COLLEGE of AMERICAN PATHOLOGISTS

Master

Point-of-Care-Testing Checklist

CAP Accreditation Program

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Point-of-Care-Testing Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-*LAB* Solutions Suite. 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.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Point-of-Care-Testing Checklist
09/22/2021 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 on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements

Requirement	Effective Date
POC.06915	09/22/2021
POC.08640	06/04/2020
POC.09625	09/22/2021

REVISED Checklist Requirements

Requirement	Effective Date
POC.06850	09/22/2021
POC.06875	09/22/2021
POC.06910	09/22/2021
POC.06920	09/22/2021
POC.07300	09/22/2021
POC.08715	09/22/2021
POC.09035	09/22/2021

POC.09500	09/22/2021
POC.09600	09/22/2021
POC.09700	09/22/2021

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.

***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 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 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.

Inspector Instructions:

	• Review the Point-of-Care Testing Detail Report located in the inspector packet of materials and discuss the various test sites with the POCT coordinator to determine which sites to visit. Indicate which POCT sites were visited by placing an "X" in the corresponding box on the Point-of-Care Testing Detail Report and return it to the CAP with the Inspector's Summation Report. 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 (eg, 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 system 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 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.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Essential Tools for Implementation and Management of a Point-of-Care Testing Program; Approved Guideline.* 3rd ed. CLSI document POCT04-ED3. Clinical and Laboratory Standards Institute, Wayne PA; 2016.

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 (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 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 (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 troubleshooting.

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 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:

READ	• Sampling of reporting policies and procedures • Sampling of patient reports
DISCOVER	• Select a point-of-care test result and identify the individual who performed the test

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

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
2) Hortin GL, *et al*. Managing information from bedside testing. *Med Lab Observ.* 1995;27(1):28-32
3) Jones JB. The importance of integrating POCT data into an organized database. *Advance/Lab.* 1999;8(9):8-10
4) DuBois JA. Getting to the point: integrating critical care tests in the patient care setting. *Med Lab Observ.* 2000;32(6):52-56
5) Clinical and Laboratory Standards Institute. *Point-of-Care Connectivity; Approved Standard*. 2nd *ed.* CLSI document POCT01-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2006
6) Piscitelli J, *et al.* Are data obtained from a nonintegrated point-of-care glucose monitoring system reliable and accessible? *Arch Pathol Lab Med.* 2002;126:787

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 (eg, unconfirmed or pending confirmation)**
5. **A statement that unconfirmed results are to be used only for medical (ie, treatment) purposes. Unconfirmed screening results must not be used for non-medical purposes (eg, 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.

Laboratories are encouraged to identify the detected drugs as parent compounds, metabolites, or impurities of drugs in the report or in a separate chart/memorandum available to clinicians.

POC.04575 Group A Streptococcus Direct Antigen Detection **Phase I**

If group A Streptococcus direct antigen testing is performed on pediatric patients, confirmatory testing is performed on negative samples.

NOTE 1: Policies must be established for the use of cultures or other confirmatory tests on pediatric specimens that test negative when using antigen detection methods or if the manufacturer's guidelines include recommendations for culture follow-up. 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 culture) is rapid turn-around-time.

REFERENCES

1) Shulman S, Bisno A, Clegg H, et al. Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2012;55(10). doi: 10.1093/cid/cis629.

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
- Refractometer calibration check records

POC.06300 Instrument/Equipment Approval **Phase II**

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

REFERENCES
1) Sevens C, Libeer JC. Point-of-care testing (POCT) regulations in hospitals. The Belgian approach. *Clin Chem.* 2001;47(suppl):A185

POC.06330 Refractometer Calibration Check **Phase I**

Refractometers with specific gravity capability are checked at least annually with appropriate solutions of known specific gravity and/or refractive concentration index.

NOTE: This annual calibration check is required in addition to the daily QC requirement for non-waived testing.

REFERENCES
1) Haber MH. Quality assurance in urinalysis. *Clinics in Lab Med.* 1988;8:432-436
2) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.

