



CLIA Updates

March 2018

Montana CLIA Program, 2401 Colonial Drive-2nd Floor, PO Box 202953, Helena, MT 59620 406-438-1793
<http://dphhs.mt.gov/qad/Certification/CLIA> Email: jshepard@mt.gov or mtssad@mt.gov

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Lab Director Responsibilities

The CLIA regulations include specific Lab Director responsibilities. Many Lab Directors are not in the lab on a daily basis, so the lab must maintain evidence the Lab Director fulfills these vital responsibilities. The regulations (42 CFR §493.1403 moderate and 42 CFR §493.1441 high complexity) state:

42 CFR §493.1403/493.1441 The laboratory must have a director who meets the qualification requirements of §493.1405/§493.1443 of this subpart and provides overall management and direction in accordance with §493.1407/§493.1445 of this subpart.

What documentation demonstrates Lab Director involvement in your lab? Some common examples include:

- 1) Document consultation calls with the Lab Director.
- 2) Document Lab Director on-site visits.
 - a. Create a checklist for onsite visits for the Lab Director to complete and sign. This can ensure an efficient, effective, thorough site visit is accomplished.
 - b. Request the Lab Director sign/initial any documents reviewed during the visit including:
 - i. Blood bank quality control (QC) and patient logbook.
 - ii. New policies and procedures since the last visit.
 - iii. New analyzer/test verification data.
 - iv. Reviewed QC data.
 - v. Proficiency testing attestation statements and corrective action records.
 - vi. Quality assurance (QA) projects or troubleshooting.
 - vii. Consultations on abnormal patient charts.
 - viii. Monitoring areas of previous deficiencies to ensure continued compliance.
 - ix. Staff meeting minutes.
 - c. Document a summary of the visit and have the Director sign it. This is helpful if the Director reviewed electronic records difficult to sign.

The lab must maintain evidence the Lab Director fulfills these vital responsibilities.

While the Lab Director can delegate some responsibilities to the Technical Consultant/Supervisor, the Lab Director remains ultimately responsible for ensuring compliance with the federal regulations.

Proficiency Testing (PT) Excused Nonparticipation

PT companies can assign an artificial score of 100% instead of a 0% failure score for PT analytes under specific circumstances, which is termed excused nonparticipation. A common example is when an analyzer is broken and waiting for repair, thus prohibiting the lab from testing PT samples by the submission deadline. Do you know there is a **regulation** addressing this situation?

42 CFR §493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the

laboratory receives a zero score for nonparticipation, or late return or results).

Receiving an artificial score of 100% is not a free pass for labs. The lab must verify the accuracy of the analyte to ensure the analyte is accurate prior to releasing patient results. The documentation must be retained for at least 2 years.

PT companies report a list of labs who receive an artificial score of 100% for each event to the Montana CLIA Program. Anytime the lab requests an excuse from participating from the PT company, the lab must retain documentation of the accuracy of that analyte before testing patient samples.

Now You Know!

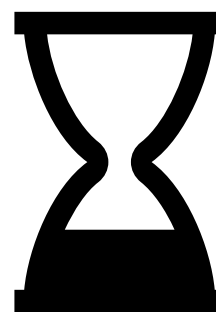
Why can't the lab use a reagent that expired yesterday?
The lab knows it is still good!

The CLIA regulation at 42 CFR §493.1252(d) states:

- *42 CFR §493.1252 Test systems, equipment, instruments, reagents, materials, and supplies (d) 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.*

CMS Interpretive Guidelines under 42 CFR §493.1252(d) state to look for outdated or deteriorated materials. Also, look for contamination, drying or other signs of deterioration. This is as important as checking expiration dates.

Performing a monthly quality assurance check for outdated and expired reagents is an effective technique to ensure the lab never uses expired products for patient testing.



Most Frequently Cited Deficiencies- 2016

With a change as big as the Individualized Quality Control Plan (IQCP), it is not a surprise that the regulations related to IQCP dominate the most cited deficiencies of calendar year 2016. The top four most cited deficiencies are all related to IQCP. IQCP continues to be an important element in surveys.

