Every patient deserves the GOLD STANDARD ...
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If a Checklist has been updated since receiving your packet, you will be inspected based upon the Checklists that were mailed. If you have any questions about the use of Checklists in the inspection process, please e-mail the CAP (accred@cap.org), or call (800) 323-4040, ext. 6065.

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# Point-of-Care-Testing Checklist

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Please refer to the listed sections for detailed information.
SUMMARY OF CHECKLIST EDITION CHANGES
Point-of-Care-Testing Checklist
07/11/2011 Edition

The following requirements have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the requirements included may not appear in the customized checklist. Such requirements are not applicable to the testing performed by the laboratory.

Note: For revised checklist requirements, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.

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UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

To provide laboratories with a better means to engage in and meet their accreditation requirements, the CAP has enhanced the checklist content and updated its design. New components containing additional information for both the laboratory and inspectors include Subject Headers, Declarative Statements and Evidence of Compliance. See below for a definition of each new feature as an example of how they appear in the checklists.

**Using Evidence of Compliance (EOC)**

This component, which appears with several checklist requirements, is intended to:

1. Assist a laboratory in preparing for an inspection and managing ongoing compliance
2. Drive consistent understanding of requirements between the laboratory and the inspector
3. Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.)

In addition to the Evidence of Compliance listed in the checklist, other types of documentation may be acceptable. Whenever a policy/procedure/process is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies/procedures/processes covered in the CAP checklists must be documented. A separate policy is not needed for each item listed in EOC as it may be referenced in an overarching policy.
**HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES**

*Read, Observe, Ask, Discover*

CAP has streamlined the inspection approach used during onsite inspections and is now offering guidance to inspectors by providing assessment techniques to facilitate a more efficient, consistent, and effective inspection process. Specific inspector instructions are listed at the beginning of a grouping of related requirements.

Rather than reviewing each individual requirement, CAP inspectors are encouraged to focus on the Inspector Instructions for a grouping of related requirements. Once an area of concern has been identified through "Read," "Observe," "Ask," "Discover," or a combination thereof, inspectors are encouraged to "drill down" to more specific requirements, when necessary and review more details outlined in the Evidence of Compliance statements. If a requirement is non-compliant, circle the requirement number to later list on the Inspector Summation Report. Inspectors may also make notes in the margins of the checklist document.

Inspector Instructions and Icons used to evaluate a laboratory's performance now appear in several areas throughout the Inspector Checklists. Please note that all four R.O.A.D elements are not always applicable for each grouping, or sections of related requirements.

**Inspector Instructions:**

| **READ** | Review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff.  
(Example of the complimentary inspector instructions for Quality Management/Quality Control General Issues section appearing across checklists):  
- Sampling of QM/QC policies and procedures  
- Incident/error log and corrective action |
| --- | --- |
| **OBSERVE** | Laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures.  
(Example)  
- Observe the settings/QC range limits established in the laboratory LIS/HIS to ensure that the laboratory's stated ranges are accurately reflected |
| **ASK** | Open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process.  
(Example)  
- As a staff member, what is your involvement with quality management?  
- How do you detect and correct laboratory errors? |
| **DISCOVER** | A technique that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously.  
(Example)  
- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action |
INTRODUCTION

An inspection of a laboratory section, or department will include the discipline-specific checklist(s), the Laboratory General Checklist, and the All Common Checklist.

In response to the ongoing request to reduce the redundancy within the Accreditation Checklists, the CAP accreditation program is introducing the All Common Checklist (COM).

The purpose of the All Common Checklist is to group together those requirements that were redundant in Laboratory General and the discipline-specific checklists. Therefore, the CAP centralized all requirements regarding: proficiency testing, procedure manuals, test method validations, and critical results into one checklist, the COM checklist.

Note for non-US laboratories: Checklist requirements apply to non-US laboratories unless the checklist items contain a specific disclaimer of exclusion.

APPLICABILITY

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

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 that site (e.g. capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g. operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space; these are covered under the Limited Service Laboratory Checklist.

CLIA classifies tests according to complexity into waived and nonwaived categories. The non-waived category is further subdivided into tests of moderate and high complexity.

This checklist covers only tests that are classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests). In this edition of the checklist, requirements for quality control, reagents and calibration are different for waived tests, as compared to moderately complex tests; please refer to the relevant individual checklist sections, below, for further details. Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and moderately complex tests.