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 or transcripts, or primary source verification reports confirming credentials, 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.*

Inspector Instructions:

- Sampling of training records
- Sampling of competency assessments for assessment of all six elements of competency for each nonwaived test system, semi-annual competency assessments for new employees, and assessments done by qualified individuals based on complexity of testing performed
- Records identifying personnel authorized to perform POCT
- Diplomas or transcripts, or primary source verification reports for nonwaived testing personnel

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

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.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline. 3rd ed*. CLSI document POCT12-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2013

***REVISED** 09/22/2021*
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.

Evidence of Compliance:
✓ Written procedure for training of POCT personnel

***REVISED** 09/22/2021*
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**
- *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.*

If more stringent state or local regulations are in place for competency assessment for waived testing (eg, California), they must be followed.

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, 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 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. 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).

Evidence of Compliance:

- ✓ Written procedure defining the method and frequency for assessing competency **AND**
- ✓ Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required 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(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413].
2) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med.* 2000;124:190-191
3) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202
4) Kost GJ. Preventing medical errors in point-of-care testing. *Arch Pathol Lab Med.* 2001;125:1307-1315
5) Deobald GR, *et al*. Two approaches to competency assessment for point of care testing. *Clin Chem*. 2001;47(suppl):A187

*****REVISED** 09/22/2021***

POC.06910 Competency Assessment Elements - Nonwaived Testing Phase II

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:

- ✓ Written procedure defining the method for assessing competency **AND**
- ✓ Records of competency assessment reflecting the specific skills assessed for each test system and the method of evaluation

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(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413]
2) Deobald GR, *et al*. Two approaches to competency assessment for point of care testing. *Clin Chem*. 2001;47(suppl):A187
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

*****NEW** 09/22/2021***

POC.06915 Competency Assessment Frequency - Nonwaived Testing Phase II

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 initiation 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:

- ✓ Written policy for the frequency of competency assessment **AND**
- ✓ Records of competency assessment for new and existing personnel at the required 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(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413].
2) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202
3) Kost GJ. Preventing medical errors in point-of-care testing. *Arch Pathol Lab Med.* 2001;125:1307-1315
4) Deobald GR, *et al*. Two approaches to competency assessment for point of care testing. *Clin Chem*. 2001;47(suppl):A187
5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

***REVISED** 09/22/2021*

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*

*For **moderate complexity testing**, the individual assessing competency must have a minimum of a bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology, with at least two years of training and/or experience in nonwaived testing in the designated specialty or subspecialty area of service for which the individual is responsible. This includes moderate complexity testing performed within the main laboratory, as well as moderate complexity testing performed in blood gas laboratories and point-of-care testing locations.*

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

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

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(Oct 1):1065-66 [42CFR493.1451(b)],1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

QUALITY CONTROL

QUALITY CONTROL – WAIVED TESTS

Inspector Instructions:

READ	• Sampling of quality control policies and procedures • Sampling of QC records
ASK	• How do you determine when QC is unacceptable and when corrective actions are needed?
DISCOVER	• Review a sampling of QC data over the previous two-year period. 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 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:

- ✓ Written procedure consistent with manufacturer's instructions for each waived test **AND**
- ✓ Records showing confirmation of acceptable QC results

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

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?
	• Review a sampling of QC data over the previous two-year period. 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** 09/22/2021***

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

Controls are run at least each day testing is performed, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests, 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**
- ✓ Written quality control procedures **AND**
- ✓ Manufacturer product insert or manual

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):3708 [42CFR493.1256(d)(3)], [42CFR493.1256(d)(6)].
2) Clinical and Laboratory Standards Institute (CLSI). *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI document EP12-A2 (ISBN 1-56238-654-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

POC.07456 Control Range Establishment or Verification — Phase II

An acceptable control range is established or verified for each lot of control material.

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

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

Evidence of Compliance:

- ✓ Written procedure to establish or verify control ranges **AND**
- ✓ Records for control range establishment or verification of each lot

REFERENCES

1) Clinical and Laboratory Standards Institute. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*. 3rd ed. CLSI Document EP05-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
2) Clinical and Laboratory Standards Institute. *Statistical Quality Control for Quantitative Measurement Procedures, Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

POC.07484 QC Corrective Action — Phase II

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 (eg, trending for repeat failures, etc.).

