 defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP 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**
- ✓ Manufacturer product insert or manual

POC.09090 Daily QC - Blood Gas Instruments **Phase II**

The control materials for pH, pCO_2 and pO_2 represent both high and low values on each day of patient testing.

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

Evidence of Compliance:
- ✓ QC records reflecting the appropriate use of controls

POC.09145 QC - Blood Gas Instruments **Phase II**

At least one level of quality control for pH, pCO_2 and pO_2 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 (eg, electronic/procedural/built-in) may be used to meet this requirement if an individualized quality control plan (IQCP) has been approved by the laboratory director.

Evidence of Compliance:

✓ QC results **OR** record of internal calibrator

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.

POC.09172 Safety Manual **Phase II**

The POCT program has defined safety practices commensurate with the scope of its activities to ensure the safety of patients and health care personnel.

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

Personnel use standard precautions for point-of-care testing.

NOTE: Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions. Hands must be cleaned using an effective antimicrobial method.

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.

POC.09190 Testing Devices - Disinfection **Phase II**

Personnel disinfect portable and handheld testing devices following infection control policies to prevent transmission of infections.

NOTE: Compliance with the manufacturer's guidelines when provided is required. Handheld or portable testing devices must be disinfected after each patient use. Devices and materials designed for single use must not be disinfected and reused.