



CLIA Updates

September 2017

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

INSIDE THIS ISSUE

- 1 Rapid Flu Changes
- 2 Primary Source Verification
- 2 Now You Know
- 3 Calculating INRs
- 4 Procedure Manual
- 5 Q & A

Rapid Flu Test Changes

The Food and Drug Administration (FDA) reclassified antigen based rapid influenza diagnostic tests from class I to class II in January of 2017 with the goal of improving detection of the current circulating strains of the flu virus. Historically, manufacturers proved specificity and sensitivity to flu strains only for initial FDA approval of the test. Over time, this led to false negative and false positive patient results as the circulating antigenic strains changed over time, as well as the emergence of novel pandemic strains.

With the change from class I to class II, the FDA will have the authority to mandate the manufacturers prove every year the influenza tests sold detect the strains circulating from the past three flu seasons. Kits that do not meet the new requirement (cannot detect the circulating strains from the past 3 seasons) cannot be sold after January of 2018.

Due to this change, labs are getting a lot of attention from sales representatives to switch to new tests and to use newer detection methods. If you are using a flu test that will be discontinued in January of 2018 due to not meeting the new class II requirements, you will need to look at and change to a class II approved flu test.

The options for class II approved flu tests include manual visual read kits, automated readers, or molecular tests. Please feel free to explore your options to determine which method is best for your lab. While the automated readers and molecular technologies provide better sensitivity and reduce the subjectivity of the visual read, they are encouraged but not required by the Clinical Laboratory Improvement Amendments (CLIA).

The change from class I to class II does not alter the waived status of most of the available kits but each lab needs to know whether their test is classified as moderate or waived complexity by the FDA. Labs also need to be aware of potential changes in the manufacturer instructions. Lab managers need to pay extra attention to manufacturer instructions for any changes in the manufacturer requirements to keep the test waived through this flu season.

Class I flu tests may be used until they expire, but will be unavailable from manufacturers in January 2018.

Primary Source Verification

During a Clinical Laboratory Improvement Amendments (CLIA) survey, the State Surveyor evaluates the qualifications of testing personnel performing moderate and high complexity testing. All testing personnel should be listed on the CMS-209 form (laboratory personnel report).

This evaluation requires proof of an applicable Montana professional state license, proof of education (diploma or transcript), and evidence of experience (if required to meet the regulations).

The Centers for Medicare and Medicaid (CMS) released Survey and Certification (S & C) Memo 16-18-CLIA allowing surveyors to accept verification of these requirements from a Primary Source Verification (PSV) company. Some employers use a PSV company to verify employee credentials prior to hire.

If you use a PSV company, the report needs to show verification of all the required aspects in the regulation including applicable Montana professional state license, education, and experience (if required).

The laboratory director is responsible for proving credentials not included in the PSV report.

Now You Know!

Why document the room, refrigerator, and freezer temperatures every day?

The CLIA regulations at the Code of Federal Regulations (CFR) §493.1252(a)-(b) state the labs must monitor temperatures and document meeting the manufacturer directions for proper storage. The surveyor checks compliance by looking at temperature charts, acceptable reagent temperatures, out of range temperatures, etc.

- **CFR §493.1252 Test systems, equipment, instruments, reagents, materials, and supplies**
- *(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.*
- *(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and*

documented and, if applicable, include the following:

- *(b)(1) Water quality.*
- *(b)(2) Temperature.*
- *(b)(3) Humidity.*
- *(b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.*

- **CMS Interpretive Guidelines §493.1252(b)**
- Temperature-controlled spaces, equipment, and instruments must be monitored and results documented for acceptable temperature ranges. Corrective action is needed when acceptable temperature ranges are exceeded. Continuous monitoring of temperatures by a recording thermograph is acceptable provided the data and time of use are annotated. The charts must be retained to document that temperatures were within the limits established by the laboratory.



Calculating INRs

$$\left(\frac{PT_{(patient)}}{\text{Mean } PT_{(normals)}} \right)^{ISI}$$

Calculation of the International Normalized Ratio (INR) requires each facility to calculate the normal patient mean for their patient population and use the International Sensitivity Index (ISI) for the lot of thromboplastin (e.g. Innovin, RecombiPlastin, etc) in use. Failure to use the correct normal patient mean or ISI will result in an incorrect calculation of the patient INR.

Most facilities order enough thromboplastin reagents to last an entire year, which may result in the laboratory forgetting to calculate a new patient mean and enter the new ISI when the new lot is opened. This has a high potential for poor patient outcomes.