POC.07512 QC Handling **Phase II**

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 analysts 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

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):3708 [42CFR493.1256(d)(8)]

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

If the laboratory performs test procedures for which control materials are not commercially available, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include 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:

✓ Written procedures for alternative quality control **AND**

✓ Records of alternative control procedures

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): [42CFR493.1256(h)].

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

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

Evidence of Compliance:

✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results **AND**

✓ Records of control result approval

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):3708[42CFR493.1256(f)]

2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline.* 4th ed. CLSI document C24-ED4. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

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 (eg, 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 or lot, and shipment of stains, using known gram-positive and gram-negative organisms.

Evidence of Compliance:

✓ Records of QC for stain reactivity 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):3708 [42CFR493.1256(e)(2)]

CALIBRATION OF QUANTITATIVE SYSTEMS

CALIBRATION AND VERIFICATION PROCESSES – WAIVED TESTS

Inspector Instructions:

	• Sampling of calibration policies and procedures • Sampling of calibration/calibration verification records
	• 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?
	• Further evaluate the responses, corrective actions and resolutions for unacceptable calibration/calibration verification

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:

- ✓ 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 AND VERIFICATION PROCESSES – NONWAIVED TESTS

Inspector Instructions:

	• Sampling of calibration AMR policies and procedures • Sampling of calibration/calibration verification records • Sampling of AMR verification records
	• 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.

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 studies (see CHM.13720).

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 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, 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.

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):3707 [42CFR493.1255]
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule. *Fed Register*. 2003(Jan 24):3707 [42CFR493.1255]
3) Clinical and Laboratory Standards Institute. *Evaluation of Matrix Effects; Approved Guideline.* 3rd ed. CLSI Document EP14-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2014
4) Miller WG. Quality control. In: Henry's Clinical Diagnostic and Management by Laboratory Methods, 21st Edition, ed McPherson RA, Pincus MR. Saunders Elsevier , 2007,p 99-111

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:

✓ Written policy defining appropriate calibration and calibration verification materials

REFERENCES

1) ISO 17511:2003 In vitro diagnostic medical devices--Measurement of quantities in biological samples--Metrological traceability of values assigned to calibrators and control materials.

POC.08300 Recalibration/Calibration Verification Criteria — Phase II

Criteria are established for frequency of recalibration or calibration verification, and the acceptability of results.

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:

✓ 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

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):3707 [42CFR493.1255]
2) Miller WG. Quality control. In: Henry's Clinical Diagnostic and Management by Laboratory Methods, 21st Edition, ed McPherson RA, Pincus MR. Saunders Elsevier, 2007: 99-111.

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:

✓ Written policy defining criteria for recalibration **AND**

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

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): [42CFR493.1255(a)(3)]

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

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

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):3707 [42CFR493.1253]

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.*

Evidence of Compliance:

- ✓ Written policy for AMR verification defining the types of materials used and acceptability criteria

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):3702 [42CFR493.2]
2) Clinical and Laboratory Standards Institute. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline. 3rd ed*. CLSI document POCT12-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2013
3) Shah VP, Midha KK, Dighe S, et al. Bioanalytical Method Validation - Pharm Res.1992;9(4):588–92.

4) Hartmann C, Smeyers-Verbeke J, Massart DL, McDowall RD. Validation of bioanalytical chromatographic methods. J Pharm Biomed Anal. 1998;17(2):193–218.
5) Findlay JW, et al. Analytical Methods Validation - Bioavailability, Bioequivalence and Pharmacokinetic Studies. Pharm Res. 2000;17(12):1551-7.
6) Killeen AA, Long T, Souers R, Styler P, Ventura CB, Klee GG. Verifying Performance Characteristics of Quantitative Analytical Systems: Calibration Verification, Linearity, and Analytical Measurement Range. Arch Pathol Lab Med. 2014;138(9): 1773-81.

POC.08600 AMR Verification Criteria — 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 (ie, three points) and 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 validate 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).

Evidence of Compliance:

✓ Written policy for AMR verification defining the frequency performed **AND**
✓ Records of AMR verification at least every six months

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): [42CFR493.1255(b)(3)]

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.

The reference method for total bilirubin is described in Doumas et al, Candidate reference method for determination of total bilirubin in serum: development and validation, Clin Chem, 1985.