The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Tests/instruments that are NOT covered by the POC checklist include all tests classified under CLIA as high complexity, as well as legal drug testing, multichannel blood cell counters, bacterial cultures, and tests that use instruments requiring high levels of maintenance or technical skill. The CAP central office may be contacted for information about whether a specific test or instrument may be inspected using the POC checklist.
If a POCT site has a scope of service in a particular laboratory discipline that exceeds those addressed in this checklist, then a section-specific checklist (e.g. Hematology, Microbiology) may be required.

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

**PRINCIPLES OF POCT OPERATIONS**

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

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

**QUALITY MANAGEMENT**

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

**Inspector Instructions:**

- Sampling of QM policies and procedures
- QM program, including pre-analytic, analytic and post-analytic monitor records and corrective action when indicators do not meet threshold
- Incident/error log and corrective action
- Organizational chart

- How do you evaluate data on the incident/error log? How do you determine appropriate corrective action?
- As a staff member, what is your involvement with quality management?
- How do you detect and correct point of care testing errors?
- How do you determine appropriate corrective action?
- 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
- Select several problems identified by the QM plan and follow tracking and corrective action. Determine if the methods used led to discovery and effective correction of the problem.
POC.03500  Documented QM Plan  

The point-of-care testing program has a written QM program.

NOTE: The QM program for POCT must be clearly defined and documented. The program must ensure quality throughout the preanalytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, and processing; and accurate result reporting. The program must be capable of detecting problems and identifying opportunities for system improvement. The POCT program must be able to develop plans of corrective/preventive action based on data from its QM system.

REFERENCES

POC.03550  Organizational Chart  

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 or procedures defining responsibilities of POCT users. These elements may be combined in one document or included in lab policies on delegation of responsibilities and/or individual POCT procedures.

POC.03700  Unusual Laboratory Results  

There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual or unexpected test results, in a timely manner.

NOTE: This system may need to include feedback from clinicians, with subsequent investigation and monitoring of patient results for unusual patterns (e.g. a series of unexplained hypoglycemic values) suggesting analytic error. Where POCT personnel are also the individuals who will act upon test results (e.g. by altering insulin dosage in response to whole blood glucose results, or altering heparin dosage in response to activated clotting time or aPTT), there should be defined criteria for correlating unexpected test results with other clinical findings to validate such results whenever possible.
The intent of this requirement is NOT to require verification of all results outside the reference (normal) range.

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

POC.03800 Troubleshooting Responsibilities Phase II

There is a documented 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 policy (i.e. sending the sample to a central laboratory), retesting by a different method/device, or having a suitably trained individual from the laboratory, nursing service, or medical staff available on all shifts to assist with troubleshooting.

SPECIMEN HANDLING

Proper specimen collection and handling are critical for correct laboratory results. The proximity of testing to the patient does not allow compromises in standard laboratory practice. Specific instructions for the proper collection and handling of specimens must be made available to POCT personnel.

Inspector Instructions:
- Sampling of specimen collection and handling policies and procedures

POC.04300 Specimen Collection Manual Phase II

There is a documented procedure describing methods for patient identification, patient preparation, specimen collection and labeling, specimen accessioning, and specimen preservation (if applicable) before testing.

NOTE: The proximity of the patient to POCT test systems does not preclude the need for proper identification systems to prevent reporting of one patient's result to another's record. The specific selection of identifiers is at the discretion of the director. Refer to the Phlebotomy section of the Laboratory General checklist for additional information.

Identification requirements apply to aliquots as well as to primary specimens.

REFERENCES

RESULTS REPORTING
**NEW** 06/17/2010

POC.04450 Legible Results

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

POC.04500 Reference Intervals

When applicable, all patient results are reported with accompanying reference (normal) intervals or interpretive ranges.

**NOTE:** Age- and/or sex-specific reference ranges (normal values) or interpretive ranges must be reported with patient test results, as applicable. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions, which are based on the test result.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals.
to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.

REFERENCES

POC.04525 Reference Intervals Established

Reference intervals (normal ranges) are established or verified for the population being tested.

NOTE: If a formal reference interval study is not possible or practical, then the POCT site should carefully evaluate the use of published data for its own reference ranges, and retain documentation of this evaluation.

