



cap



How to Pass a CAP Inspection



cap



Don't Pull out your hair;

It's "Just" Point of Care



www.cap.org

Learning Objectives

After participating in this session, you will be able to:

1. List the CAP requirements for waived and non waived testing
2. Explain new or changing requirements for POCT
3. Understand how best to prepare your POCT for inspection
4. Recognize common POCT deficiencies and what you need to do to correct.

Summary of **Waived** Testing Requirements

- **Quality Control**

- Follow manufacturer instructions
- Verify QC is acceptable before reporting patient results
- Document corrective action if QC exceeds tolerance limits
- Internal QC results need not be documented for instruments using such controls, if an unacceptable instrument control automatically locks the instrument & prevents the release of patient results.
- Frequency of QC is defined by the manufacturer
- External controls run as required by manufacturer

Summary of **Waived** Testing Requirements

- **Correlation**

- Initial correlation between **waived** instruments not required
- Correlations between **waived** instruments & main lab instruments not required
- Multi-instrument comparison not required

Summary of **Waived** Testing Requirements

- **Method Performance Specifications**
 - Verification not required except for reference range
- **Calibration/Calibration Verification**
 - Follow manufacturer instructions
 - Calibration verification every 6-month not necessary unless required by manufacturer
- **Analytical Measurement Range (AMR)**
 - Follow manufacturer instructions
 - Initial AMR validation & 6-month interval validation not necessary unless required by manufacturer

Summary of **Waived** Testing Requirements

- **Reagents**
 - Lot-to-lot reagent validation not required
 - Follow manufacturer instructions for handling & validating

- **Competency**
 - During 1st yr that an individual is performing patient testing, competency assessed at least semiannually
 - Competency must at least be reassessed annually



cap



UNDERSTANDING THE POC CHECKLIST

CAP Point of Care

- **Requirements are the same for waived & non-waived testing in the following areas:**
 - Proficiency Testing
 - Instrument maintenance
 - Procedure manuals
 - Personnel
 - Specimen Handling
 - Results reporting
 - Safety

New edition released June 17, 2010

- Current edition for each checklist
- Change document for each checklist showing revisions since previous editions
 - New checklist questions
 - Revised questions
 - Deleted questions
 - “Migrated” questions
- List of new, deleted and revised questions at beginning of each checklist, with date of change (items on list for 18 mos.)

New edition released June 17, 2010

- Remember the “*NOTE*”
 - Valuable information
 - Clarification
 - Additional guidelines

- Evidence of Compliance

- ROAD

Proficiency Testing

- Enrollment in CAP Surveys or another proficiency testing program accepted by CAP
- This applies to all tests, waived & non-waived
 - *List of analytes requiring enrollment available on the CAP web site [<http://www.cap.org>]*
 - *Analytes NOT requiring enrollment may use alternative assessments*

Proficiency Testing

POC.03225

- *For tests that CAP doesn't require PT, lab can participate in external PT/alternative assessment*
 - *Perform semiannually*
 - *Perform on tests for which PT isn't available*
 - Ungraded proficiency surveys
 - Split sample (with reference or other labs, established in-house method)
 - Assayed material
 - Regional pools
 - Clinical validation by chart review
 - Other suitable & documented means

Proficiency Testing

POC.03250

- Testing personnel must participate in PT
 - Don't have to get everyone every year
- Recommend rotation schedule
- Integrate PT samples within routine workload
- Can repeat if patient would be repeated
- Must be in PT policy
 - No interlaboratory communication
 - No referral of PT specimens

Proficiency Testing

POC.03275

- Review results in a timely manner
 - Within 1 month (prompt and timely)
 - Investigate unacceptable results
 - Solve any problems/document corrective action
 - Retain records for 2 years (unless specific discipline requires longer)
 - Acceptable or good

Quality Management Program Requirements

- The Point of Care Laboratory must have:
 - Indicators and/or Quality Measures defined
 - Evidence of review of the indicators and /or quality measures
 - Thresholds for each indicator and /or quality measures
 - Corrective action when the indicator or quality measure falls below the threshold.
 - Changes to operations as a result of the QM activities as specified in the program
 - POC QM activities reported as specified in the plan

Quality Management Program Requirements

- The Point of Care Laboratory must have a program to identify, document, and correct problems that affect patient care services.
 - Examples would be areas not notifying physicians of a critical value or not notifying the laboratory of a high glucose value that needs tested by the laboratory if required by policy.
 - An example in Point of Care when a root cause analysis needs to be performed is when a PT-INR result is reported incorrectly and the patient is treated based on the result and experiences an adverse outcome.