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

1) Lo SF, Doumas BT, Ashwood ER. Bilirubin proficiency testing using specimens containing unconjugated bilirubin and human serum: results of a College of American Pathologists study. *Arch Pathol Lab Med* 2004; 128:1219-1223.
2) American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. *Pediatrics* 2004; 114:297-316.
3) Doumas BT, Kwok-Cheung PP, Perry BW, et al. Candidate reference method for determination of total bilirubin in serum: development and validation. *Clin Chem* 1985; 31:1779-1789.
4) Lo SF, Doumas BT. The status of bilirubin measurements in U.S. Laboratories: Why is accuracy elusive? *Semin Perinatol* 2011; 35:141-147.
5) Barrington KJ, Sankaran K. Canadian Paediatric Society. Fetus and Newborn Committee. Guidelines for detection, management, and prevention of hyperbilirubinemia in term and late preterm newborn infants. http://www.cps.ca/documents/position/hyperbilirubinemia-newborn. Accessed August 18, 2014.

HIV PRIMARY DIAGNOSTIC TESTING

Inspector Instructions:

- Sampling of HIV diagnostic testing policies and procedures
- Sampling of HIV result reports

***NEW** 06/04/2020*

POC.08640 HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing Phase I

The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- *Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or*
- *Sends additional testing to a referral laboratory if the specimen is suitable, or*
- *Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.*

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the CDC and APHL websites.

This checklist item does not apply to the testing of individuals from whom human derived products for therapeutic use are being derived or other types of testing performed for the

monitoring of HIV infection (eg, viral load, CD4 counts). Reporting HIV results to public health is not within the scope of this checklist item.

Evidence of Compliance:

- ✓ Written policy for the performance of HIV testing **AND**
- ✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES

1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed 11/19/2019.
2) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at APHL Publications. Accessed 11/19/2019.

MOLECULAR-BASED MICROBIOLOGY TESTING - WAIVED TESTS

The requirements in this section apply to molecular-based microbiology tests classified as waived performed in the point-of-care setting. Microbiology testing performed by nonwaived molecular-based methods must be inspected with the Microbiology Checklist.

Inspector Instructions:

READ	• Sampling of QC statistics • Sampling of molecular microbiology specimen handling and processing policies and procedures • Sampling test reports (test methodology, clinical interpretation)
ASK	• What is your course of action when monitored statistics increase above the expected positive rate?

POC.08675 Quality Monitoring Statistics **Phase I**

There are written procedures to monitor for the presence of false positive results (eg, due to nucleic acid contamination) for all molecular microbiology tests.

NOTE: Examples of this may include review of summary statistics (eg, monitoring percentage of positive results relative to current local and regional rates and increased positive Strep results above historical rate within a run or over multiple runs), performance of wipe (environmental) testing, review and investigation of physician inquiries, and use of process controls to minimize risk of contamination.

Evidence of Compliance:

- ✓ Written procedure for monitoring for presence of false-positive results **AND**
- ✓ Records of data review, wipe testing, statistical data evaluation and corrective action if indicated

REFERENCES

1) Borst A, Box AT, Fluit AC. False-positive results and contamination in nucleic acid amplification assays: suggestions for a prevent and destroy strategy. *Eur J Clin Microbiol Infect Dis*. 2004; 23(4):289-99.
2) Cone RW, Hobson AC, Huang ML, Fairfax MR. Polymerase chain reaction decontamination: the wipe test. *Lancet*.1990; 336:686–687.
3) McCormack JM, Sherman ML, Maurer DH. Quality control for DNA contamination in laboratories using PCR- based class II HLA typing methods. *Hum Immunol*. 1997;54:82–88.

4) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments;* 1st ed. CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, 2011.

POC.08690 Specimen Handling Procedures **Phase II**

There are written procedures to prevent specimen loss, alteration, or contamination during collection, transport, processing and storage.

NOTE: Specimen collection, processing and storage must follow manufacturer's instruction and limit the risk of preanalytical error. For example, there must be a procedure to ensure absence of cross-contamination of samples during processing/testing for respiratory specimens tested at the point-of-care that may be sent to the laboratory for further testing.

