COLLEGE of AMERICAN PATHOLOGISTS

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Point-of-Care-Testing Checklist

CAP Accreditation Program

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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text. **Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2024 CHECKLIST EDITION CHANGES
NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
		New	POC	03325
		New	POC	04425
		New	POC	09146
		New	POC	09147
		New	POC	09148

*Deleted – Removed the requirement from the checklist edition
*Merged – Combined the requirement with a similar requirement in the same or different checklist
*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

ON-LINE CHECKLIST DOWNLOAD OPTIONS

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

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

INTRODUCTION

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

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

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

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

DEFINITION OF POINT-OF-CARE TESTING

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

PROFICIENCY TESTING

*****NEW** 12/26/2024***

POC.03325 Hemoglobin A1C Testing **Phase I**

For laboratories that use accuracy-based proficiency testing (PT) for hemoglobin A1C, the laboratory evaluates its results based on acceptable performance criteria of +/- 6% from the target value, with appropriate corrective action taken for each unacceptable result.

NOTE: The CAP recommends use of accuracy-based PT products, when possible, to evaluate the accuracy of hemoglobin A1C results. Due to limitations in product stability, this may not be available for laboratories outside of the US.

The Centers for Medicare and Medicaid Services (CMS) have established acceptable performance criteria for hemoglobin A1C as a regulated analyte at +/- 8% from the target value. The CAP and all CAP-accepted PT providers must use the +/- 8% criteria in the formal grading of the PT for reporting non-waived results to the CMS. For laboratories participating in the CAP's accuracy-based PT program for hemoglobin A1C, the CAP will also evaluate their results against the target value using +/- 6% performance criteria. This is provided in the participant evaluation and participant summary report. Laboratories must review their performance against +/- 6% criteria and perform corrective action for each unacceptable result.

Evidence of Compliance:
✓ Records of accuracy-based PT evaluation using the +/- 6% performance criteria

REFERENCES
1) Sacks DB, Arnold M, Bakris GL, et al. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. *Clin Chem*. 2023;69(8):808-68.

QUALITY MANAGEMENT
RESULTS REPORTING

POC.04425 eGFR and LDL Cholesterol Calculated Test Results **Phase I**

Clinicians have access to information regarding the equation used to calculate results for estimated glomerular filtration rate (eGFR) and low density lipoprotein (LDL) cholesterol.

NOTE: Calculated results may differ based on which equation is used. This may limit clinical assessment of results and/or comparability of calculated results across laboratories, particularly when the source equation is not readily available to providers.

The information can be made available to clinicians using different approaches, such as on the patient report, test reference guide, or inclusion of the equation name in the test name.

Evidence of Compliance:
✓ Patient reports with information on the calculation used **OR**
✓ Test reference guide or other mechanism for providing calculation information

REFERENCES
1) Inker LA, Eneanya ND, Coresh J, et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. *N Engl J Med*. 2021;385(19):1737-49.
2) Sampson M, Ling C, Sun Qian, et al. A New Equation for Calculation of Low-Density Cholesterol in Patients With Normolipidemia and/or Hypertriglyceridemia. *JAMA Cardiol*. 2020; 5(5):540-48.

PERSONNEL

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

POC.06875 Competency Assessment - Waived Testing **Phase II**

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

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

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

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

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

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

*For waived test systems, the laboratory may select which elements to assess. It is not necessary to assess all six elements listed below at each assessment event unless more stringent state and local regulations are in place (eg, California~~, where each assessment **must include***** regulation CCR Title 17 1036.3, which includes elements 1, 2, 3, 4, and 6, below). Elements of competency assessment include, but are not limited to:*

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

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

Evidence of Compliance:

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

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
6) California Code of Regulations, Title 17 § 1036.3

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

POC.06920 Competency Assessment - Assessor Qualifications Phase II

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

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

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

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

*~~For~~*If both moderate and high 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~~performed, a general supervisor or individual meeting those qualifications may assess the competency for both moderate and high complexity testing ~~performed within the main laboratory, as well as~~ .*

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

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

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

~~For~~For waived testing performed at laboratories with California laboratory licensure, ~~competency of waived testing personnel must be assessed by an individual meeting~~California regulation CCR Title 17 1036.3 states that a waived laboratory supervisor ~~qualifications~~ is responsible for evaluating and documenting competency (refer to GEN.78250).

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

Evidence of Compliance:

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

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~~ [2023(Dec 28):[42CFR493.1451(b)]~~,1053-54~~ [)(8)],[42CFR493.1413~~], 1992 (Feb 28) 7184~~(b)(8)], and [42CFR493.~~1713]. 1463~~(b)(4)].
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. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf
3) California Code of Regulations, Title 17 § 1036.3

HIV PRIMARY DIAGNOSTIC TESTING

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:

✓ 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) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US).. Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available at: https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 4/2/2023.
3) 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.

