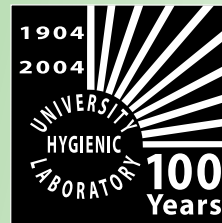


CLIA Corner

The University of Iowa Hygienic Laboratory

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In This Issue...

Celebrate National Laboratory Week (April 23-29, 2006) by Taking the CLIA Corner Challenge.

Time for Spring Cleaning — CLIA Record Retention Requirements

CLIA Corner Challenge

RULES

1. All answers are based on the CLIA regulations and interpretative guidelines, which can be found in the *Appendix C: Interpretative Guidelines for Laboratories and Laboratory Surveyors* located at www.cms.hhs.gov/clia.
2. Questions get more complex as the challenge progresses.
3. An answer key has been provided at the end of the challenge. Please feel free to grade yourself to see how familiar you are with the CLIA regulations. Have fun!!

1. **For 2 points:** What does CLIA stand for:
 - a. Classy Laboratorians of Iowa Association
 - b. Clinical Laboratory Improvement Amendments
 - c. Chemical Limits for Industrial Agriculture
 - d. Calcium, Lithium, Iron, and Arterial Blood Gas panel
2. **For 2 points:** How often should competency assessments be completed for testing personnel who have been employed by the laboratory for more than one year?
 - a. Annually
 - b. Every two years
 - c. Every four years
 - d. Never
3. **For 2 points:** Which of the following are acceptable forms of educational documentation for testing personnel?
 - a. Transcripts
 - b. Licensures
 - c. Diplomas
 - d. Both "a" and "c"

- 4. For 2 points:** How often do controls need to be performed on an automated cell counter/hematology analyzer?
- One control every 4 hours
 - Two controls every 8 hours
 - Two controls each day of patient testing
 - Three controls each day of patient testing
- 5. For 2 points:** Of the following test systems or methods, which one is classified as a waived test?
- Urine sediment examination
 - Bayer Clinitek 50 analyzer for urinalysis
 - Fern test
 - Potassium hydroxide (KOH) preparations
- 6. For 5 points:** How often does the laboratory need to perform calibration for a non-waived chemistry analyzer?
- Every 3 months
 - Every 6 months
 - Every 12 months
 - Follow the manufacturer's requirements
- 7. For 5 points:** Your office performs KOH and wet prep analysis, and testing is performed by the physicians. How should the laboratory verify the accuracy of this testing?
- At least twice annually have the physicians perform a split sample comparison
 - Enroll in proficiency testing for KOH and wet prep analysis
 - Physicians are not required to verify the accuracy of testing
 - Either "a" or "b"
- 8. For 5 points:** When the laboratory discontinues a test method, how long must the procedure be retained?
- 3 months
 - 6 months
 - 2 years
 - 5 years
 - 10 years
- 9. For 5 points:** How often does the laboratory have to perform control procedures for the bacitracin discs used in bacteriology?
- Each new lot number or shipment received
 - Each day of testing
 - Each week of testing
 - Each month of testing
- 10. For 5 points:** When the laboratory receives a proficiency testing performance score of 80 percent for the analyte creatinine, which of the following is the most appropriate course of action to be taken by the laboratory manager?
- Sign the forms that the results have been reviewed
 - Document an investigation that includes identity of the problem and corrective action to prevent the problem from re-occurring
 - Nothing, 80% is passing grade for creatinine testing
 - Document an investigation that includes repeat testing of the sample and monitoring this test