Evidence of Compliance:
✓ Record of reference range study OR records of verification of manufacturer’s stated range when reference range study is not practical (e.g. unavailable normal population) OR other methods approved by the laboratory director

REFERENCES
2) Knight JA. Laboratory issues regarding geriatric patients. Lab Med. 1997;28:458-461

POC.04537 Urine Drugs of Abuse

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

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

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

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

POC.04700 Testing Personnel Identification

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.
**REAGENTS**

**Inspector Instructions:**

- Sampling of test procedures for reagent handling
- Sampling of new reagent lot validation records
- Sampling of refrigerator, freezer and room temperature logs (as applicable)

- Sampling of reagents (expiration date, labeling, storage)

- How do you store reagents and controls used in test procedures?
- How do you validate new reagent lots?
- What are your laboratory's criteria for mixing components from one lot number of reagent kit with components from another lot number of kit?
- How does your laboratory manage and control inventory?

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**REVISED** 07/11/2011

**POC.04750** Reagent Storage

**Phase II**

**All reagents are stored as recommended by the manufacturer.**

*NOTE:* If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored and recorded daily. The two acceptable ways of recording temperatures are: 1. recording the numerical temperature, or 2. placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be documented (recording the initials of the individual is adequate).

If ambient storage temperature is indicated, there must be documentation that the defined ambient temperature range is maintained.

The use of automated (including remote) temperature monitoring systems is acceptable, providing that point-of-care personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. The functionality of the system must be documented daily.

**Evidence of Compliance:**

✓ Records of reagent storage consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring, as applicable

**REFERENCES**


The remaining checklist requirements in the REAGENTS section do not apply to waived tests.

For non-waived tests, the verification of reagent performance is required and must be documented. Any of several methods may be appropriate, such as direct analysis with reference materials, parallel testing of old vs. new reagents, and checking against routine controls. The intent of the requirements is for new reagents to be checked by an appropriate method and the results recorded before being placed in service. Where individually...
Packaged reagents/kits are used, there should be criteria established for monitoring reagent quality and stability, based on volume of usage and storage requirements. Processing of periodic “wet controls” to validate reagent quality and operator technique is a typical component of such a system.

**POC.04800 Reagent Labeling**

Calibrators, reagents, and solutions are properly labeled, as applicable and appropriate, with the following elements.

1. Content and quantity, concentration or titer
2. Storage requirements
3. Date prepared or reconstituted by the user
4. Expiration date

**NOTE:** The expiration date must be recorded on each container. The other elements listed above may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with “date received” is not routinely required. There is no requirement to routinely label individual containers with “date opened”; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

**Evidence of Compliance:**

✓ Written policy defining elements required for reagent labeling

**REFERENCES**


**POC.04900 Reagent Expiration Date**

All reagents are used within their indicated expiration date.

**NOTE:** The laboratory must assign an expiration date to any reagents that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.

For laboratories not subject to US regulations, expired reagents may be used only under the following circumstances: 1. The reagents are unique, rare or difficult to obtain; or 2. Delivery of new shipments of reagents is delayed through causes not under control of the laboratory. The laboratory must document validation of the performance of expired reagents in accordance with written laboratory policy. Laboratories subject to US regulations must not use expired reagents.

**Evidence of Compliance:**

✓ Written policy for evaluating reagents lacking manufacturer's expiration date

**REFERENCES**


**POC.05000 New Reagent Lot Verification**

The POCT program has established criteria for acceptability of new reagent lots and/or
shipments to ensure that quality control ranges are similar to those from the previous lot.

NOTE: The laboratory must run and compare results of material of known value prior to and following changing/priming of new reagent lots or shipments. The comparison studies must be performed before or at the same time that new reagent lots are placed in service. The material of known value may include either patient samples or control material. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot. Best clinical laboratory science includes patient-based comparisons in many situations, since it is patient results that are “controlled.” A weakly positive control should also be used in systems where patient results are reported in that fashion.

Evidence of Compliance:
✓ Written procedure for the verification of new lots and shipments prior to use AND
✓ Records of verification of new reagents/shipments

POC.05050 Reagent Kit Components Phase II

If there are multiple components of a reagent kit, the components of reagent kits are used only within the same kit lot unless otherwise specified by the manufacturer.

Evidence of Compliance:
✓ Written documentation defining allowable exceptions for mixing kit components from different lots

REFERENCES

INSTRUMENTS AND EQUIPMENT

There is a wide variety of instruments in use in POCT, and some requirements may not apply to every instrument. These requirements check factors common to most instruments, and inspectors should exercise judgment in applying the requirements to the particular instruments in use. The procedures and schedules for instrument maintenance must be as thorough and as frequent as specified by the manufacturer.

