The University of Iowa | State Hygienic Laboratory

# CLIA CORNER

State Hygienic Laboratory at The University of Iowa — Third Quarter 2024

## In This Issue…

- Personnel competency assessment policies;
- Procedure manual requirements; and
- BD BACTEC™ Blood Culture bottle shortage.

Three of the top ten deficiencies cited nationally in the first half of 2024 by Clinical Laboratory Improvement Amendment (CLIA) surveyors, were related to policies and procedures! In this issue of the CLIA Corner, we will address these three commonly cited deficiencies regarding personnel competency assessment policies and general procedures.

## §493.1235 Standard: Personnel competency assessment policies (D5209)

**As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.**

Each laboratory must have policies and procedures established for laboratory personnel training and competency, including but not limited to, technical and clinical consultants, technical supervisors, general supervisors and other laboratory staff. This deficiency is cited when laboratories have developed training and competency policies, but are not following the established policies. For example, if the training documents were not completed as outlined in the policy or if semi annual competency did not get documented as specified in the policy for new employees, this deficiency would be cited. Refer to the First Quarter 2018 CLIA Corner for competency assessment criteria.

## §493.1251 Standard: Procedure manual (D5401)

**A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.**

Procedures may be printed and organized in binders or retained electronically. However, every procedure must be accessible to all laboratory personnel and also made available to surveyors during the inspection.

**If you would like your name added to our CLIA Corner Google Group, send an email to:**

**Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu**

If the laboratory has procedures that are not used for test performance but are use for reference purposes, these procedures can be organized in a reference section of the procedure manual. This deficiency is cited when procedures are not available to laboratory personnel. For example, procedures may be located on an electronic shared drive but part time testing personnel have not been granted access to the electronic shared drive or a user name and password is required to access procedures and the necessary security rights have not be given to new staff. Additionally, this deficiency can be cited when laboratory personnel are not following written procedures. For example, when the procedure states the incubation time is 15 minutes for a test kit, but it is discovered that laboratory personnel are only letting the specimen incubate for 10 minutes before reporting out the result. While CLIA may not require annual review of procedures, it is considered a good laboratory practice and annual review of procedures by laboratory personnel will help to prevent future deficiencies.

## §493.1251 Standard: Procedure manual (D5403)

**The procedure manual must include the following when applicable to the test procedure:**

- Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.
- Microscopic examination, including the detection of inadequately prepared slides.
- Step-by-step performance of the procedure, including test calculations and interpretation of results.
- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
- Calibration and calibration verification procedures.
- The reportable range for test results for the test system as established or verified in §493.1253.
- Control procedures.
- Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
- Limitations in the test methodology, including interfering substances.
- Reference intervals (normal values).
- Imminently life-threatening test results, or panic or alert values.
- Pertinent literature references.
- The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.
- Description of the course of action to take if a test system becomes inoperable.

This deficiency is commonly cited when one of the procedural requirements are missing or not addressed. ***The laboratory may choose to use manufacturer's operator manuals and/or instructions and package inserts as procedures, provided they include all of the necessary requirements.*** If it is crucial that the specimen be refrigerated prior to testing, then the procedure for that analyte should include the instructions for specimen storage, preservation and transportation. A deficiency would be cited if this information was omitted from the procedure. The surveyor would also cite this deficiency if the operator's manual doesn't include all of the necessary procedural requirements. For example, when a laboratory implements a new hematology analyzer and chooses to use the operator's manual as the procedure. The operator's manual usually doesn't include the corrective action steps to take when quality control fails or how to communicate panic values to providers.

Procedures are an excellent resource for laboratory testing personnel and are necessary to ensure accurate and reliable test results.

## Questions and Answers—BD BACTEC™ Blood Culture Media Bottle Shortage

### 1. Is CMS aware of the disruptions in the availability of BD BACTEC™ Blood Culture Media Bottles?

The CMS Division of Clinical Improvement and Quality (DCLIQ) is responsible for the oversight of clinical laboratories and laboratory testing. DCLIQ is aware of the BD BACTEC™ blood culture media bottle supply issue and has heard from multiple stakeholders about the disruptions caused by this shortage. CMS remains in close contact with the FDA and other HHS partners to monitor the supply situation.

Laboratories experiencing disruptions in their supply of BD BATEC blood culture media bottles and health care providers who order blood cultures should consider developing strategies to prioritize the use of blood culture media bottles, based on clinical need, to maintain quality and safety of patient care. Additional information can be found at the following links:

Statement from Secretary Becerra on Disruptions in Availability of Blood Culture Media Bottles | HHS.gov

Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers | FDA

BD BACTEC™ Update (bdbactec-update.com)

### 2. Can a laboratory use expired BD BACTEC™ Blood Culture Media Bottles during the shortage?

The CLIA regulations at 42 C.F.R. § 493.1252(d) state that "Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality." BD™ has extended the shelf-life for specific lots of BD BACTEC™ Blood Culture Media Vials in the US. Please contact BD™ for additional information. **For lots that have not had their shelf-life extended, the use of expired reagents would be considered a test modification and would require the laboratory to establish performance specifications for a modified procedure. In addition, the test would default to high complexity.**

**3. BD™ has communicated that they will be launching the BD BACTEC™ Lytic Anaerobic media in glass. What type of verification needs to be performed if my laboratory switches to glass bottles?**

When the laboratory introduces an unmodified, FDA-cleared or approved test system, it must conduct a verification of performance specification study per § 493.1253(b)(1). CLIA regulations are not prescriptive about the number or type of samples used to perform the verification of performance specification study. The laboratory director is responsible for determining whether the verification of performance specifications study meets the regulatory requirements at § 493.1253(b)(1) and which performance characteristics apply (accuracy, precision, reportable range, and reference intervals). Laboratories should also contact their accrediting organization or state agency as they may have more stringent requirements. More information on the glass bottles and the manufacturer's verification protocol may be found on the BD™ website.

If the laboratory previously verified the performance specifications for glass blood culture bottles AND have retained those records, the laboratory can use the original performance specifications studies. The verification of performance specification requirements is considered met. However, if the laboratory cannot locate the original glass bottle performance specification records, or has never verified the performance specifications for the glass bottles, then studies will be required. As a reminder, CLIA does not specify the number of specimens that must be tested when verifying performance specifications. It is up to the laboratory director (with guidance from the manufacturer) to determine the suitable number of specimens needed to demonstrate accuracy, precision, reportable range, and reference range.

For additional questions regarding the BD BACTEC™ Blood Culture Bottle shortage contact your State Agency.