CAP Approach to Point of Care Inspections

American Society For Clinical Laboratory Science - Michigan

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March 31, 2016
Objectives:

• Discuss most commonly cited deficiencies
• Discuss solutions to mitigate being cited for these common deficiencies
• Off Label Use of Whole Blood Glucose Instruments
• CAP Approach to Inspecting Individualized Quality Control Plans (IQCP)
Most Commonly Cited Deficiencies
Most Commonly Cited Deficiencies (2015)

- Competency
- Activity Menu
- Document Control
- PT Evaluation
- Procedure Manual
- Attestation Page
- Procedure Review
- Reagent Labeling
- Reagent Storage
- Personnel Records

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Most Commonly Cited POCT Deficiencies

Percentage of POCT Labs Cited

- Competency
- Method Comparisons
- Control Frequency
- Following Manufacturer QC Instructions
- Monthly Control Review

Percentage of POCT Labs Cited
Competency Assessment

POC.06910 & GEN.55500 The competency of each person performing testing to perform his/her assigned duties is assessed.

- Annual assessment for waived testing (6 month not required)
- Annual assessment for non-waived (semi-annual in 1st year)
- All six elements for non-waived (less for waived)
- On going process
Competency Assessment (Continued)

The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements.
Competency Assessment (Continued)

- High complexity - assessments by section director, or individual meeting general supervisor requirements for high complexity
  - Doctoral / Master’s / Bachelor’s degree in clinical laboratory science or chemical, physical or biological science and 1 year training and experience in high-complexity
  - Associate’s degree in Medical Laboratory Technology and 2 years laboratory training and/or experience in high complexity testing.
Competency Assessment (Continued)

- Moderate complexity – assessments by individual meeting the qualifications of a technical consultant for moderate complexity testing
  - Doctoral / Master’s degree in clinical laboratory science or chemical, physical or biological science and 1 year training and/or experience in non-waived testing in designated specialty
  - Bachelor’s degree in clinical laboratory science or chemical, physical or biological science and 2 years experience in non-waived testing in designated specialty
Competency Assessment - Waived

• POC.06875 There is a written program to ensure that each person performing waived testing maintains satisfactory levels of competence.
  o Must have initial training (POC.06850)
  o Competency assessment after performing duties for 1 year and annually thereafter
  o May be assessed by whomever the laboratory director delegates to perform this function
  o All six competency elements are not required for waived testing. The POCT program and the laboratory director determine which are used.
How to Prevent Competency Citations:

1. Ensure assessments do not exceed 1 year.
2. Ensure new staff performing non-waived testing are assessed semiannually the first year of testing.
3. Ensure that your POC Test Systems are defined and all 6 elements of competency are used for each non-waived test system.
4. Ensure it is clear which element was used when documenting.
5. Ensure qualified individuals are assessing competency.
Do you have the right person assessing competency?

Your Point of Care Department performs ACT testing. The Nursing Supervisor who has been performing the testing for five years and has a Bachelor of Nursing degree is performing the competency assessments for this test system.

Is this acceptable?

Yes
Do you have the right person assessing competency?

- What if in the same scenario the RN with the Bachelor’s Degree had been performing the testing for 1 year? Is this acceptable?
  - No, Since the RN with the Bachelor’s Degree has been performing the testing for only 1 year, she would not qualify. She would need 2 years experience performing non-waived testing in this specialty.
Do you have the right person assessing competency?

- The manager of Respiratory Therapy has been reviewing blood gas competency assessments for twenty years. She has an Master’s Degree in Business Administration and an Associates Degree in Respiratory Therapy and has 30 years experience testing blood gases.
- Is this acceptable?
- No, a technical consultant must have at least a Bachelor’s Degree in a Science.
Personnel Records

GEN.54400 Personnel files are maintained on all current technical personnel and personnel records include:

- Copy of academic diploma or transcript
- License, if required by state
- Summary of training and experience
- Certification, if required by state or employer
- Records of continuing education
Personnel Records (Continued)

GEN.54400 Personnel files are maintained on all current technical personnel and personnel records include….

- Description of current duties and responsibilities as specified by the laboratory director
  - a) What procedures is the individual authorized to perform?
  - b) Is supervision required (processing, testing, result reporting)?
  - c) Is supervisory or section director review required to report?
GEN.54400 Personnel files are maintained on all current technical personnel and personnel records include....

