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CAP Approach for Point of Care Requirements

North Country POCT Network

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Point of Care

- **Fast is fine but accuracy is everything.** (Wyatt Earp)
- **Believe it or not, you are the entire laboratory when you perform point of care testing.**

Objectives

- Understand POC checklist changes
- Recognize common deficiencies in Point of Care
- Discover how to comply with regulatory inspection requirements

Mission of the CAP Laboratory Accreditation Program

- Improve patient safety by advancing the quality of pathology and laboratory services through education and standard setting, and ensuring laboratories meet or exceed regulatory requirements
- Purpose of inspection is to
 - Improve quality of lab services for the benefit of the patient
 - Fulfill a regulatory role, deemed status with CMS and agreement with TJC
 - Educate utilizing inspectors with laboratory experience

4 Standards

- Qualified medical director
- Physical resources of the laboratory
- Quality Management
- Administrative requirements-comply with terms of accreditation and checklist requirements with on site inspection

CAP Statistics 2012 and New Programs

- Accredit 7330 laboratories
 - 330 international
 - 363 new laboratories
- CARA –new readiness assessment program
- BAP-new biorepository accreditation
- Inspector Mentoring Program
- 2932 checklist requirements

Elements of an Inspection

- Quality Management Program
- Laboratory Safety
- Document Control
- Quality Control Program
- Proficiency Testing Program
- Laboratory Information System
- Laboratory Reports and Requisitions
- Test Method Validations
- Technical Processes
- Staff Qualifications, Training & Competency

Checklists: What's New in 2012 / 2013?

- Checklist language has been “globalized.”
- Infrequently cited items have been removed.
- Layout has been improved.
- Consistent language used wherever possible.
- Every Checklist has new or modified requirements.

All Common Checklist (COM)

- Includes requirements that had appeared in multiple, discipline-specific checklists
 - proficiency testing
 - quality management
 - procedure manual
 - results reporting
 - reagents
 - test method validation
- Each team member carries a COM checklist

Quality Management

COM.04000 Documented QM/QC plan

The laboratory has a written quality management/quality control (QM/QC) program.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

Unusual Laboratory Results

COM.04050 Unusual Laboratory Results

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

NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data for single analyte tests that do not include interpretation. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, i.e. before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable.

Instrument Maintenance

COM.04200 Instrument Maintenance Evaluation

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

NOTE: There must be documentation of ongoing monitoring of instrument function and maintenance records on all devices. Monitoring of device operation must be in accordance with manufacturers' instructions. If the manufacturer does not provide monitoring recommendations, the laboratory must document the specific monitoring procedures used. Limits of acceptable variation must be defined in laboratory procedures. For cytopathology, a sample of slides from slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, should be routinely reviewed microscopically for technical acceptability.

Reagents

- **COM.30300** Reagents, calibrators, cellular controls, and solutions are properly labeled...
- **COM.30350** All reagents and media are stored as recommended by the manufacturer.
- **COM.30400** All reagents and media are used within their indicated expiration date.
- **COM.30450** New reagent lots and/or shipments are checked against...
- **COM.30500** The laboratory uses components of reagent kits only within the kit lot...

POC.03810 (NEW 2013)

Manufacturer Instructions

- **The POCT program follows manufacturer instructions for all test systems without modification.**
- *NOTE: If any manufacturer's instruction is modified, the test is considered a laboratory-developed assay and may not be inspected with the POCT Checklist. In such a case, the appropriate discipline-specific checklist must be used.*

POC.04575 (NEW 2012)

Group A Streptococcus Direct Antigen Detection

- **If group A Streptococcus direct antigen testing is performed, additional confirmatory testing is performed on negative samples.**
- *NOTE 1: Guidelines should be established for the use of cultures or other additional tests on specimens that test negative, as appropriate. These guidelines should take into account the sensitivity of the assay in use, the age and clinical presentation of the patient, and other factors.*
- *NOTE 2: Direct antigen tests should be performed and reported in a timely fashion, since their principal advantage (compared to more sensitive methods such as culture) is rapid turn-around time.*

POC.06475 (NEW 2013)

Thermometric Standard Device

- **An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards) is available.**
- *NOTE: Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices should be recalibrated or recertified prior to the date of expiration of the guarantee of calibration.*
- **Evidence of Compliance:**
- Thermometer certificate of accuracy

POC.06875 (NEW 2013)

Competency Assessment - Waived Testing

- **There is a documented program to ensure that each person performing waived testing maintains satisfactory levels of competence.**
- *NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450. 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.*
- *For waived test systems, it is not necessary to assess all 6 elements etc*

POC.06910 (NEW 2013)

Competency Assessment - Nonwaived Testing

- **There is a documented program to ensure that each person performing nonwaived testing maintains satisfactory levels of competence.**
- *NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450. 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.*
- *For nonwaived test systems, competency using all six elements etc*

POC.07300 (REVISED 2012)

Daily QC - Nonwaived Tests (revision to notes)

- **Controls are run daily for quantitative and qualitative tests.**
- ** A "surrogate sample" is a specimen designed to simulate a patient sample for quality control purposes. For example, traditional external liquid control materials are considered surrogate sample controls.*

POC.07300 continued

- *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.