Inspector Instructions:
- Sampling of instrument(s) policies and procedures
- Documentation of equipment approval
- Sampling of instrument maintenance logs and repair records

POC.06300 Equipment Approval Phase II

The equipment in use is approved by the laboratory director or designee.

REFERENCES

POC.06400 Function Checks Phase II

There is a schedule or system for the regular checking of the critical operating
characteristics of all instruments in use.

NOTE: This must include, but is not limited to, electronic, mechanical, and operational checks, with documentation of compliance.

**REVISED** 06/17/2010
POC.06450 Instrument Maintenance Evaluation Phase II

There is documentation of monthly evaluation of instrument maintenance and function, including temperatures of refrigerators/freezers in which reagents or patient specimens are kept.

PERSONNEL

Inspector Instructions:

- Medical director’s qualifications
- Sampling of initial training records
- Sampling of competency assessments
- Sampling of color-blindness testing
- Listing of POCT personnel

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

POC.06600 Director Qualifications Phase II

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

NOTE: The director is responsible for all aspects of testing in the POCT program.

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

POC.06700 Personnel Training Phase II

There is evidence that testing personnel have adequate, specific training to ensure competence.

Evidence of Compliance:
✓ Written policy for training POCT personnel
✓ Records of training in personnel file

REFERENCES
POC.06800  Authorized POCT Personnel  Phase II

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

**NEW** 06/17/2010

POC.06850  Initial Training  Phase I

There is documentation that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

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

Retraining must occur when problems are identified with employee performance.

**REVISED** 07/11/2011

POC.06900  Competency Assessment  Phase II

There is a documented program to ensure that each person performing POCT maintains satisfactory levels of competence.

NOTE: The competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing. Thereafter, during the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of employee competency must occur when problems are identified with employee performance. Elements of competency assessment include but are not limited to:

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

Competency must be reassessed at least annually.

Other elements of competency may be assessed, as applicable. A laboratory must evaluate and document the competency of all testing personnel for each test system. A TEST SYSTEM is the process that included pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment, or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

The laboratory must identify the test systems that an employee used to generate patient results. Many of the elements of competency assessment are performed during routine supervisory
review of an employee. Documentation of these elements, including observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed by routine supervisory review, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment by routine supervisory review may be documented by a checklist. For nonwaived test systems, all the above six elements must be assessed annually (unless any are not applicable to the test system). For waived test systems, it is not necessary to assess all elements at each assessment event: the POC program may select which elements to assess.

The competency of physicians and midlevel providers who perform POC tests may be established and reassessed through the credentialing process of the institution's medical staff. Please refer to the Provider-Performed Testing (PPT) section of this checklist for further details.

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

REFERENCES

POC.06950 Visual Color Discrimination Phase I

POCT personnel are tested for difficulty with visual color discrimination.

NOTE: Formal color-blindness testing is not required for personnel who do not perform laboratory tests requiring color discrimination. Functional testing limited to discrimination of those colored items pertinent to the job is sufficient.

Evidence of Compliance:
✓ Record of color discrimination testing OR functional assessment, if indicated

QUALITY CONTROL

QUALITY CONTROL – WAIVED TESTS

Inspector Instructions:
- Sampling of quality control policies and procedures
- Sampling of QC records
How do you determine when QC is unacceptable and when corrective actions are needed?

Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action.

POC.07037  Documented QC Results - Waived Tests  Phase II

Control results are documented for quantitative and qualitative tests, as applicable.

NOTE: Quality control must be performed according to manufacturer instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run. The laboratory director or designee must review QC data at least monthly. Because of the many variables across laboratories, the CAP makes no specific recommendations on the frequency of any additional review of QC data.

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

All unacceptable control results must be documented (see below).

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

POC.07124  QC Corrective Action - Waived Tests  Phase II

There is evidence of corrective action when control results exceed defined acceptability limits.

