Hot Topics
From Current POCT Forums
Who Performs (External) QC?

Peggy A. Mann, MS, MT(ASCP), CPP

POCT Boot Camp
Pittsburgh, PA
November 8, 2019
Artery Question

Subject of post: poc team members performing qc on waived tests instead of personnel performing patient testing

“Hi Colleagues:

Our POC team wants to streamline workflows and supply chains for our nursing colleagues performing WAIVED poc testing. One step that would help would be if our team can perform qc on various items such as pH paper, urine dipsticks, etc., rather than nursing performing this duty.

Our question is whether or not this is acceptable by CMS? <...>”
Discussion: Waived testing QC

Regulation:
External control material samples must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions.

Pro & Con – Give opinion please!
Is it an ‘OK’ practice that the lab staff/POCCs perform all the WT QC?
Questions?

Contact Information: pmann@utmb.edu
Reconnaissance Patrol: Personnel Requirements

POCT Boot Camp
Pittsburgh, PA
November 8, 2019

Lou Ann Wyer, MS, MT(ASCP), CQA(ASQ)
Discussion: Personnel Requirements

- 1. MLTs
- 2. RNs
- 3. RRTs
<table>
<thead>
<tr>
<th>Waived Testing</th>
<th>Moderate Complexity Testing</th>
<th>High Complexity Testing</th>
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<tbody>
<tr>
<td>Not Applicable</td>
<td>1. MD, DO, or DPM with a current medical license with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR</td>
<td>Not Applicable</td>
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<td></td>
<td>2. Doctoral or Master’s degree in a chemical, physical, biological or clinical laboratory science with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR</td>
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<td>3. Bachelor’s degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least 2 years of experience in nonwaived testing in the designated specialty/subspecialty area</td>
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<td>Testing Personnel</td>
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<td>No specific requirements outlined in the CAP or CLIA regulations, however each laboratory must ensure waived testing personnel meet facility-defined minimum requirements and have records of training and competency assessment.</td>
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<td>1. MD or DO with a current medical license; OR 2. Doctoral degree in clinical laboratory science, chemical, physical, or biological science; OR 3. Master's degree in medical technology, clinical laboratory, chemical, physical, or biological science; OR 4. Bachelor's degree in medical technology, clinical laboratory, chemical, physical or biological; OR 5. Associate degree in chemical, physical or biological science or medical laboratory or equivalent education and training (refer to 42CFR493.1489(b)(2)(ii) for details on required courses and training); OR 6. 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 (refer to CLIA regulation 42CFR493.1489(b) for details on required training) OR 7. Individual previously qualified or could have qualified as a technologist under CFR.493.1489 and CFR.493.1491 on or before February 28, 1992</td>
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### General Supervisor

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<td>1. Qualified as a Director for high-complexity testing; OR</td>
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<td>2. Qualified as a Technical Supervisor for high complexity testing; OR</td>
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<td>3. Doctoral degree in clinical laboratory science or chemical, physical or biological science with 1 year training and experience in the designated specialty/subspecialty area of service; OR</td>
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<td>4. Master's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in the designated specialty/subspecialty area of service; OR</td>
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<td>5. Bachelor's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in the designated specialty/subspecialty area of service; OR</td>
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<td>6. Associate degree in laboratory science or medical technology (or pulmonary function) or equivalent education and training (refer to 42CFR493.1489(b)(2)(ii) for details on required courses and training) AND 2 years laboratory training or experience, or both, in the designated specialty/subspecialty area of service</td>
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Refer to the CLIA regulation 42CFR493.1461 for additional qualifications.
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For the disciplines of Transfusion Medicine, Cytogenetics, Molecular Pathology, and Histocompatibility, refer to checklist requirements TRM.50050, CYG.50000, MOL.49650, and HSC.40000, respectively for details on educational qualifications and experience.

For the specialties of Anatomic, Cytopathology and Clinical Pathology:
1. MD or DO with a current medical license and board-certification in Anatomic, Cytopathology, and Clinical Pathology or possess qualifications equivalent to those required for certification; OR
2. MD or DO with a current medical license and board-certification in Anatomic or Clinical Pathology or possess qualifications equivalent to those required for certification.
   - Technical supervisors overseeing anatomic or cytopathology services must have board-certification in anatomic pathology or equivalent qualifications.
   - Technical supervisors overseeing a clinical pathology specialty must have board-certification in clinical pathology or equivalent qualifications.
   - Technical supervisors responsible for anatomic pathology, cytopathology, and clinical pathology must have board-certification in both anatomic and clinical pathology or equivalent qualifications.

For other specialties, not including Anatomic Pathology and Cytopathology:
1. MD or DO with a current medical license and 1 year training and experience in high-complexity testing in the respective specialty; OR
2. Doctoral degree in clinical laboratory science, chemical, physical or biological science with 1 year training and experience in the respective specialty; OR
3. Master's degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 2 years training and experience in high-complexity testing in the respective specialty; OR
4. Bachelor's degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 4 years training and experience in high-complexity testing in the respective specialty.