POC.07300 continued

- 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. Quantitative tests: 2 levels of electronic/procedural/built-in internal controls are run daily
 2. Qualitative tests: electronic/procedural/built-in internal control run daily
 3. FDA-cleared or approved, and not modified by the laboratory**
 4. The system is not classified as highly complex
 5. Performed studies to validate the adequacy of limiting daily QC to the electronic/procedural/built-in controls.
 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.***

POC.07300 continued

- *Some surrogate sample controls may not be external, but may be contained within an instrument (e.g. in a cartridge); systems using these built-in controls must meet the requirements in Note 2*
- *** Sample types (or use of collection devices) not listed in manufacturer instructions are acceptable, if validated by the laboratory.*

POC.09180 (NEW 2012)

Standard Precautions - Hand Hygiene

- **Standard precautions are used for point-of-care testing by testing personnel.**
- *NOTE: Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions.*
- **Evidence of Compliance:**
- Written policy detailing proper hand/glove hygiene when testing patients using point-of-care devices

POC.09185 (NEW 2012 / REVISED 2013)

Single-Use Devices – Fingertstick

- **Only auto-disabling single-use fingertstick devices are used for assisting monitoring of blood glucose and other point-of-care testing.**
- *NOTE: These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. All waste sharps are discarded in compliance with the Laboratory General Checklist in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.*
- **Evidence of Compliance:**
- Written policy detailing requirement of limitation of single-use devices to one patient

POC.09190 (NEW 2012)

Testing Devices – Disinfection

- **There is an infection control policy in effect to prevent transmission of infection via portable or handheld testing devices.**
- *NOTE: Compliance with the manufacturer's guidelines when provided is required. Handheld or portable testing devices must be disinfected after each patient use.*

Most Common Deficiencies



Requirements with the most Deficiencies in 2012

- **Competency Assessment - 625 times**
- **Document Control Program - 507 times**
- **Personnel files - 256 times**
- **Safety - 530 times**
- **Reagents - 284 times**
- **Proficiency Testing - 426 times**
- *Number of times asked=3552*

Most Common Deficiencies

- **GEN.55500 Competency Assessment Phase II**

The competency of each person to perform his/her assigned duties is assessed.

NOTE: Elements of competency assessment include but are not limited to:

- 1. Direct observations of routine patient test performance*
- 2. Monitoring the recording and reporting of test results*
- 3. Review of intermediate test results or worksheets, QC records, PT results, and maintenance records*
- 4. Direct observation*
- 5. Assessment of blind samples or PT samples*
- 6. Evaluation of problem-solving skills*

Competency Assessment

- *The laboratory must identify the test systems that an employee uses to generate patient test results. Competency must be evaluated and documented for all testing personnel for each test system. A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use 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. In many situations, tests performed on the same analyzer may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform (e.g. pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure staff are performing those aspects correctly.*

Most Common Deficiencies

- **GEN.23075 Document Control Phase II**

The laboratory has a document control system.

NOTE: Document control requirements apply to all policies, procedures and forms (including quality management documents) for all processes and activities that are subject to CAP accreditation. The laboratory must have a document management or control system to assure that: 1) all copies of policies and procedures are current; 2) personnel have read the policies/procedures relevant to their job activities; 3) all policies/procedures have been authorized by the laboratory director, before implementation; 4) policies and procedures are reviewed at least biennially by the laboratory director or designee; 5) discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine).

Most Common Deficiencies

- **GEN .54400 Personnel Records Phase II**

Personnel files are maintained on all current technical personnel and personnel records include all of the following items.

- **Summary of training and experience**
- **Copy of academic degree or transcript**
- **License, if required by state**
- **Certification, if required by state or employer**
- **Job Description – patient testing**
- **Records of continuing education**

Most Common Deficiencies - Safety

- **GEN.75400 Annual Fire Drill Phase II**

Fire drills are conducted at least annually.

- **GEN.77400 Emergency Eyewash Phase II**

The laboratory has adequate plumbed or self-contained emergency eyewash facilities in every area where there are hazardous chemicals as defined by the laboratory's chemical hygiene plan (e.g. chemicals that are irritating, corrosive, toxic by contact or absorption, etc.)

Most Common Deficiencies - Reagents

- **COM.30450 New Reagent Lot Verification Phase II**
New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service.
- **COM.30300 Reagent Labeling Phase II**
Reagents, calibrators, cellular controls, 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 laboratory
 4. Expiration date

Most Common Deficiencies - Reagents

- **COM.30400 Reagent Expiration Date Phase II**

All reagents and media are used within their indicated expiration date.