- 1) 42 CFR §493.1256 Control procedures (D5447)
(d)(3)(i) At least once each day patient specimens are assayed or examined, perform the following for - Each quantitative procedure, include two control materials of different concentrations.
- 2) 42 CFR §493.1256 Control procedures (D5449)
(d)(3)(ii) At least once each day patient specimens are assayed or examined, perform the following for - Each qualitative procedure, include a negative and positive control material.
- 3) 42 CFR §493.1256 Control procedures (D5477)
(e)(4) Before, or concurrent with the initial use--
(e)(4)(i) Check each batch of media for sterility if sterility is required for testing;
(e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and
(e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.
- 4) 42 CFR §493.1256 Control procedures (D5471)
(e)(1) For reagent, media, and supply checks, the laboratory must do the following: Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in §493.1261 (a)(3)) and identification systems when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

It is not a surprise that the regulations related to IQCP dominate the most cited deficiencies of 2016.

Other recurring themes of the most frequently cited deficiencies in 2016 included correct calculation of patient international normalized ratio (INR)(see September 2017 newsletter), antimicrobial sensitivity testing, quality assessment, competency assessment, and calibrations.



14 Required Elements for Procedures

**STANDARD
OPERATING
PROCEDURE**

Do you know the CLIA regulations have 14 required elements for procedures? Each individual procedure must include all pertinent elements. Notice that 42 CFR §493.1251(c) allows the laboratory to use the manufacturer instructions for #1-12, but the lab must have a separate policy to address #13 and #14.

- ❖ 42 CFR §493.1251 **Procedure manual** (D5401, 5403, 5405, and 5407)
- ❖ (a) 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.
- ❖ (b) The procedure manual must include the following when applicable to the test procedure:
 - (1) 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.
 - (2) Microscopic examination, including the detection of inadequately prepared slides.
 - (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.
 - (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
 - (5) Calibration and calibration verification procedures.
 - (6) The reportable range for test results for the test system as established or verified in §493.1253.
 - (7) Control procedures.
 - (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
 - (9) Limitations in the test methodology, including interfering substances.
 - (10) Reference intervals (normal values).
 - (11) Imminently life-threatening test results, or panic or alert values.
 - (12) Pertinent literature references.
 - (13) 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.
 - (14) Description of the course of action to take if a test system becomes inoperable.
- ❖ (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.
- ❖ (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

Questions and Answers (Q & A)

Q: Why does the Lab Director need to sign the proficiency testing attestations for Blood Bank testing?

A: The Technical Supervisor qualifications for blood bank (42 CFR §493.1449(q)-D111) are limited to a Pathologist or a doctor with one year of lab experience in blood bank. A Clinical Lab Scientist does not qualify as Technical Supervisor for high complexity blood bank testing. The CLIA regulations require the Lab Director or Technical Supervisor to sign the proficiency testing attestation statements. The Lab Director can fill both positions for blood bank testing. The lab must ensure the correct person signs all blood bank proficiency testing attestations.

The lab must also have evidence of the Lab Director involvement and oversight as the Technical Supervisor in blood bank testing to meet 42 CFR §493.1451.

Q: The lab paid for the CLIA certificate but hasn't received a new certificate yet. Where is it?

A: If the lab has paid for the CLIA certificate, the certificate will be automatically mailed 3-4 weeks prior to the expiration of the current certificate. Watch for the new certificate to arrive in the mail 2-3 weeks prior to the expiration of the current certificate. If the lab's CLIA certificate has expired, contact the Montana CLIA Program to check the status.

References:

2017 CMS CLIA Interpretive Guidelines
CMS CLIA Federal Regulations
CMS S&C Memos

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

Questions about the information discussed in this CLIA Update?

The Montana CLIA Program would love to answer them. Contact us at:

Montana CLIA Program

2401 Colonial Drive-2nd Floor
PO Box 202953
Helena, MT 59620

Phone:

406-438-1793 or 406-444-2099

Fax:

406-444-3456

E-mail:

mtssad@mt.gov or jshepard@mt.gov