It is also essential to follow the manufacturer's instructions for the handling of wastes (eg, used test cartridges) to prevent contamination.

*****REVISED** 09/22/2021***

POC.08715 Safe Specimen Handling/Processing **Phase II**

There are written policies and procedures for the safe handling and processing of specimens, including those suspected to contain highly infectious pathogens.

NOTE: These policies may be part of an institution's plan, but the plan must specifically address point-of-care.

Suggested topics to be considered in the policies and procedures for the safe handling and processing of specimens include the need for tight sealing of containers, avoiding spills of hazardous materials, requirements for wearing gloves, the need for respirator protection, availability and use of vaccinations.

For samples suspected of containing highly infectious pathogens, laboratories must review national, federal, state (or provincial), and local guidelines for the handling of samples from patients suspected to have high risk pathogens, such as Francisella tularensis, avian influenza, Ebola, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community.

REFERENCES

1) Jamison R, *et al*. Laboratory Safety in Clinical Microbiology, Cumitech 29, July 1996, ASM Press; Washington DC
2) Fleming DO, Hunt DL. Biological Safety, Principles and Practices, 3rd ed. ASM Press; Washington DC

POC.08730 Final Report **Phase I**

The final report includes a summary of the test method and information regarding clinical interpretation if appropriate.

NOTE: For tests that may be performed by either direct antigen or molecular-based methods (PCR), including the test method in the report is important for interpretation of the results. The report must include a brief description of the method if the methodology is not explicit in the test name.

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 • Review a sampling of QC data over the previous two-year period. 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.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

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.

POC.08760 Collateral Circulation **Phase II**

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

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

1) Vaghadia H, *et al*. Evaluation of a postocclusive circulatory hyperaemia (PORCH) test for the assessment of ulnar collateral circulation. *Can J Anaesth.* 1988;35:591-598
2) Cheng EY, *et al*. Evaluation of the palmar circulation by pulse oximetry. *J Clin Monit*. 1989;5:1-3
3) Levinsohn DG, *et al*. The Allen's test: analysis of four methods. *J Hand Surg.* 1991;16:279-282
4) Fuhrman TM, *et al*. Evaluation of collateral circulation of the hand. *J Clin Monit*. 1992;8:28-32

5) Furhman TM, *et al*. Evaluation of digital blood pressure, plethysmography, and the modified Allen's test as a means of evaluating the collateral circulation to the hand. *Anaesthesia.* 1992;47:959-961
6) Fuhrman TM, McSweeney E. Noninvasive evaluation of the collateral circulation to the hand. *Acad Emerg Med*. 1995;2:195-199
7) O'Mara K, Sullivan B. A simple bedside test to identify ulnar collateral flow. *Ann Intern Med.* 1995;123:637
8) Starnes SL, *et al*. Noninvasive evaluation of hand circulation before radial artery harvest for coronary artery bypass grafting. *J Thorac Cardiovasc Surg*. 1999;117:261-266
9) Cable DG, *et al*. The Allen test. *Ann Thorac Surg.* 1999;67:876-877

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

1) Ishikawa S, *et al*. The effects of air bubbles and time delay on blood gas analysis. *Ann Allergy.* 1974;33:72-77
2) Mueller RG, *et al*. Bubbles in samples for blood gas determinations. *Am J Clin Pathol*. 1976;65:242-249
3) Madiedo G, *et al*. Air bubbles and temperature effect on blood gas analysis. *J Clin Pathol.* 1980;33:864-867
4) Biswas CK, *et al*. Blood gas analysis: effect of air bubbles in syringe and delay in estimation. *Brit Med J*. 1982;284:923-927
5) McKane MH, *et al*. Sending blood gas specimens through pressurized transport tube systems exaggerates the error in oxygen tension measurements created by the presence of air bubbles. *Anesth Analg.* 1995;81:179-182
6) Astles JR, *et al*. Pneumatic transport exacerbates interference of room air contamination in blood gas samples. *Arch Pathol Lab Med*. 1996;120:642-647
7) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.