Procedure Manual

- POCT Procedures should include:
 - Principle
 - Clinical Significance
 - Specimen Type
 - Required Reagents
 - Test Calibration
 - Quality Control
 - Procedural Steps
 - Calculations
 - Reference Intervals
 - Interpretation of Test Result

Procedure Manual

Other Considerations:

- Copy of the POCT Procedure Manual at each area
 - *Physical manual or electronic access (i.e. via an intranet).*
 - *If electronic procedures, back-up plan in case of a system failure*
 - *If paper manuals distributed, mechanism to ensure they contain the current versions (i.e. a document control system)*
- Archiving process must be established
- Annual review process

Quality Control

- General Requirements (waived & non-waived)
 - Performed by testing personnel
 - QC reviewed at least monthly (includes temp & instrument checks)
 - QC performed & acceptable before patient results reported
 - When out-of-range, document corrective actions

Quality Control (**waived**)

POC.07037

- Follow manufacturer instructions for frequency
- QC must be acceptable/documented prior to release of patient data
- Evidence of corrective action when QC exceeds tolerance limits
- Internal control results need not be documented for instruments using such controls, if there is a 'lock out' feature

Quality Control (Non-waived)

POC.07300 Controls are run daily for quantitative and qualitative tests.

- External only:
 - Qualitative (positive & negative) – daily
 - Quantitative (2 levels) – daily
- External (liquid) and Internal
 - External QC required each new reagent lot / shipment and every 30 days (at a minimum)
 - Internal QC (built-in/on-board or electronic)

Quality Control (Non-waived)

- Specific QC Requirements:
 - 2 levels of QC run daily
 - For pH, pCO₂, pO₂ 1 level every 8 hrs of operation
 - For coagulation 2 levels required every 8 hrs
 - For qualitative tests: run positive & negative QC daily

Quality Control (Non-waived)

- Evidence of Compliance:
 - Records of QC results including external and internal (electronic/procedural/built-in) controls
AND
 - Records documenting in-house validation of electronic/procedural/built-in control systems, if used

Method Comparison

POC.07568

- Must be performed for all **non-waived** instruments or methods twice/year
 - QC comparison for tests on the same instrument, using same QC lot#/manufacturer
 - Use of fresh patient samples is preferred, but not required
- *Remember this only applies to instruments within a single laboratory number.

Frequently Asked Question / Method Comparison

- The POCT Department has 50 i-STAT meters.
- Does the lab have to correlate all meters?

Single-Use Device / Method Comparison

POC.07568

- Perform twice/year
- Use fresh human samples unless specimen stability is an issue
- If must use QC or reference materials, verify they respond the same as a patient sample
- Single-use devices can use alternative approach

Single-Use Device / Method Comparison

- For identical single-use **non-waived** devices using the same reagent lot:
 - Place analyzers into groups & select a representative device from each group
 - compare to each other and/or main lab instrument
 - If devices correlate, compare remaining devices to the subgroup using QC data

Analytical Measurement Range (AMR)

POC.08450 AMR – range of values that a method can measure without any dilution, concentration, or other pretreatment not part of the usual assay process

- Must be defined
- Revalidate at least every 6-months & reagent lot changes
- Does not apply to coagulation tests

Analytical Measurement Range (AMR)

POC.08500

- If the materials used for the calibration/cal verification include low, midpoint, & high values that are near the AMR, the AMR has been validated

Analytical Measurement Range (AMR)

POC.08500

- AMR Validation of Single-use Devices (**non-waived**):
- Initial validation & following service/repair
- Revalidation performed on sample of devices
- Devices not sampled, revalidation of AMR may be inferred using other approaches
 - review of QC
 - comparison of POCT results with near-simultaneously collected specimens analyzed in main lab. (This type of comparison is facilitated when POCT results are downloaded to central data management computer.)

Provider-Performed Testing (PPT)

- Testing that is personally performed by a physician or midlevel practitioner credentialed by the institution's medical staff.
- Includes both "waived" and PPM tests - 13 on list

Provider-Performed Testing (PPT)

PPT – subject to CAP inspection if:

- The Laboratory Director is responsible for competency assessment.

and

- PPT is performed under the same CLIA# as the laboratory.