- Records of continuing education
- Records of radiation exposure where applicable (such as with *in vivo* radiation testing), but not required for low exposure levels such as certain *in-vitro* testing
- Work-related incident and/or accident records
- Dates of employment
Credentialing Organizations can be used to verify education if:

a) Laboratory has a policy for acquiring copies of diplomas or transcripts within 7 days

b) Laboratory has documentation that it has validated the process initially and at least annually including an audit of the process

The Veterans Administration and Department of Defense credentialing system is acceptable for these laboratories

The State license may be used in states that require personnel licensure. (Only applies to laboratory personnel)
How to Reduce Potential POCT Personnel Deficiencies

- Develop a checklist to ensure all documents are present
- If using a credentialing organization ensure process was verified initially and repeat verification annually and have documentation available
- Non-laboratory staff members must have a diploma or transcript or can be verified by the credentialing organization
- Job descriptions are sufficiently detailed
Method Comparisons

POC.07568 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.

- If the laboratory and POCT are under the same CLIA number ensure all non-waived tests performed in both are compared twice per year
- Ensure documentation includes criteria for acceptability and the comparison meets the limits of acceptability
Quality Control Frequency

POC.07300  Controls are run at least daily, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests.

- Ensure the number and frequency of controls meet manufacturer’s requirements
- If the POC staff were following EQC rules for non-waived POC tests, it is very likely an Individualized Quality Control Plan (IQCP) is required.
- If the POCT area has not developed an IQCP for a qualified test, ensure that the POCT staff members are using the CLIA default QC.
- Ensure that the staff follow the test procedure for controls
Following Manufacturer’s Control Requirements for Waived Testing

POC.07037 The laboratory follows manufacturer instructions for quality control, reviews results, and records acceptability prior to reporting patient results.

- Thoroughly review manufacturer’s instructions for Quality Control requirements.
- Ensure that controls were performed as required by the procedure.
- Ensure staff members review controls for acceptability before reporting patients.
Monthly Control Review – Non-waived Tests

POC.07550  Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

- Ensure the individual performing the review is on the director’s designee list
- Place the review due dates on a planner/organizer or electronic calendar
- Review that QC was within range and that it was documented when patients were tested
- If errors are discovered during the QC review, ensure corrective action is documented
Glucose Meters and Critically-ill Patients
Glucose Meters

• Manufacturer’s intended use and limitations
  o Glucose meters are waived complexity when used as specified by the manufacturer for specimen types validated by manufacturer and approved/cleared by FDA

• Modifying manufacturer’s instructions
  o Off label use = Laboratory Developed Test
  o Validate per COM.40250
Glucose Meters (Continued)

- Review manufacturer’s intended use and limitations
  - Diabetic patients only?
- Define “Critically-ill”
  - Check manufacturer’s limitations to ensure population is defined
- If using the meter off label on critically ill patients
  - Must perform a method validation
  - Personnel must qualify for high complexity testing
  - Competency assessments
    - 2 assessments first year then annually
    - All six elements of competency must be used
Accuracy - Modified FDA-Cleared/ Approved and LDT’s

COM.40350 For modified FDA cleared/approved and laboratory-developed tests (LDTs), validation of analytic accuracy includes testing with an appropriate number of samples.

• New item for 2015
• Quantitative tests: ≥ 20 samples that span the AMR
Waived + Modification = High Complexity

- Certificate of Waiver versus Certificate of Accreditation
- Method validation requirements (initially)
- AMR (at least every six months)
- Lot to lot reagent verification (at lot changes)
- Meter to meter comparisons (twice per year)
Waived + Modification = High Complexity

• Testing personnel requirements for high complexity
  o Competency requirements – all six elements semi- and annually
  o Minimum Associates degree or High School diploma if testing prior to 4/24/1995
    o Individuals performing high complexity testing on or before April 24, 1995 with a high school diploma or equivalent with documented training may continue to perform testing only on those tests for which training was documented prior to September 1, 1997 (CLIA Regulation 42CFR493.1489(b)
Scenario #1

- You are inspecting a hospital point of care section that is included on the laboratory’s CLIA number. You are visiting ICU and notice a High School graduate Certified Nursing Assistant performing a glucose test on a hand held glucose meter. She was recently hired and trained. You review the manufacturer’s information and discover that the instrument was not intended to test “critically ill” patients. You discover that this patient would be considered “critically ill” by the laboratory’s definition. You ask the point of care coordinator about this and she informs you that they did validation studies. They performed an analytic measurement range study (5 points spanning the range), a precision study (20 replicates from a “critically ill” patient’s sample) and a correlation for accuracy using 10 patients sample. Analytic specificity, interferences and analytic sensitivity reference ranges were appropriately addressed in the validation studies.
Scenario #1 (continued)

• What issues if any do you see in this scenario?
  o High school graduates cannot perform high complexity testing unless performing testing and trained before 9/1/1997.
  o Insufficient number of samples for the accuracy study. It must be at least 20 samples.