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, 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.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.
2) 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): [42CFR493.1255]

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:

✓ 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)]

2) 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): [42CFR493.1255]

***REVISED** 09/22/2021*

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:

- ✓ 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)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline.* 4th ed. CLSI document C24-ED4. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

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:

- ✓ 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)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline.* 4th ed. CLSI document C24-ED4. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Ng VL, *et al*. The rise and fall of i-STAT point-of-care blood gas testing in an acute care hospital. *Am J Clin Pathol.* 2000;114:128-138

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:

- ✓ 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)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline.* 4th ed. CLSI document C24-ED4. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

D-DIMER STUDIES

Inspector Instructions:

- Sampling of D-dimer policies and procedures
- Sampling of patient records

POC.09150 D-dimer Unit Results **Phase II**

The unit type (eg, FEU or D-DU) and unit of magnitude (eg, ng/mL) reported with the patient results are the same units as generated directly by the D-dimer method (following manufacturer's product insert); or if different units are reported, the laboratory verifies the correct conversion of the units on an annual basis.

NOTE: The CAP and Clinical Laboratory and Standards Institute (CLSI) recommend that units not be converted from those stated in the package insert. If units are converted, the laboratory must verify the conversion of the units in patient reports for patient values, cut-off values, and reference intervals with changes in reagents, instrument and at least once per year in the absence of a change, with records retained.

The units generated directly by the D-dimer method can be determined from the package insert. If units are not stated in the package insert, consult with the manufacturer of the D-dimer method.

The following chart demonstrates the correct conversion factor for the different reporting units:

Manufacturer Units	Final Units	Correct Conversion Factor	Equivalency Equation
FEU ng/mL	D-DU ng/mL	0.5	1 FEU ng/mL = 0.5 D-DU ng/mL
FEU ng/mL	D-DU µg/mL	0.0005	1 FEU ng/mL = 0.0005 D-DU µg/mL
FEU µg/mL	FEU ng/mL	1000	1 FEU µg/mL = 1000 FEU ng/mL
D-DU ng/mL	FEU ng/mL	2	1 D-DU ng/mL = 2 FEU ng/mL
D-DU µg/mL	FEU ng/mL	2000	1 D-DU µg/mL = 2000 FEU ng/mL
D-DU µg/mL	D-DU ng/mL	1000	1 D-DU µg/mL = 1000 D-DU ng/mL

Evidence of Compliance:

- ✓ Patient reports with unit type (FEU vs. DDU) and unit of magnitude (ng/mL vs. µg/mL) that are the same as the units directly generated by the D-dimer method and in the manufacturer's product insert **OR**
- ✓ Records of the annual verification to confirm correct conversion of the unit type (FEU vs. DDU) and unit of magnitude (ng/mL vs. µg/mL) if units are reported that are different than those directly generated by the D-dimer method

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline.* CLSI document H59-A (ISBN 1-56238-723-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2010.
2) Olson JD, Cunninghan MT, Higgins RA, et. al. D-dimer: simple test, tough problems. 2013; 137:1030-1038

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 (ie, 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
1) Olson J, Cunningham M, Brandt J, *et al*. Use of the D-Dimer for Exclusion of VTE: Difficulties Uncovered through the Proficiency Testing Program of the College of American Pathologists (CAP). *J Thromb Hemostasis*, Abstract, August 2005
2) Spannagl M, Haverkate F, Reinauer H, Meijer P. The performance of quantitative D-dimer assays in laboratory routine. *Blood Coagul Fibrinolysis*. 2005 Sep;16(6):439-43
3) Goodacre S, Sampson FC, Sutton AJ, *et al*. Variation in the diagnostic performance of D-dimer for suspected deep vein thrombosis. QJM. 2005 Jul;98(7):513-27. Epub 2005 Jun 13
4) Gardiner C, Pennaneac'h C, Walford C, *et al*. An evaluation of rapid D-dimer assays for the exclusion of deep vein thrombosis. *Br J Haematol*. 2005 Mar;128(6):842-8
5) Diamond S, Goldweber R, Katz S. Use of D-dimer to aid in excluding deep venous thrombosis in ambulatory patients. *Am J Surg*. 2005 Jan;189(1):23-6
6) Wolf SJ, McCubbin TR, Feldhaus KM, *et al*. Prospective validation of Wells Criteria in the evaluation of patients with suspected pulmonary embolism. *Ann Emerg Med*. 2004 Nov;44(5):503-10
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
8) Stein PD, Hull RD, Patel KC, *et al*. D-dimer for the exclusion of acute venous thrombosis and pulmonary embolism: a systematic review. *Ann Intern Med*. 2004 Apr 20;140(8):589-602
9) Clinical and Laboratory Standards Institute (CLSI). *Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline.* CLSI document H59-A (ISBN 1-56238-747-2). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2011.