For the specialty of Oral Pathology, the Technical Supervisor must be a MD or DO with a current medical license and have specific training/experience as defined in 42CFR493.1449(m).

Refer to the CLIA regulation 42CFR493.1449 for additional qualifications.
### Laboratory Director

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<td>1. MD or DO with a current medical license2 and board-certification in Anatomic and/or Clinical Pathology or possess equivalent qualifications as those required for certification; OR</td>
</tr>
<tr>
<td>2. MD, DO, or DPM with a current medical license2</td>
<td>2. MD, DO or DPM with a current medical license2 and laboratory training/experience consisting of:</td>
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<td>a. 1 year experience supervising non-waived testing; OR</td>
<td>a. 1 year laboratory training during medical residency; OR</td>
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<td>b. 20 CME credit hours in laboratory practice commensurate with director responsibilities; OR</td>
<td>b. 2 years’ experience supervising high-complexity testing; OR</td>
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<td>c. Equivalent laboratory training (20 CME’s) obtained during medical residency; OR</td>
<td>3. Doctoral degree in chemical, physical, biological or clinical laboratory sciences with current certification by a board approved by HHS</td>
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### Clinical Consultant

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References


Questions?

Contact Information: l.wyer@cox.net
Asset Audit: Managing Your Reagent Lots

Kerstin Halverson, MS, BA
How do you handle receipt of new lots of reagents?
New Reagent Lot/Shipments Confirmation of Acceptability

- New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service.

NOTE: The purpose of this check is to confirm that the use of new reagent lots and shipments do not affect patient results. Matrix interferences between different lots of reagents may impact the calibration status of instruments and consistency of patient results. Improper storage conditions during shipping of reagents may have a negative impact on their ability to perform or exhibit the same levels of reactivity as intended. Testing of new reagent lots and shipments must follow manufacturer's instructions at a minimum.
Qualitative: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. A weakly positive sample is recommended in systems where patient results are reported in that fashion.

Quantitative: For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. The use of patient samples confirms the absence of matrix interference.

For hematology analyzers, reservoirs containing testing reagents and cleaning/decontaminating solutions must be checked according to manufacturer's instructions.

REFERENCE: CAP All Common Checklist, September 17, 2019
Examples:

**Inventory:**

- Level 1 Lot Number:
- Level 2 Lot Number:

**Performance:**

- **Analyte Date**
  - i-STAT
  - i-STAT is Red)

**Values:**

- **CL**
  - 0.00 #DIV/0! 5%

- **K**
  - 0.00 #DIV/0! 10% or 0.5

- **Na**
  - 0.00 #DIV/0! 4

- **BUN**
  - 0.00 #DIV/0! 9% or 2

- **iCa**
  - 0.00 #DIV/0! 0.1

- **pH**
  - 0.00 #DIV/0! 0.04

- **Glucose**
  - 0.00 #DIV/0! 10% or 6

- **Creat**
  - 0.00 #DIV/0! 15% or 0.3

- **PO2**
  - 0.00 #DIV/0! 18

- **PCO2**
  - 0.00 #DIV/0! 8% or 5

- **TCO2**
  - 0.00 #DIV/0! 20% or 4

- **LACT**
  - 0.00 #DIV/0! 4

**Performed By:**

- [Name]

**Level 1 Lot Number:** [Lot Number]

**Level 2 Lot Number:** [Lot Number]
Questions?

Contact Information: khalverson@ilww.com
Getting Your Bugs in Formation!
Disinfecting in POCT

Jeanne Mumford, MT(ASCP)
Procedures

XXII. CLEANING THE METER

A. The Nova StatStrip Glucose Hospital Meter must be cleaned and disinfected between each patient use or if there is evidence of blood contamination. There is to be no adhesive residue or quality control solution visibly present on the meter or docking station.
   1. CAUTION:
      a. DO NOT immerse the meter or hold the meter under running water.
      b. DO NOT spray the meter with a disinfectant solution
      c. DO NOT get any liquid in the strip port or docking connection.

B. Disinfect the meter with a cloth that has been slightly dampened (not wet) with one of the following solutions
   1. A freshly mixed solution of 1:10 bleach in water (1 part bleach in 9 parts water).
   2. Appropriate commercial surface decontamination preparations that are approved for use by the Hospital Epidemiology and Infection Control Department

C. Use a water dampened (not wet) cloth to remove all cleaning residue as needed or when screen becomes cloudy.
Manufacturer’s Instructions

**Acceptable Cleaning and Disinfecting Materials**
Nova Biomedical recommends the use of Clorox Healthcare® Bleach Germicidal Wipes, EPA Registration #67619-12, or any disinfectant product with EPA Registration #67619-12 may be used.
The StatStrip Glucose Hospital Meter cleaning and disinfection procedure was validated a total of 10,950 times to simulate a 3 year use life of 10 patient tests per day, 365 days per year.

**Meter Cleaning and Disinfection Procedure**
Clean and disinfect after each patient use by following this protocol to help ensure effective cleaning and disinfection.
Cleaning is not the same as disinfecting. Disinfecting means to kill or prevent the growth of disease carrying microorganisms.

