



# CLIA Updates

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## Compliant IQCPs

### INSIDE THIS ISSUE

- 1 Compliant IQCPs
- 2 Hematoxylin and Eosin (H&E) Stain
- 2 Beware the Pitfalls of Thermal Paper
- 3 Retaining Policies and Procedures
- 4 Backup Moderate Complexity Analyzers
- 4 Hemocytometers
- 5 Q & A

Effective January 1, 2016, the Center for Medicare and Medicaid Services (CMS) CLIA program established Individualized Quality Control Plan (IQCP). Between January 1, 2016 and December 31, 2017, compliance laboratories in Montana received feedback on improving their IQCPs to meet the CMS requirements from the State Agency during survey.

The expectation was the laboratories would use the feedback to improve their IQCPs. However, many laboratories have not utilized the feedback to revise their IQCPs, resulting in numerous IQCP deficiencies in recent surveys.

This is a reminder to use the previous feedback to revise IQCPs to meet the CLIA requirements.

Some recent trends include:

- 1) Not revising any IQCPs since the last survey.
- 2) Revising one IQCP and not applying the changes to other affected IQCPs.
- 3) Not retaining supporting data, which must be kept for the life of the IQCP.
- 4) Not following the Quality Control Plan (QCP) in the laboratory.
- 5) Not having the Laboratory Director sign the IQCP.
- 6) Not retaining discontinued or retired IQCPs for two years.



## Hematoxylin and Eosin (H & E) Stain

The regulation pertaining to H & E Quality Control (QC) is at 42 CFR §493.1256(e)(2).

42 CFR §493.1256 Control Procedures (D5473)  
*(e)(2) For reagent, media, and supply checks, the laboratory must do the following: Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.*

Since H & E does not have a classic “positive and negative” reactivity, the Interpretive Guidelines state the laboratory must check and document the acceptability of H & E

stain each day for intended response and predicted characteristics.

Laboratories performing H & E staining need to document whether the H & E stain is acceptable each day of staining and retain the documentation for two years.

Other stains that have classic “positive and negative” reactivity, such as acid-fast stain or trichrome stain, must be checked each day of use for positive and negative reactivity or intended reactivity.



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## Beware the Pitfalls of Thermal Paper

Thermal paper is used with many analyzers as the physical record of test results. Without an interface, the thermal paper must be retained to meet the retention requirements at 42 CFR §493.1105(a)(3).

However, thermal paper may fade over time. The ink may be smeared or wiped beyond recognition, dissolved under tape, or erased by spills.

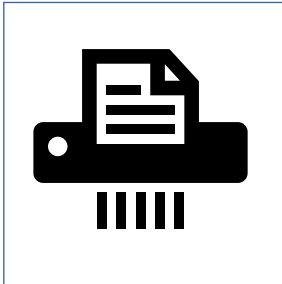
The Interpretive Guidelines specify that when necessary, the laboratory is expected to make an electronic or hard copy of applicable result printouts to ensure that they are retrievable and legible for at least two years.

42 CFR §493.1105 Retention requirements (D3031)  
*(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§493.1252 through 493.1289 for at least 2 years.*

Many laboratories tape the thermal paper to a piece of paper and make a copy. This is an acceptable method to meet the retention requirements. Laboratories may also scan the thermal paper and retain the documentation electronically.

## Retaining Policies and Procedures

Laboratory procedures must be labeled with the date of initial use and the discontinued date per 42 CFR §493.1251(e).



42 CFR §493.1251 Procedure manual (D5409)  
*(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).*

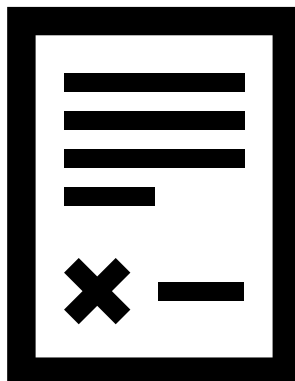
Discontinued policies and procedures may be labeled as “discontinued,” “retired,” or “no longer in use.”

The date when the procedure was discontinued must be clearly written. Procedures discontinued for at least two years may be discarded. Procedures discontinued less than two years must be retained. The discontinued procedures may be removed from the “official” procedure manuals but they must be retained and retrievable for two years per 42 CFR §493.1105.

42 CFR §493.1105 Retention requirements (D3029)  
*(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.*

Discontinued procedures include those for discontinued tests, retired analyzers, and original versions of updated procedures.

If the manufacturer’s manual is used as the procedure manual, make sure to retain a labeled copy for two years after the analyzer has been retired. Do not send the only copy of the manufacturer’s manual with the retired analyzer or toss it into the garbage for at least two years.



## Backup Moderate Complexity Analyzers

In a state where the distance from a service representative to the laboratory ranges from hours to days, an analyzer breaking down may potentially have a large impact on patient care. To help prevent patient impact, some laboratories have invested in backup analyzers to be able to provide the most critical lab tests during the downtime. Make sure you know and meet the regulation at 42 CFR §493.1281 for having the same analyte on two separate moderate or high complexity analyzers.

42 CFR §493.1281 Comparison of test results (D5775)

*(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.*

The Interpretive Guidelines state the laboratory may use proficiency testing samples, split patient samples, or blind samples with known values (i.e. split sample with the reference laboratory). The laboratory may use calibration verification samples, if the materials used for calibration verification meet the laboratory's criteria for acceptable differences in test values.

Further, the laboratory must have written criteria for acceptable differences in test values between the main and backup analyzers, and when corrective action must be taken.

Retain all comparison data between the two analyzers for two years.

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## Hemocytometers

If the laboratory has a hemocytometer for counting semen, analyzing body fluids, or evaluating cerebral spinal fluid (CSF), ensure compliance with hemocytometer quality control and testing requirements per 42 CFR §493.1269.

42 CFR §493.1269 Hematology (D5543)

*(a) For manual cell counts performed using a hemocytometer--*

*(a)(1) One control material must be tested each 8 hours of operation; and*

*(a)(2) Patient specimens and control materials must be tested in duplicate.*

The Interpretive Guidelines state that the laboratory may meet the requirement for duplicate testing by counting two chambers from one dilution. The count from both chambers must be documented with the technician name, date, and time of testing. This documentation must be retained for two years.

## Questions and Answers (Q & A)

**Q: In regard to the calculation checks mentioned in the previous newsletter, do I have to verify calculations performed by the LIS and not the analyzer?**

A: Yes, the regulation states that the results and patient specific data must be accurately and reliably sent from the point of data entry to the final destination, including the calculated results. Therefore, if the calculation is performed by the analyzer, laboratory information system (LIS), or electronic medical record (EMR), the lab needs to verify calculations are accurate and transmitted reliably.

**Q: What is the test complexity of synovial fluid crystal examinations?**

A: The Food and Drug Administration (FDA) classifies synovial fluid microscopic examination as high complexity under a general heading of “All Body Fluid Elements Microscopic Identification (ID) Procedures” in the hematology subspecialty.

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**References:**

[www.cms.gov/clia](http://www.cms.gov/clia)  
CMS CLIA Interpretive Guidelines  
CMS CLIA Federal Regulations  
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](mailto:jshepard@mt.gov).

Questions about the information discussed in this CLIA Newsletter?

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

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