POC.09156 D-dimer Reporting **Phase II**

If a D-dimer test is used for evaluation of venous thromboembolism (VTE), the laboratory reports the VTE exclusion cut-off value as stated by the manufacturer. If the D-dimer test is intended for other purposes (eg, DIC evaluation), a reference interval is required.

NOTE: This requirement only applies to quantitative D-dimer tests.

The cut-off value and upper limit of the reference interval are not always identical. The upper limit of the reference interval may be used to evaluate disseminated intravascular coagulation (DIC), while the cut-off value is used for evaluation of VTE (see COM.29950 regarding reference interval reporting). The cut-off value and/or reference interval must be reported in units identical to the patient results, including both unit type (FEU or D-DU) and unit of magnitude (eg, ng/mL).

Evidence of Compliance:

✓ Patient reports including the reference interval and/or the cut-off value for VTE evaluation

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline.* CLSI document H59-A (ISBN 1-56238-747-2). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2011.

POC.09160 Sensitivity of D-dimer Test - Evaluation of VTE **Phase I**

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.

NOTE: Manual agglutination D-dimer and FDP (fibrin degradation products) assays are not adequately sensitive for evaluation of deep vein thrombosis and/or pulmonary embolism.

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:

	• Sampling of POCT safety policies and procedures
	• Patient specimen collection and testing • Glove use and proper hand hygiene practices between patients • Single use fingerstick devices • Disinfection of portable or hand-held test devices after each patient use
	• 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
	• Follow the specimen collection and testing process. Determine if appropriate standard precautions and infection control practices defined in policies and procedures are being followed.

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. Hands must be cleaned using an effective antimicrobial method.

Evidence of Compliance:

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

REFERENCES
1) Clinical and Laboratory Standards Institute. *Essential Tools for Implementation and Management of a Point-of-Care Testing Program; Approved Guideline.* 3rd ed. CLSI document POCT04-ED3. Clinical and Laboratory Standards Institute, Wayne PA; 2016.
2) Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51.
3) World Health Organization. WHO Guidelines on Hand Hygiene in Health Care, 2009. http://apps.who.int/iris/bitstream/10665/44102/1/9789241597906_eng.pdf, accessed 12/5/2015.

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
2) Food and Drug Administration, Center for Devices and Radiological Health. Blood Lancet Labeling - Guidance for Industry and Food and Drug Administration Staff. Rockville, MD: Food and Drug Administration; 2010.

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

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. Devices and materials designed for single use must not be disinfected and reused.

REFERENCES
1) Food and Drug Administration, Center for Devices and Radiological Health. Blood Lancet Labeling - Guidance for Industry and Food and Drug Administration Staff. Rockville, MD: Food and Drug Administration; 2010.

PROVIDER-PERFORMED MICROSCOPY (PPM) AND LIMITED WAIVED TESTING

IMPORTANT INFORMATION FOR LABORATORIES AND INSPECTORS

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

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

The Provider-Performed Microscopy and Limited Waived Testing section is used alone to inspect the tests listed above when performed by a qualified provider; the other sections of the POC Checklist do NOT apply. A limited number of requirements from the COM Checklist are also used for inspection of this testing, including:

- *COM.01200 (Activity Menu)*
- *COM.10200 (New Procedure Review) - laboratories subject to US regulations*
- *COM.10250 (New Procedure Review) - laboratories not subject to US regulations*

The performance of tests, other than those tests listed above, is subject to inspection with the other sections of the POC and COM Checklists and/or other discipline-specific checklists, as appropriate.