BLOOD GAS ANALYSIS

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

POC.08760 Collateral Circulation **Phase II**

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

NOTE: ~~The~~Any of the various technologies ~~available have been~~ evaluated in the published literature are acceptable. Consensus should be established between the point-of-care program and involved clinicians to define situations that require testing for collateral circulation, ~~to include preferred technique(s) and situations in which such a test is medically useful in averting potential patient injury. The site from where the sample was obtained must be recorded.~~if any, to potentially avert patient injury.

Evidence of Compliance:

✓ 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

COAGULATION

SPECIMEN COLLECTION AND HANDLING - COAGULATION

***NEW** 12/26/2024*

POC.09146 Specimen Handling for Whole Blood-Based Testing - Coagulation **Phase II**

Specimens for whole blood-based coagulation testing are handled according to manufacturer's instructions or as validated by the laboratory.

NOTE: Specimens must not be:

- *Heated, refrigerated, or frozen*
- *Centrifuged - Centrifuged specimens must be rejected. Reconstitution of a centrifuged specimen by mixing is not adequate.*

For additional specimen handling for platelet function studies, refer to POC.09147.

***NEW** 12/26/2024*

POC.09147 Specimen Handling - Platelets **Phase II**

Blood specimens for platelet aggregation and platelet function studies are handled at room temperature before testing.

NOTE: Platelets develop a cold-induced conformational change and dysfunction when handled at temperatures <20°C. Even when re-warmed, platelets may not regain normal function. Therefore, platelet specimens must always be handled at "room temperature," which is generally defined as 20 to 25°C (68 to 77°F) before testing and must never be refrigerated, chilled on ice or frozen.

REFERENCES
1) Winokur R, Hartwig JH. Mechanism of shape change in chilled human platelets. *Blood.* 1995; 85:1796-1804.
2) Clinical and Laboratory Standards Institute (CLSI). *Platelet Function Testing by Aggregometry; Approved Guideline*. CLSI document H58-A. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2008.
3) Mani H, Kitchmayr K, Klaffling C, et al. Influence of blood collection techniques on platelet function. *Platelets.* 2004;15(5):315-318.
4) Kattlove HE, Alexander B. The effect of cold on platelets. I. Cold-induced platelet aggregation. *Blood.* 1971;38(1):39-48.
5) Kattlove HE, Alexander B, White F. The effect of cold on Platelets. II. Platelet function after short-term storage at cold temperatures. *Blood*. 1972;40(5):688-695.

***NEW** 12/26/2024*

POC.09148 Coagulation Testing and Therapeutic Anticoagulant Recommendations **Phase I**

Recommendations are available to clinicians on the following:

- **Laboratory tests used for monitoring heparin, low molecular weight heparin, direct thrombin inhibitors (eg, lepirudin, bivalirudin, argatroban) and/or oral anticoagulant therapy**
- **Utility and limitations of viscoelastic testing**
- **The therapeutic range for the tests, if available**
- **Information about potential interferences of anticoagulant medications on coagulation testing.**

NOTE: The coagulation tests available to clinicians should be applicable to the anticoagulant drugs in use, and information is available on the test values that indicate that the anticoagulant is present and/or is in a therapeutic range, when available.

For vitamin K antagonists (eg, warfarin), the prothrombin time (PT/INR) is recommended. Direct oral anticoagulant medications (non-vitamin K) should not be monitored with PT/INR or aPTT because the effect of these tests is not predictable. For unfractionated heparin the activated partial thromboplastin time (aPTT) and/or activated clotting time are commonly used, but the heparin assay (factor Xa inhibition) may also be employed. For low molecular weight heparin or danaparoid, monitoring is often not necessary, but the heparin assay (Xa inhibition assay) may be used in certain circumstances, as the aPTT is generally insensitive to the effect of these agents. Direct parenteral thrombin inhibitors are often monitored using the aPTT. The thrombin time may be useful to qualitatively verify the presence of direct thrombin inhibitors.