NOTE: The laboratory must assign an expiration date to any reagents and media 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.

- **COM.30350 Reagent Storage Phase II**

All reagents and media are stored as recommended by the manufacturer.

Most Common Deficiencies

- **COM.01700 PT Evaluation Phase II**

There is ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results.

- **COM.01400 Attestation Page Phase II**

The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing.



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Is This a Deficiency?

You be the inspector

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Annual Competency Assessment Form for XYZ

Annual Competency Assessment

Employee: Robert Maxwell

Laboratory Section: Main Laboratory

Competency assessment for each individual must include all of the following elements that are applicable to the individual's duties:

Item	Competent Yes/No	Issues
1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.	Yes	
2. Monitoring the recording and reporting of test results	Yes	
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance functions	Yes	
4. Direct observation of performance of instrument maintenance and function checks	Yes	
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; and	Yes	
6. Evaluation of problem-solving skills	Yes	

Supervisor: PD

Date: 2011

Does this documentation meet the requirement?

- A. Yes
- B. No
- C. Unsure



Competency Assessment Form for ABC

Form B

Competency Assessment

Key			
Direct Observation	DO	Proficiency Testing	PT
Monitoring Test Results	MTR	Performance of Maintenance	PM
Record Review	RR	Problem Solving	PS

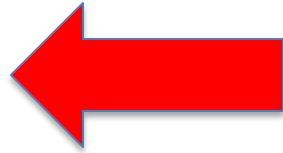
Laboratory Name		Employee Date of Hire					
ABC Laboratory		2/1/2011					
Section		Employee Name					
Chemistry		Rodney Stewart					
Task Assessed	Date of Assessment	Employee Initials	Method used to assess	Period of Assessment			
				Date and assessors initials when deemed competent	Initial 6 months after training	Second 6 months after training	Annual
Operating Profile Instrument	8/1/2011	RJS	DO, PM	8/5/2011 JB	X		
HDL	8/1/2011	RJS	RR, PT	8/10/2011 JB	X		
Glucose	8/1/2011	RJS	MTR, RR	8/10/2011 JB	X		
Calibration	8/1/2011	RJS	DO, RR	8/11/2011 JB	X		
Maintenance	8/1/2011	RJS	PM,RR	8/11/2011 JB	X		
Immunoassay Analyzer	8/4/2011	RJS	DO, PM	8/12/2011 JB	X		
Hemoglobin A1C	8/6/2011	RJS	DO,RR	8/13/2011 JB	X		
Quantitative B-HCG	8/6/2011	RJS	PT	8/13/2011 JB	X		
Digoxin	8/6/2011	RJS	PT	8/13/2011 JB	X		
Thyroxine	8/6/2011	RJS	RR	8/13/2011 JB	X		
Calibration	8/6/2011	RJS	DO,RR	8/13/2011 JB	X		
Maintenance	8/6/2011	RJS	PM	8/13/2011 JB	X		
Critical Value Reporting	8/8/2011	RJS	MTR	8/14/2011 JB	X		
Instrument Troubleshooting	8/10/2011	RJS	PS	8/20/2011 JB	X		
Supervisor Review - <i>Christina Cheng</i>							

Does this documentation meet the requirement?

A. Yes

B. No

C. Unsure



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**

- **COM.10300** Does the POCT program have 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** Is there 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** Are primary specimen containers labeled by at least 2 identifiers?

Is this a deficiency?

- Your current glucose meter control lot number has a manufacturer expiration date on the bottle of November 2013. You find glucose meter controls currently in use marked “opened on 8/15/2013”. 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

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?

Individualized Quality Control Plan (IQCP)

- **What I know** (or think I know)
 - Starts Jan 2014 with a 2 year period of transition
 - Optional / voluntary
 - Non-waived testing, including existing and new
 - Includes all phases of testing (maintenance, training, competency, temperatures, reporting, etc)
 - All disciplines except pathology
 - Minimal - follow the manufacturer's requirement
 - No more EQC at the end of the 2 year transition
 - Laboratory Director responsible for implementation

Individualized Quality Control Plan (IQCP)

- **What I do NOT know**
 - What the CAP requirements will be in the next 2 years

Resources

- For test complexity:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm

- For more information on IQCP:

www.cms.hhs.gov/clia/ (on left go to IQCP)

CLSI EP-23 (2011)

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

CAP Technical Resources

- Technical Specialists available 8:00 am – 5:00 pm M – F
 - Via Phone: 800-323-4040, option 1
 - Email: accred@cap.org

Point of Care

- **Fast is fine but accuracy is everything.** (Wyatt Earp)
- **Believe it or not, you are the entire laboratory when you perform point of care testing.**

Thank you!!



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