Inspector Instructions:

	• Sampling of policies and procedures for testing performed by physicians and mid-level practitioners (including specimen handling and QM) • Sampling of records for QC, instrument maintenance, proficiency testing, and reagent storage • Sampling of training records • Sampling of competency assessments for PPM • Sampling of patient reports for completeness
	• How do you ensure that physicians and mid-level practitioners are trained and competent?
	• Trace the process from test order to resulting to ensure the departmental procedures and manufacturer's requirements are followed

POC.09200 Scope of Testing **Phase II**

There is a written policy outlining laboratory testing personally performed by physicians and mid-level practitioners within their scope of clinical practice, and includes the following items, as applicable:

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

POC.09300 Procedure Manual **Phase II**

There is a written procedure for each test performed by physicians and mid-level practitioners, including specimen handling information.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline* 2nd ed. CLSI document POCT10-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2011.

POC.09400 QMS for Physician and Mid-Level Practitioner Testing **Phase II**

A quality management system (QMS), appropriate for the nature of the testing performed by physicians and mid-level practitioners is defined and includes records of 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)**

Evidence of Compliance:
- ✓ Written QMS **AND**
- ✓ Records of quality monitoring

REFERENCES
1) Clinical and Laboratory Standards Institute. *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline* 2nd ed. CLSI document POCT10-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2011.

*****REVISED** 09/22/2021***
POC.09500 Personnel Training - Physicians and Mid-Level Practitioners **Phase II**

There are records that all physicians and mid-level practitioners have satisfactorily completed training on the performance of the specific tests performed.

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

Evidence of Compliance:
- ✓ Written procedure for training

REFERENCES
1) Clinical and Laboratory Standards Institute. *Training and Competence Assessment, Approved Guideline.* 3rd ed. CLSI Document QMS03-S3. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.
2) Centers for Disease Control and Prevention. Provider-Performed Microscopy Procedures: A Focus on Quality Practices Accessed March 12, 2021. https://www.cdc.gov/labquality/docs/PMP_Booklet_7252019.pdf.

*****REVISED** 09/22/2021***
POC.09600 Competency Assessment Elements - PPM **Phase II**

The competency of physicians and mid-level practitioners performing provider-performed microscopy (PPM) is assessed by the laboratory director or a qualified designee for each test system.

NOTE: This requirement does not apply to waived testing. The laboratory director may determine how competency of waived testing is determined.

Competency for PPM procedures must be assessed by the laboratory director or be delegated to an individual meeting technical consultant qualifications (GEN.53625).

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 used to generate PPM test results.

*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 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 specimens (eg, de-identified patient specimens), or external proficiency testing specimens*
6. *Evaluation of problem-solving skills*

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:

- ✓ Written policy defining the method and frequency for assessing competency **AND**
- ✓ Record of competency assessment for new and existing physicians and mid-level practitioners reflecting the specific skills assessed and the method of evaluation

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(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html
3) Centers for Disease Control and Prevention. Provider-Performed Microscopy Procedures: A Focus on Quality Practices Accessed March 12, 2021. https://www.cdc.gov/labquality/docs/PMP_Booklet_7252019.pdf.

*****NEW** 09/22/2021***

POC.09625 Competency Assessment Frequency - PPM **Phase II**

The competency of physicians and mid-level practitioners performing provider-performed microscopy is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

NOTE: This requirement does not apply to waived testing. The laboratory director may determine how competency of waived testing is determined.

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 initiation of testing and second assessment no longer than 12 months from the start of testing) during the first year an individual tests patient specimens (new employees)*
- *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 providers performing PPM 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:

✓ Written policy for the frequency of competency assessment **AND**

✓ Records of competency assessment for new and existing physicians and mid-level practitioners at the required 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(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html
3) Centers for Disease Control and Prevention. Provider-Performed Microscopy Procedures: A Focus on Quality Practices Accessed March 12, 2021. https://www.cdc.gov/labquality/docs/PMP_Booklet_7252019.pdf.

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POC.09700 Result Reporting System **Phase I**

The system for reporting results of testing performed by physicians and mid-level practitioners is adequate.

NOTE: Acceptable test result reporting requires all of the following components for every result:

1. *Patient identifier*
2. *Test ordered/performed and provider's name/identifier*
3. *Date/time of specimen collection*
4. *Specimen source, when applicable*
5. *Test result*
6. *Reference interval or interpretive notes, as appropriate.*