For viscoelastic testing, recommendations on the utility of testing in clinically meaningful situations must be available, including the following as applicable:

- *Proper test selection*
- *Instrument comparability and/or*
- *Recommendations for viscoelastic testing-based monitoring of antiplatelet or anticoagulant medications.*

Evidence of Compliance:

✓ Memoranda to physicians, test reference guide, interpretive comments in patient reports, or other mechanism for providing recommendations to physicians for ordering and interpreting coagulation tests used for diagnostic purposes and anticoagulant therapy monitoring

REFERENCES
1) Leech BF, Carter CJ. Falsely elevated INR results due to the sensitivity of a thromboplastin reagent to heparin. *Am J Clin Pathol.* 1998;109:764-768.
2) Fairweather RB, *et al*. College of American Pathologists conference XXXI on laboratory monitoring of oral anticoagulant therapy. *Arch Pathol Lab Med.* 1998;122:768-781.
3) Olson JD, *et al*. College of American Pathologists conference XXXI on laboratory monitoring of oral anticoagulant therapy. Laboratory monitoring of unfractionated heparin therapy. *Arch Pathol Lab Med.* 1998;122:782-798.
4) Davis KD, *et al*. Use of different thromboplastin reagents causes greater variability in international normalized ratio results than prolonged room temperature storage of specimens. *Arch Pathol Lab Med.* 1998;122:972-977.
5) Laposata M, *et al*. College of American Pathologists conference XXXI on laboratory monitoring of low-molecular-weight heparin, danaparoid, hirudin and related compounds, and argatroban. *Arch Pathol Lab Med.* 1998;122:799-807.
6) Smythe MA, *et al*. Use of the activated partial thromboplastin time for heparin monitoring. *Am J Clin Pathol.* 2001;115:148-155.
7) Smythe MA, et al. Different heparin lots. Does it matter? *Arch Pathol Lab Med*. 2001;125:1458-1462.
8) Hirsh J, *et al*. Heparin and low-molecular-weight heparin: Mechanisms of action, pharmacokinetics, dosing, monitoring, efficacy and safety. *Chest.* 2001; 119:64s-94s.
9) Hirsh J, *et al*. Guide to anticoagulant therapy. Heparin: a statement for healthcare officials from the American Heart Association. *Circulation.* 2001 19:2994-3018.
10) Lippi G and Favaloro EJ. Recent guidelines and recommendations for laboratory assessment of the direct oral anticoagulants (DOACs): is there consensus? *Clin Chem Lab Med.* 2015; 53(2):185-197.
11) Tomaselli GF, Mahaffey KW, Cuker A, et al. 2017 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. *J Am Coll Cardiol.* 2017; 70(24):3042-67.
12) Cuker A, Siegal D. Monitoring and reversal of direct oral anticoagulants. Hematology Am Soc Hematol Educ Program. 2015(1):117-124.
13) Adcock DM, Gosselin R. Direct Oral Anticoagulants (DOACs) in the Laboratory: 2015 Review. *Thromb Res.* 2015; 136(1):7-12.
14) College of American Pathologists. Coagulation Limited Proficiency Testing - Participant Summary Report (CGL-B 2016: Therapeutic Anticoagulants) Continuing Education: 46-58. Published July 2016.
15) Funk DM. Coagulation assays and anticoagulant monitoring. Hematology Am Soc Hematol Educ Program. 2012(1):460-5.
16) Kottke-Marchant K (ed). An Algorithmic Approach to Hemostasis Testing. 2nd edition. CAP Press: 2016.
17) Favaloro EJ, Lippi G. Interference of direct oral anticoagulants in haemostasis assays: high potential for diagnostic false positives and false negatives. *Blood Transfus*. 2017; Oct; 15(6):491-494.

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~~ie, physician ~~assistants~~assistant, nurse ~~practitioners, certified~~practitioner, nurse ~~midwives~~midwife, nurse anesthetist, or clinical nurse specialist licensed to practice in the jurisdiction in which the laboratory is located) in conjunction with the physical examination or treatment of a patient, and is limited to the following bright field or phase contrast provider-performed microscopy (PPM) procedures and waived tests.

1. *Vaginal pool fluid smears for fern*ing
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 of the POC Checklist 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. Applicable requirements in the GEN, DRA, and COM checklists are also used.

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

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

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). If PPM is performed under a CLIA Certificate of Provider-Performed Microscopy Procedures, the laboratory director may only delegate competency assessment to another individual qualified as a PPM laboratory director (DRA.10100~~).~~) or a midlevel practitioner licensed in the jurisdiction in which the laboratory is located, if required.

Competency assessment records must include all ~~six~~five 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~~five ***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.~~4. *Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens), or external proficiency testing specimens*

~~6.~~5. *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:

✓ 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~~ [2023(Dec 28):[42CFR493.~~1453~~]1359(c)] and ~~1053-4~~ [2003(Oct 1)[42CFR493.1413~~]~~ (b)(8)].
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. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf
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~~.