- 11. For 10 points:** Which of the following is NOT an acceptable test request?
- Patient's chart
 - Written physician order
 - Written note from your mother
 - Patient's medical record
- 12. For 10 points:** How often do controls need to be performed on an automated coagulation analyzer?
- One control every 4 hours
 - Two controls every 8 hours
 - Two controls each day of patient testing
 - Three controls each day of patient testing
- 13. For 10 points:** When the laboratory discovers a potential problem during its quality assessment process, which of the following is NOT part of the corrective action process?
- Identification of the problem
 - Resolution of the problem
 - Monitoring to determine if the problem re-occurs
 - Ignore the problem
 - Communication of the problem to appropriate personnel.
- 14. For 10 points:** Of the following microbiology media, which one requires the laboratory to perform quality control even though the manufacturer's quality control meets CLSI guidelines?
- Campylobacter agar
 - Phenylethyl-alcohol agar
 - XLD agar
 - MacConkey agar
- 15. For 20 points:** How often does an individual who screens gynecological cytology slides need to participate in a CLIA-approved proficiency testing program?
- Three times per calendar year
 - Twice per calendar year
 - Once every 2 years
 - Once per calendar year
- 16. For 20 points:** Which of the following is NOT required to be on the test report?
- Test name
 - Test results
 - Testing personnel
 - Testing site
 - Test date
- 17. For 20 points:** In which of the following scenarios have the calibration verification requirements NOT been met?
- The laboratory performs a calibration protocol using 3 or more levels of calibration material that include a low, mid, and high value at least every 6 months.
 - The laboratory follows the manufacturer's instruction for instrument operation and performs a weekly calibration using a low and high value.
 - The laboratory follows the manufacturer's instructions for instrument operation and tests 2 levels of control materials each day of testing for the *hematology analyzer*.
 - The laboratory follows the manufacturer's instruction for instrument operation and routinely tests three levels of control materials more than once each day of testing.

- 18. For 25 points:** When the laboratory introduces an *unmodified*, FDA-approved test system, which of the following is NOT required as a part of verifying the performance specifications?
- Analytic sensitivity and specificity
 - Accuracy
 - Precision
 - Reportable range and reference ranges
- 19. For 25 points:** Which of the following analytes does not require enrollment in a CLIA-approved proficiency testing program?
- Alpha-fetoprotein (tumor marker)
 - Calcium
 - Direct bilirubin
 - Cortisol
- 20. For 50 points:** When did the CLIA Final Rule become effective?
- April 24, 1995
 - January 24, 2003
 - April 24, 2003
 - January 12, 2004

KEY

- 1-b
- 2-a
- 3-d
- 4-c
- 5-b
- 6-d
- 7-d
- 8-c
- 9-a
- 10-b
- 11-c
- 12-b
- 13-d
- 14-a
- 15-d
- 16-c
- 17-b
- 18-a
- 19-c
- 20-c

SCORES

0-35 points:

You may want to consider reviewing the regulations found at
www.cms.hhs.gov/clia.

36-75 points:

You are making progress, but still have some work to do.

76-135 points:

Great job, keep up the good work.

136-235 points:

Excellent, give yourself a pat on the back!

Time For Spring Cleaning: CLIA Record Retention Requirements

Want to get rid of some of the paper and boxes cluttering or taking up space in your laboratory? Here are the CLIA requirements on amount of time a laboratory must keep records, specimens and slides. Keep in mind retention requirements vary, depending on the type of record being stored by the laboratory. Also, remember that CLIA requirements are minimal; check with your facility guidelines and, if applicable, your accrediting agency before discarding any laboratory records. Use the following chart as a guideline for determining the minimal amount of time to retain your laboratory records.

CLIA RECORD RETENTION REQUIREMENTS

(As of January 2003)

Type of Record	Specialty/Subspecialty	Retention Time
Test Requisitions & Authorizations <ul style="list-style-type: none"> Including patient's chart or medical record 	All	2 years
Test Procedures <ul style="list-style-type: none"> Include dates of initial use and discontinuance 	All	2 years after procedure has been discontinued
Analytic Systems Records <ul style="list-style-type: none"> Quality control, including instrument printouts, if applicable Patient test records, including instrument printouts, if applicable Analytic systems activities (maintenance, temperatures, functions checks), including instrument printouts, if applicable. Test performance specifications 	Immunochemistry (Transfusion-related Only)	As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(v), & (d): Currently 5 years (After processing records have been completed or six months after the latest expiration date, whichever is the later date.)
	All Others	2 years
Proficiency Testing <ul style="list-style-type: none"> All records, including reporting forms, test records, signed attestation statement, program test reports 	All	2 years
Laboratory Quality Systems Assessment	All	2 years
Test Reports <ul style="list-style-type: none"> Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) 	Immunochemistry (Transfusion-related Only)	As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), & (d): Currently 5 years (After processing records have been completed or six months after the latest expiration date, whichever is the later date.)
	Pathology Cytology & Histopathology	10 years
	All Others	2 years
Slides	Cytology	5 years
	Histopathology, Oral Pathology, Dermatopathology	10 Years
	All Others	No requirements
Specimen Blocks	Pathology	2 years
Tissue Remnants	Pathology	Completion of diagnosis

NOTE: If the laboratory ceases operation, the laboratory must make provisions for record retention for the specified requirements.