POC.07211  QC Verification - Waived Tests  Phase II

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

Evidence of Compliance:
✓ Records showing verification of acceptability of QC

QUALITY CONTROL – NONWAIVED TESTS

Inspector Instructions:

- Sampling of quality control policies and procedures
- Sampling of QC records (including staining QC)
- Biannual instrument correlation records
Point-of-Care-Testing Checklist

**REVISED** 07/11/2011

POC.07300 Daily QC - Nonwaived Tests  Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE 1:  Except for tests meeting the criteria in Note 2, below, daily external controls must be run as follows:

- For quantitative tests, 2 controls at 2 different concentrations must be run daily or with each batch of samples/reagents, except for coagulation tests (2 controls required every 8 hours), or unless otherwise required elsewhere in this checklist.
- For qualitative tests, a negative control and a positive control (when available) must be run daily.

Control testing is not necessary on days when patient testing is not performed.

NOTE 2: Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

1. For quantitative tests, the test system includes 2 levels of electronic/procedural/built-in internal controls that are run daily
2. For qualitative tests, the test system includes an electronic/procedural/built-in internal control run daily
3. The system is FDA-cleared or approved, and not modified by the laboratory
4. The system is not classified as highly complex under CLIA
5. The laboratory has performed studies to validate the adequacy of limiting daily QC to the electronic/procedural/built-in controls. Validation studies must include daily comparison of external controls to built-in controls for at least 20 consecutive days when patient samples are tested. For validation of multiple identical devices, the minimum of 20 consecutive daily comparisons applies to the initial device; the laboratory director is responsible for determining the extent of the validation studies for the other devices. Acceptable validation is required before daily quality control can be limited to built-in controls. The laboratory director is responsible for determining criteria for acceptability, and other details of the validation. Validation records must be retained while an instrument is in service, and for 2 years afterwards. The requirement of 20 consecutive daily comparisons is effective for validation studies performed after 1/31/2012. Corrective action must be taken if either the internal or external control is out of acceptable range during or after the evaluation process. Repeating controls or re-evaluation of the internal control system may be necessary to achieve acceptable results.
6. **External surrogate sample controls are run for each new lot number or shipment of test materials** after major system maintenance; and after software upgrades. Regarding the positive external control for qualitative tests, best practice is to run a weak positive control, to maximize detection of problems with the test system.

7. **External surrogate sample controls are run at a frequency as recommended by the test manufacturer, or every 30 days, whichever is more frequent.**

* Repetition of the initial validation study is not required when running external controls with new lots/shipments of test materials, after system maintenance or software upgrade or in accordance with paragraph 7 in the Notes.

**Evidence of Compliance:**

✓ Records of QC results including external and electronic/procedural/built-in control systems AND

✓ Records documenting in-house validation of electronic/procedural/built-in control systems, if used

**REFERENCES**


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**POC.07428 QC Data**

**Phase II**

**Quality control data are evaluated daily to detect instrument or process failure.**

**NOTE:** Quality control data must be reviewed daily by testing personnel or supervisory technical staff to detect problems, trends, etc. The laboratory director or designee must review QC data at least monthly. Because of the many variables across laboratories, the CAP makes no specific recommendations on the frequency of any additional review of QC data.

**REFERENCES**


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**POC.07456 Acceptable Limits - Controls**

**Phase II**

**Acceptable limits are defined for control procedures.**

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

**Evidence of Compliance:**

✓ Records of verification of acceptable limits for control range of each lot

**REFERENCES**


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**POC.07484 QC Corrective Action**

**Phase II**

**There is documentation 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.

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, recognizing that pre-analytic and post-analytic processes may differ from those encountered with patients.

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

REFERENCES

POC.07540 QC Verification Phase II

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

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

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

REFERENCES

**REVISED** 07/11/2011
POC.07568 Comparability of Instrument/Method Phase II

If the laboratory/POCT program uses more than one instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for correlation of results.

NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods. This comparison must include all nonwaived instruments/methods. The laboratory director must establish a protocol for this check.

Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number.

Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential matrix effects. The use of pooled patient samples is acceptable since there is no change in matrix. In cases when availability or pre-analytical stability of patient/client specimens
is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/methods involved.

This checklist requirement applies only to instruments/methods accredited under a single CAP number.

Evidence of Compliance:
✓ Written procedure for performing instrument/method correlation including criteria for acceptability AND
 ✓ Records of correlation studies reflecting performance at least twice per year with appropriate specimen types

REFERENCES

POC.07600 QC Stain Reactivity

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

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

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

REFERENCES

CALIBRATION OF QUANTITATIVE SYSTEMS

Inspector Instructions:

Waived Testing:
• Sampling of calibration policies and procedures
• Sampling of calibration records

Non-Waived Testing:
• Sampling of calibration and AMR policies and procedures
• Sampling of calibration records
• Sampling of AMR validation records

Non-Waived Testing:
• Sampling of calibration materials (labeling, storage)
Non-Waived Testing:
- What is your course of action if calibration 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?