• Why was it important that I mentioned that the POCT section was under the laboratory’s CLIA number?
  o If the POCT was under their own Certificate of Waiver they would be required to have a Certificate of Accreditation if performing high complexity testing.
IQCP and CAP
Individualized Quality Control Plan Eligibility for POCT

• Non-waived testing that employs an internal (electronic/procedural/built-in) quality control system

• Number of controls tested cannot be less than indicated by the manufacturer

• Frequency of control cannot be less than the manufacturer

• Must test external controls at least every 31 days
IQCP Checklist Requirements

• COM.50200 – IQCP Test List – requires completion of two forms to be provided to the inspection team if IQCP is used
  o List of Individualized Quality Control Plans
  o Individualized Quality Control Plan Summary

• Download forms from CAP website (http://www.cap.org) through e-LAB Solutions Suite under CAP Accreditation Resources, Accreditation Forms and Instructions
IQCP Checklist Requirements

• COM.50300 – Risk Assessment – evaluate potential sources of errors including:
  
  o **Three phases** of the testing process – pre-analytic, analytic, and post-analytic
  
  o **Five components** – Reagents, Environment, Specimen, Testing Personnel, Test System
  
  o Variations in the components based on use of test
  
  o **Data from the laboratory's own environment, instrument/equipment performance, and testing personnel**
  
  o Manufacturer’s Instructions and recommendations
IQCP Checklist Requirements

• COM.50400 - Quality Control Plan Approval
  o QCP signed and dated by the laboratory director prior to implementation
  o No delegation allowed
  o Separate approved quality control plan for each laboratory with a separate CAP/CLIA number
IQCP Checklist Requirements

• COM.50500 - Quality Control Plan - defines all aspects monitored based on risk assessment
  o The number, type (external and internal quality control systems), and frequency of quality control
  o Criteria for acceptable performance
  o Monitoring of the testing environment and reagents
  o Specimen Quality
  o Instrument calibration, maintenance, and function checks
  o Training and competency of testing personnel
  o Provisions for multiple identical devices and variation for uses covered under one IQCP
IQCP Checklist Requirements

• COM.50500 - Quality Control Plan - defines all aspects monitored based on risk assessment
  o Follow manufacturer’s instructions and recommendations for QC at minimum
  o Include the use of external control materials at least every 31 days and with new lots and shipments of reagents
IQCP Checklist Requirements

- COM.50600 - Quality Assessment Monitoring - requires ongoing monitoring of the effectiveness of the IQCP
  - Review of quality control and instrument/equipment maintenance and function check data at least monthly
  - Evaluation of errors relating to all phases of the testing process
  - Review of complaints from clinicians and other healthcare providers regarding the quality of testing
  - Evaluation of corrective actions taken if problems are identified
  - Re-approval of the quality control plan by the laboratory director or designee at least annually
CAP Inspection Preparation

• All laboratories inspected on or after January 1, 2016 must do the following:
  o Discontinue EQC option AND
  o Perform external quality control following the frequency defined in the CAP inspection checklist (default CLIA QC) OR
  o Implement an IQCP, if eligible
CAP Website Resources

• The following are available in eLab Solutions Suite under CAP Accreditation Resources – Guidance Documents
  o Eligibility Determination for IQCP Option
  o CAP/ASM/CLSI Microbiology IQCP template and examples
  o IQCP Frequently Asked Questions
  o CAP forms and instructions for inspection

• CAP IQCP webinar presentation in August
  o Webinar is posted on CAP website. Rebroadcast with live Q & A in October
Other IQCP Resources

• Clinical and Laboratory Standards Institute Guideline EP23-A and companion documents
• Manufacturer tools, if available
Scenario # 2

You are reviewing an IQCP for a non-waived point of care test risk assessment that includes all phases of testing and components for reagent, specimen, testing personnel and the test system. The quality plan indicates that the staff will document internal controls daily and perform external controls at lot and shipment changes. The IQCP has been approved by the laboratory director and has appropriate Quality Assessment. Manufacturer’s instructions are being followed. The laboratory staff have completed the list of IQCP performed and the IQCP Summary forms.
Scenario #2 (Continued)

• Based on the information provided what would you tell the author of the IQCP?
  o The risk assessment does not include environment
  o There is no mention of testing external controls every 31 days.
Thank You
Questions?