Due to the potential adverse patient outcome, CMS requires an ongoing quality assurance (QA) project in the Interpretive Guidelines for INR (CFR §493.1252(a), §493.1269(b), §493.1289(a), and §493.1299(a)).

- Find the ISI on the instrument. Does it match the ISI for the current lot of thromboplastin reagent? Does the expiration date and lot number match, too? Did you retain the ISI for each lot used in the past two years?
- Was a new patient mean calculated for the current lot and entered into the computer? Is this data kept for at least two years?
- Is there a policy and procedure for changing the ISI and patient mean?
- Is a system in place to monitor to ensure the correct ISI and normal patient mean are always used to calculate the patient INR? Do you test the calculation to make sure it is correctly calculating?

Setting up a QA monitor to answer those questions on a regular basis will ensure an error is prevented. With poor patient outcome on the line, can you afford to not have this QA project?

A Monthly Checklist is a great way to check the INR on a regular basis

Certificate of PPMP Regulation Compliance

The Center for Disease Control (CDC) released a new booklet with information for entities with CLIA Certificates of Provider Performed Microscopy Procedures (PPMP)(download from <https://wwwn.cdc.gov/CLIA/Resources/PPMP/default.aspx>). This booklet includes resources to assist in compliance with the federal CLIA regulations pertaining to moderate complexity microscope tests used in a PPMP facility.

The Centers for Medicare and Medicaid Services (CMS) also released a webinar through the Medicare Learning Network (MLN) covering what PPM facilities need to document to be compliant with the federal CLIA regulations. The webinar can be downloaded from the CMS MLN website at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events.html> under the original air date of 2017-06-28. Please pass along this information to any collaborating providers with a Certificate of PPM.

Laboratory managers with a Certificate of Compliance may also find these resources informative for quality assessment of your microscopic tests for compliance with the federal regulations such as approved procedures, accuracy verification or proficiency testing, competency, quality control, etc.



Is Your Procedure Manual Up to Date?

When was the last time you edited your procedure book? How many procedures are old and no longer applicable but are still stuck in your binders? Are there active procedures for instruments that you no longer have?

Let's highlight a few of the CLIA procedure regulations:

- *CFR §493.1251(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.*
- *CFR §493.1251(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.*
- *CFR §493.1251(d): Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.*
- *CFR §493.1251(e): The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2).*
- *CFR §493.1105(a)(2): Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.*
- *CFR §493.1407(e)(13) and §493.1445(e)(14) Laboratory Director Responsibilities. Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.*

What does this mean for you, the laboratory?

- 1) Is there a **procedure** for **every** moderate and high complexity test you perform (this includes kit tests that are moderate for certain sample types)? Is it **labeled with a date of initial use**?
- 2) If you are using manufacturer instructions for procedures;
 - a. Do you have the **most up to date version** of the instructions and is it **signed/approved** by the lab director?
- 3) Do you have the **current lab director's approval signature** on your procedures? If it is an old signature date, check for old or outdated procedures.
- 4) Do you have procedures for old instruments? If so, label them with **'discontinued/retired,' the date of discontinuance**, and keep it for **two years**. If you used manufacturer instructions as the procedure, make sure to keep a copy (labeled as discontinued) if you sell the instrument, and keep it for two years.

**STANDARD
OPERATING
PROCEDURE**

If a procedure or policy is changed, the laboratory director must re-sign approval.

Questions and Answers (Q & A)

Q: I have been using urine hCG controls for my urine/serum hCG kits. Do I need to use serum hCG controls for serum patient samples?

A: Yes, the Interpretive Guidelines at CFR §493.1256 (a-c) requires the controls to have a similar matrix to that of patient specimens, be treated in the same manner as patient specimens, and go through all analytic phases of testing as applicable. Urine is a different matrix than serum, so you need to start doing serum QC unless your IQCP allows for urine QC.

Q: I still have the Interpretive Guidelines from 2004. Where can I find the updated Guidelines?

A: New Interpretive Guidelines were published in January 2016, with many changes that include IQCP. Download them from <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html> under the Interpretive Guidelines tab on the left hand side of the screen.

Q: My lab director is changing. What do I need to do?

A: To change the laboratory director, fill out and submit a CMS-116 form to the CLIA program. Please also submit any required documentation to verify the new lab director has a state license, meets the education requirements, and the experience required (if applicable).

References:
2016 CMS CLIA Interpretive Guidelines
CMS CLIA Federal Regulations
CMS S&C letters
FDA Announcement

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

Fax:
406-444-3456

E-mail:
mtssad@mt.gov or jshepard@mt.gov