Non-Waived Testing:
- Further evaluate the responses, corrective actions and resolutions for unacceptable calibration, unacceptable calibration verification, and results outside the AMR.

POC.08050 Calibration, Calibration/Verification - Waived Tests
For waived tests, the POCT program follows manufacturer instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:
✓ Written procedure consistent with the manufacturer's instructions for each waived test AND
✓ Records for calibration/calibration verification-related functions documented as required by the manufacturer

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

Definitions:

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

CALIBRATION VERIFICATION: The process of confirming that the current calibration settings remain valid for a 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 not part of the usual assay process.

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

POC.08100 Calibration Procedures
Calibration procedures for each method are adequate, and the calibration results are documented.

REFERENCES
Point-of-Care Testing Checklist

POC.08300 Calibration Verification Criteria

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

NOTE: Criteria typically include:

1. At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient test results and the range used to report patient test data, or the control value
2. When indicated by quality control data
3. After major maintenance or service
4. As recommended by the manufacturer
5. At least every six months

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

REFERENCES

POC.08400 Recalibration

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

Evidence of Compliance:
✓ Records of recalibration, as applicable

POC.08450 AMR Limits Defined

Upper and lower limits of the ANALYTICAL MEASUREMENT RANGE (AMR) for all analytes are defined, so that results falling outside these limits are appropriately reviewed and reassayed if necessary before reporting.

NOTE: In many cases, the manufacturer specifies the AMR, and the user must validate this parameter. The AMR must be revalidated at least every 6 months, and following changes in lots of analytically critical reagents (as determined by the user) or major system components.

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 validated 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 coagulation tests.
Evidence of Compliance:
✓ Written procedure defining AMR by analyte AND
✓ Records of actions taken when results fall outside defined limits

REFERENCES

POC.08500 AMR Validation

Validation of the analytic measurement range (AMR) is performed with matrix-appropriate materials of known analyte value appropriate to the AMR of the instrument, and the process is documented.

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

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

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

REFERENCES
2) NCCLS. Point-of-care blood glucose testing in acute and chronic care facilities; approved guideline-second edition C30-A2. Wayne, PA:NCCLS, 2002

POC.08600 AMR Validation Criteria

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

NOTE: The AMR must be revalidated every 6 months, and when any of the following criteria are met:

1. A change in major test system components
2. A change in lots of chemically or physically active reagents (unless the laboratory
Evidence of Compliance:
✓ Written procedure defining the method, frequency and acceptability criteria for AMR validation

REFERENCES

BLOOD GAS SPECIMENS

**Inspectors Instructions:**
- Sampling of blood gas analysis policies and procedures
- Sampling of records of collateral circulation tests performed
- Sampling of blood gas calibration records
- Sampling of blood gas QC records

- How are personnel that perform arterial punctures made aware of possible complications?
- Select a blood gas result and follow the entire process from specimen collection to final result reporting

POC.08705 Knowledgeable - Arterial Punctures

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

Evidence of Compliance:
✓ Written documentation of training in personnel files

REFERENCES

POC.08760 Collateral Circulation

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

NOTE: The various technologies available have been evaluated in the published literature. Consensus should be established between the point-of-care program and involved clinicians to define in which patients and under what circumstances such a test is medically useful in averting potential patient injury. The site from where the sample was obtained should be documented.
Evidence of Compliance:
✓ Written collection procedure defining situations that require testing for collateral circulation to include preferred technique(s)

REFERENCES

POC.08815  Ambient Air Contamination  Phase II

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

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

REFERENCES

POC.08870  Instrument Operation  Phase II

There are documented procedures for operation, calibration, and function checks of all blood gas instruments.

POC.08925  Calibration Materials  Phase II

The materials used for calibration of the pH, CO₂, and O₂ sensors are either in conformance with the instrument manufacturer's specifications or traceable to NIST Standard Reference Materials.

NOTE: Calibration materials, either liquid or gas, must be traceable to appropriate reference standards. In the case of single-use devices, the calibration material is often contained within the test cartridge.