**Cleaning the Outside of the Analyzer**
Always keep the outside of the CLINITEK Status+ analyzer clean and free of dust.

- **BIOHAZARD**
  Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see Appendix A, Safety Information.

To clean the outside of the analyzer, perform the following steps:
1. Power off the analyzer by pressing the on/off button for 2 seconds
2. Wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent.

- **CAUTION**
  Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the analyzer.
  Do not spray glass cleaner directly onto the screen.
  Do not use laboratory wipes, such as Kimwipes, because they might scratch the screen.
  Prevent liquid from entering inside the printer compartment.
  You could damage the analyzer or the printer.

**Disinfecting the Test Table and Table Insert**
Disinfect the test table and the test table insert as necessary, following your lab guidelines. Use a recommended disinfection solution for the following reasons:
- Prevent contamination
- Prevent bacterial growth
- Avoid damage to the test table and insert

- **CAUTION**
  Do not autoclave the test table or the insert because it would destroy them.

To disinfect the test table and the insert, perform the following steps:
1. Prepare one of the following solutions in a tall, narrow container (such as an empty Multistix® bottle) to a depth of about 10 cm (or 4 inches):
   - Presept, Cidex, Theracide, or Amphil solution prepare according to the product directions.
   - Household Bleach (5% sodium hypochlorite) use as full strength or dilute with water to as much as 1:20 (mix 5 mL bleach with 95 mL water for a total of 100 mL).
   - Isopropyl Alcohol (70% to 85%) use as full strength.

- **CAUTION**
  Any solutions other than the ones mentioned might damage the test table and the table insert.
Manufacturer’s Instructions

Recommended cleaning/disinfecting solutions
Use only the following solutions for cleaning/disinfecting the meter (housing and test strip guide).

- 70% ethanol or isopropyl alcohol
- 10% sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)

NOTICE
Do not use any other disinfectants/cleaning solutions on the meter (housing or test strip guide). Use of other disinfectants/cleaning solutions could result in damage to the meter.

5.2 Cleaning the Display
The display can be cleaned with alcohol, without additives.

5.3 Cleaning of the Analyzer Outer case and the Docking Station

FIGURE 5-4
a) Make sure that the Analyzer is turned off. The display should be blank.
b) The outer case of the Analyzer and the Docking Station may be cleaned with alcohol or a mild soap solution.
c) The Scanner glass should be cleaned gently with alcohol.
Example of Standard: Joint Commission

EC.01.01.01, EP 3 - Requires Hospitals to have a “library of information regarding inspection, testing, and maintenance of its equipment and systems.” The library of information should include:

- Manuals
- Procedures provided by manufactures
- Technical bulletins
- Other information as needed
**SANI CLOTH HB (Green Top)**

PATIENT CARE EQUIPMENT: that requires an alcohol free disinfectant

**QUARTERNARY AMMONIUM AND ALCOHOL FREE**

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**SUPER SANI CLOTH (Purple Top)**

MOST PATIENT CARE EQUIPMENT: (blood pressure cuff, glucometer, Crutches, stretchers, wheelchairs, carts, keyboards, leads, bed rails, furniture)

**QUARTERNARY AMMONIUM (QUAT) + ALCOHOL**

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**ALCOHOL WIPES (Easy Screen) (White Top)**

COMPUTER SCREENS, PAGERS, STETHOSCOPES

70% ISOPROPYL ALCOHOL + 30% WATER

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**SANI CLOTH PLUS (Red Top)**

Communication devices, electronic

**QUARTERNARY AMMONIUM (QUAT) + LOW ALCOHOL (14.85%)**
**SANICLOTH BLEACH (Orange Top)**
Used to disinfect all surfaces when patient has *C diff* diarrhea or Noro virus

**VIREX Quat**
For OR use: Used to sanitize all surfaces, including the floors

**QUATERNARY DISINFECTANT CLEANER** (diluted per automatic dispenser in housekeeping closet)

**SODIUM HYPOCHLORITE .63%**

**KBQ 256**
Used by **EVC** to disinfect all surfaces (beds, bed rails, bedside tables, telephone, call button, keyboards, Christmas tree adapters).

**PHOSPHATE-FREE DISINFECTANT CLEANER**

**Bru-Tab**
An effervescent disinfectant tablet which will be diluted and used by EVC

**SODIUM DICHLORO-STRIAZINETRIONE 48.21%**
Questions?

Contact Information: jmumfor3@jhmi.edu
Battling Documentation?
Advance Your Approach!

Kim Skala, MT(ASCP)
Recent ListServ Discussions

- Documentation of Diplomas/Qualifications
- Documentation of Competency Assessment

Who requests from new staff? HR, POCC, Clin Ed, Other
Who keeps the documents? HR, POCC, Clin Ed, Other
How is the documentation stored?

Paper/Filed manually, Scanned original into electronic file, e-learning system, e-learning with interface to middleware
RESOURCE ACTIVITY
Questions & Wrap Up

- jmumfor3@jhmi.edu
- khalverson @ilww.com
- pmann@UTMB.EDU
- l.wyer@cox.net
- kskala@ILWW.com

THANK YOU FOR ATTENDING!