CLIA Updates

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CLIA Regulation Changes for Proficiency Testing (PT)

As of **August 10, 2022**, laboratories with Certificates of Waiver are not exempt from the ban against referral of PT sample and other penalties required when PT referral has been substantiated.

- The referral to another laboratory of a sample from a PT program by ANY laboratory of ANY certificate type is considered PT referral. If a laboratory enrolls and participates in PT, regardless of certificate type, all rules related to PT referral apply.
- To avoid implications of PT referral, laboratories using previously tested PT samples for competency assessment, training or other in-house purposes should wait until after the PT event cut-off date for reporting results to the PT program.

Effective July 11, 2024, changes:

Bacteriology (42 CFR § 493.911)

- Must include representative from Gram negative bacilli; Gram positive bacilli; Gram negative cocci; and Gram positive cocci. Gram stains includes both stain reaction and morphology.
- Require at least two PT samples per event for susceptibility testing, including one Gram positive and one Gram negative organism with a predetermined pattern of susceptibility or resistance to common antimicrobial agents.
- Must include Mycobacterium tuberculosis complex and Mycobacterium and removed PT requirement for susceptibility or resistance testing in mycobacteriology. Laboratories required to verify accuracy of testing twice per year.

Mycology (42 CFR § 493.915)

- Must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucoromycetes; and aerobic actinomycetes.
- Requires direct antigen testing

Parasitology (42 CFR § 493.917)

- Must include intestinal parasites and blood and tissue parasites, if appropriate for the sample sources.

- Requires direct antigen testing

Virology (42 CFR § 493.919)

- Must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources.
- Requires direct antigen testing

General Immunology (42 CFR § 493.927)

- Added analytes Anti-HBs, Anti-HCV, C-reactive protein (high sensitivity)

Routine Chemistry (42 CFR § 493.931)

- Added analytes: B-natriuretic peptide (BNP), ProBNP, Cancer antigen (CA) 125, Carbon dioxide, Carcinoembryonic antigen, Cholesterol (low density lipoprotein, direct measurement), Ferritin, Gamma glutamyl transferase, Hemoglobin A1c, Phosphorus, Prostate specific antigen (total), Total iron binding capacity ((TIBC), direct measurement), Troponin I, and Troponin T
- Removed analytes: LDH isoenzymes, Ethosuximide, Quinidine, Primidone, Procainamide (and its metabolite, N-acetyl procainamide)

Endocrinology (42 CFR § 493.933)

- Added analytes: Estradiol, Folate (serum), Follicle stimulating hormone, Luteinizing hormone, Progesterone, Prolactin, Parathyroid hormone, Testosterone, Vitamin B12

Toxicology (42 CFR § 493.937)

- Added analytes: Acetaminophen (serum), Salicylate, Vancomycin

Final Rule - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing - Analytes and Acceptable Performance Final Rule (CMS-3355-F) | CMS

FREQUENTLY ASKED QUESTIONS

QUESTION. What paperwork is required to be retained for proficiency testing (PT) records?

ANSWER: The following documents are required:

- Test runs with PT results, including direct printouts
- Remedial actions for unsatisfactory results
- PT intake paperwork with the date samples were received, copies of the signed PT attestation forms, and PT performance review forms.
- For nonwaived tests not listed in Subpart I, verification of test or procedure accuracy is required twice a year.
- Policies or Procedures that address PT enrollment, PT sample handling, testing, and documentation.

QUESTION. If I perform waived tests, do I have to enroll in a proficiency testing program?

ANSWER: No. Please note that if you are a moderate or high complexity laboratory that also performs waived tests, the following applies:

- You are held to requirements for testing of PT samples if enrolled for waived tests
- Does not exclude waived tests from PT referral
- You are not required to enroll in PT for waived tests

QUESTION. Should I have an ongoing evaluation of my IQCP?

ANSWER: Yes! Things change over time, so an evaluation should be performed at least once a year and the process documented, including corrective action if needed. Any changes or additions should be reflected in your procedures, reviewed by staff, and signed by the laboratory director. See Interpretive Guidelines § 493.1256(d).

Abbott i-STAT cTnI cartridge

On November 2022 Abbott Point of Care customer letter (11-2022-168), informed labs that the current version of the i-STAT cTnI cartridge is **not FDA-cleared** due to changes made to the product since 2003.

Laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance, that have the i-STAT system, **will continue to be allowed to use the cTnI test cartridge as a moderate complexity test.** Laboratories need to follow all CLIA regulations that apply to moderate complexity testing. Frequently Asked Questions (FAQs), Abbott i-STAT [lnks.gd]

Common Deficiency Review

D5469 (Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

42 CFR §493.1256 Standard: Control procedures

(d)(10) Establish or verify the criteria for acceptability of all control materials.

(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

Interpretive Guidelines 42 CFR §493.1256(d)(10) Acceptable ranges must be verified (assayed) or established (unassayed) by the laboratory for control materials and any calibrators that are used in lieu of control materials.

If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.

Example citation: The laboratory failed to establish acceptable criteria (statistical parameters and standard deviation) for the assayed controls. Three of the three selected chemistry analytes performed on the Siemens Dimension EXL 200 analyzer failed to have acceptable standard deviations (SD) and ranges for QC level I for Biorad MultiQual.

1. Review of Biorad MultiQual level I QC ranges in the Siemens Dimension EXL 200 showed the following data:
   sodium--lot #45831 with a range of 105-129 mmol/L, a mean of 117 mmol/L and a SD of 6.0
   glucose--lot #45831 with a range of 41.8-71.8 mg/dL, a mean of 56.8 mg/dL and SD of 5.0

2. Review of Biorad MultiQual level I QC package inserts showed:
   sodium--lot #45831 with a range of 110-122 mmol/L and a mean of 116 mmol/L
   glucose--lot #45831 with a range of 54.9-65.8 mg/dL and a mean of 60.3 mg/dL

Tips to help comply: Review your procedures and instrument manual
Print and retain the most recent lot # of the QC product insert.
How do you verify new reagents and control lots? Did you perform a crossover QC study?
How do you evaluate precision and accuracy?
How does the package insert compare to the measured results? Are you within 2 SD?
How do you perform your quality control review?

Even if you use Bio-Rad's Unity program, you still must ensure your instrument has the correct information (current lot number and expiration date, established SD, mean, and ranges) for the flags to work correctly.

TEST RECALL AND UPDATES

1. Remel, Inc Recalls Thermo Scientific Gram Negative IVD AST Sensititre Plate for risk of potential false susceptible results | FDA
2. All *Ochrobactrum* species were recently reclassified [t.emailupdates.cdc.gov] into the *Brucella* [t.emailupdates.cdc.gov] genus to align taxonomical nomenclature with phylogenetic analyses. This change in nomenclature has been reflected in many of the rapid microbial identification systems used in clinical laboratories.
3. TOPIC: Important Information for Blood Establishments and Transfusion Services Regarding Bacterial Contamination of Platelets for Transfusion FDA MedWatch - Important Information for Blood Establishments and Transfusion Services (govdelivery.com)

Questions about the information discussed in this CLIA Update?
The Montana CLIA Program would love to answer them. Contact us at:

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If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Michelle Griffin at Michelle.Griffin@mt.gov

References:

CLIA (mt.gov)
Clinical Laboratory Improvement Amendments (CLIA) | CMS
eCFR :: 42 CFR Part 493 -- Laboratory Requirements
SOM- Appendix C (cms.gov)