POC.08980  Calibration - Blood Gas Instruments  Phase II

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

NOTE: Instruments used infrequently must be recalibrated each time of use. Some instruments have built in calibration that is performed automatically by the instrument; however, there must be some defined procedure for verifying the reliability of this process. If appropriate, the calibration must compensate for the influence of barometric pressure.
Evidence of Compliance:
✓ Written procedure defining frequency and criteria for performing calibration AND
✓ Records for calibration documented at defined frequency

REFERENCES

POC.09035  Daily QC - Blood Gas Instruments

A minimum of 1 quality control specimen for pH, pCO₂ and pO₂ (tonometered sample or liquid control material) is analyzed at least every 8 hours of operation when patient specimens are tested.

NOTE: Controls may be either liquid, or validated electronic controls (refer to discussion on internal controls, in Quality Control – Nonwaived Tests section).

Evidence of Compliance:
✓ Written procedure defining QC requirements AND
✓ QC records reflecting appropriate QC documentation at defined frequency

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)]

POC.09090  Daily QC - Blood Gas Instruments

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

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

Evidence of Compliance:
✓ Written procedure 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)]

POC.09145  QC - Blood Gas Instruments

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

NOTE: Controls may be either liquid or electronic.

Evidence of Compliance:
✓ Written procedure defining QC requirements AND
✓ QC results OR documentation of internal calibrator

REFERENCES
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:

- Do you ever feel that your safety or your patient's safety is compromised while performing laboratory testing?

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.

PROVIDER-PERFORMED TESTING

IMPORTANT INFORMATION FOR LABORATORIES AND INSPECTORS

The following section applies to provider-performed testing (PPT) only. PPT is defined by the College of American Pathologists as testing that is personally performed by a physician or midlevel practitioner credentialed by the institution's medical staff (e.g. physician assistants, nurse practitioners, certified nurse midwives) in conjunction with the physical examination or treatment of a patient, and is limited to the tests below. Patient management is often facilitated by immediate and direct clinician performance of certain laboratory tests at the time of a patient encounter. Although these tests may be simple to perform, standards must be maintained to ensure correct results. The other sections of the Point-of-Care Testing checklist do NOT apply to PPT.

This section is applicable only if both of the following conditions are true:

1. PPT is performed under the same CLIA number as the laboratory, and
2. The laboratory director is responsible for competency assessment of the physicians and midlevel practitioners.

This section is not applicable if both of the following conditions are true:

1. PPT is performed under the same CLIA number as the laboratory, and
2. The institutional medical staff has established the competency of physicians and mid level practitioners through the credentialing process.
This section is not applicable if PPT is performed under a different CLIA number than the laboratory, regardless of how physician and midlevel practitioner competency is established.

This PPT category is NOT the same as the US CLIA term “provider performed microscopy” (PPM). Rather, it includes certain “waived” tests under CLIA as well as PPM. PPT is currently limited to the following tests:

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

Inspector Instructions:

- Sampling of PPT policies and procedures (includes specimen handling and QM)
- Sampling of training records for providers
- Sampling of competency assessments for providers
- Sampling of PPT patient reports for completeness

- How do you ensure that physicians and mid-level practitioners who perform provider performed testing are competent?

- Trace the process from test order to resulting to ensure the departmental procedures and manufacturer’s requirements are followed

POC.09200  PPT Personnel Qualifications  Phase II

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

NOTE: The College of American Pathologists will only accredit provider-performed testing for those tests listed above.

POC.09300  PPT Procedure Manual  Phase II

There is a PPT procedure manual that includes specimen handling information.
POC.09400 PPT QM Program  
**Phase II**
A quality management program, appropriate for the nature of the testing performed, exists and includes the following items, as applicable.

1. Quality control of stains
2. Instrument maintenance (centrifuges, microscopes, etc.)
3. Assurance that manufacturer instructions are followed

POC.09500 PPT Training  
**Phase II**
There is a documented process for training providers in the performance of specific tests.

POC.09600 PPT Competency Assessment  
**Phase II**
There is evidence of competency assessment specific to the type(s) of laboratory testing performed by each provider.

*NOTE: The frequency of competency assessment is at the discretion of the laboratory director. Annual competency assessment of providers is not required by the CAP for purposes of PPT laboratory accreditation.*

**Evidence of Compliance:**
✓ Written policy for assessing competency of providers

POC.09700 PPT Reporting  
**Phase I**
The system for reporting PPT results is adequate.

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

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