

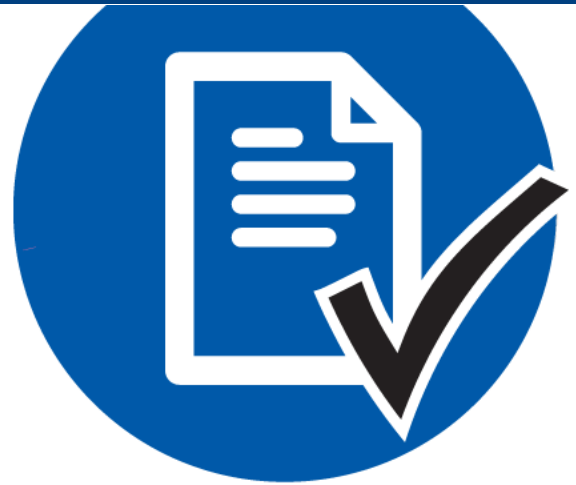


COLLEGE of AMERICAN
PATHOLOGISTS

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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

<u>Requirement</u>	<u>Effective Date</u>
POC.06875	12/26/2024
POC.06920	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



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.

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

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 - Fingertick

Phase II



Only auto-disabling single-use fingertick 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.