Frequently Asked Question

How do I know if the physicians are credentialed?

- Credentialing is handled by the facility medical staff credentialing committee
 - ✓ Documentation
 - ✓ Policy in manual could assist with the inspection



cap



PREPARATION IS KEY

www.cap.org

Where do I start?

- Identify all POCT sites and the testing performed
- Review the POCT Checklist included with your reapplication well before your inspection
- Prepare an Audit Form
- Perform a self/mock inspection to determine if any deficiencies currently exist
- Implement corrective actions for any deficiencies identified in the self/mock inspection

What will Inspectors look for?

General Items:

- Reagents labeled
- Patient results and reporting process
- QC, maintenance, and function checks
- Mechanism to determine the testing personnel
- Training & competency records
- Procedure manual in each POC testing area
 - *Evidence personnel are knowledgeable of where procedure is located and contents*
- Proficiency testing

Inspection Scenarios

- You are preparing for your upcoming inspection, and decide to do a “walk-through” of several point of care testing areas to assess their “inspection-readiness”.
- During your walk-through, you check for the following:
 - *Current procedure manual available*
 - *List of authorized testing personnel available*
 - *No unauthorized testing kits*
 - *Reagents are in-date and properly labeled*
 - *Observe patient testing procedure*
 - *Observe patient result reporting practices*
 - *Review QC results for acceptability and documented corrective actions*

Scenario 1

- You maintain a “master” manual, and distribute copies of procedures to each testing site annually and upon revision. A cover memo accompanies each procedure instructing the testing site personnel to return the old procedure to you, replace it with the enclosed procedure and have all testing personnel sign the review sheet for the new procedure. The master manual has documentation of annual review for each procedure, and the signature pages are sent to the testing sites annually following review. You visit 5 testing sites during your “walk-through”. Four of the 5 testing sites have old versions of the procedures, one of which is for a glucose meter that was replaced 18 months ago. The fifth site could not locate their procedure manual

Scenario 1 / What do you do?

1. Get the manuals up-to-date
 - Replace outdated procedures with current procedures
 - Replace missing procedure manuals
 - Ensure staff are aware of contents of new procedures and are adequately trained
2. Review process for updating procedures with the responsible parties

Scenario 2

- You ask for the list of authorized personnel. The list contains the names, ID numbers, and due dates for the next annual recertification. You note the list is dated January 2011 and several employees are past due for their recertification.

Scenario 2 / What do you do?

1. Set up recertification for overdue employees
2. Verify there are no new employees that were not on the list and set up training if needed
3. Update list

Is This a Deficiency?

- During the inspection of the glucose testing performed in the ER you ask the ER staff member performing the test to show you the procedure manual. The employee doesn't know, and says she hasn't seen the procedure before. Another nurse overhears the conversation and proceeds to show you where the manual is kept.

Is this a deficiency?

Is This a Deficiency? Yes

POC. 04200 The POCT program has a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities.

- NOTE: This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the laboratory director.

Is This a Deficiency?

- While observing a urine dipstick being performed you notice the specimen is unlabeled. The staff member tells you that labeling the specimen is unnecessary because the patient is with the specimen the entire time.

Is this a deficiency?

Is This a Deficiency? Yes

- POC.04300 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.
- GEN.40491 Primary specimen containers are labeled by at least 2 identifiers.

Is This a Deficiency?

- The laboratory has 20 waived glucose meters. You have asked for semi-annual instrument correlations. The laboratory has stated that they don't do them.
 - **Is this a deficiency?**

Is This a Deficiency? No

- What if the instruments are I-stats?

- Why or why not?

Is This a Deficiency?

Your current glucose meter control lot number has a manufacturer expiration date on the bottle of March 2011. You find glucose meter controls currently in use marked "opened on 1/15/2011". Controls are stable for 90 days after opening.

Would this be a deficiency?

Is This a Deficiency? No

- Material expires on last day of month when only month/year are indicated
- The control vials were opened less than 90 days ago, so they have not exceeded the open stability
- Controls vials are dated with the open date, and the manufacturer label indicates that the materials are stable for 90 days once opened

Thank You!

For additional information:

www.cap.org

e-mail: accred@cap.org

800-323-4040