The University of Iowa | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa First Quarter 2020

In This Issue...

- Helpful hints for starting the New Year off in the right direction

With 2019 at a close and the start of 2020 well on its way, now is a perfect time for reorganizing, reviewing policies and procedures and purging old documents! This edition of the CLIA Corner will provide helpful hints for starting the New Year off in the right direction.

Competency Assessments

Competency assessments must be performed and documented to ensure that laboratory personnel are meeting the responsibilities listed in Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) Regulations and Interpretive Guidelines. In general, competency assessments are performed annually for clinical consultants, technical consultants, technical supervisors, general supervisors, and testing personnel who perform non-waived testing. CLIA specifies that competency assessments must include six criteria and they must cover each non-waived analyzer, test kit, and manual test performed by the laboratory. *For more information about competency assessments, refer to the 2018 First Quarter CLIA Corner.*

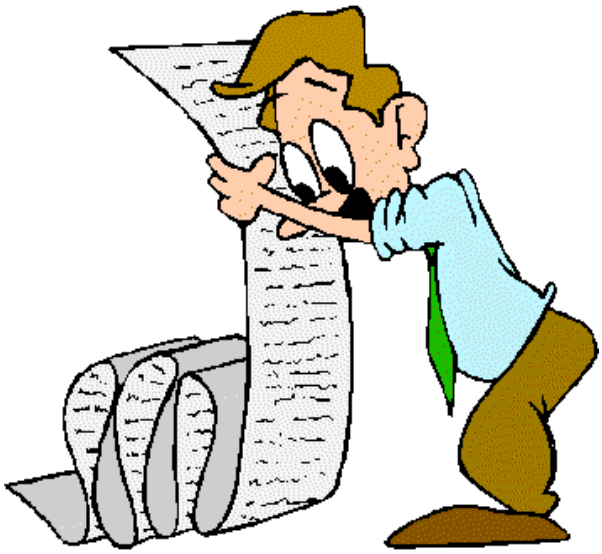
Helpful Hints:

- Did the laboratory add any new test systems and/or analytes to the test menu within the last year? Have competency assessment forms been updated to include the new testing?

- Review the laboratory's competency assessment forms to ensure they contain the six CLIA required criteria. If the laboratory cannot list the six CLIA required criteria, refer back to the 2018 First Quarter CLIA Corner!

Proficiency Testing

The CLIA Regulations and Interpretive guidelines specify that laboratories must enroll in proficiency testing (PT) for all regulated specialties, subspecialties and analytes (§493.801, D2000) and verify the accuracy twice annually for all non-regulated analytes (§493.1236, D5217). **The laboratory must review specialties, subspecialties and analytes listed in the Code of Federal Regulations, 42 CFR part 493, subpart I to determine which are considered regulated**. Non-regulated analytes are those analytes not listed in subpart I. Each year, failing to enroll in PT testing for regulated specialties, subspecialties and analytes and failing to verify the accuracy at least twice annually for non-regulated analytes are among the top ten deficiencies cited in the State of Iowa.



Helpful Hints:

- Did the laboratory add any new test systems or analytes to the laboratory's test menu within the last year? If so, are they considered regulated or non-regulated? Verify that PT has been ordered for 2020 or that there is a plan to verify the accuracy twice annually for new test systems or analytes, whichever is applicable.

- Take the laboratory's most current test menu and compare it to the proficiency testing results from the first event of 2020. Are any analytes missing? Pay special attention to tests performed infrequently.

Regulated Analytes for Common Subspecialties:

Routine Chemistry

Alanine Aminotransferase	Cholesterol, total	Magnesium
Albumin	Cholesterol, HDL	Potassium
Alkaline Phosphatase	Creatinine Kinase	Sodium
Amylase	Creatinine Kinase, Isoenzymes	Total Protein
Aspartate Aminotransferase	Creatinine	Triglycerides
Bilirubin, total	Glucose	Urea Nitrogen
Blood Gases (pH, pO2, pCO2)	Iron, total	Uric Acid
Calcium, total	Lactate Dehydrogenase (LDH)	
Chloride	LDH Isoenzymes	

Endocrinology

- Cortisol
- Free Thyroxine
- Human Chorionic Gonadotropin (serum)
- T3 Uptake
- Triiodothyronine
- Thyroid Stimulating Hormone
- Thyroxine, total

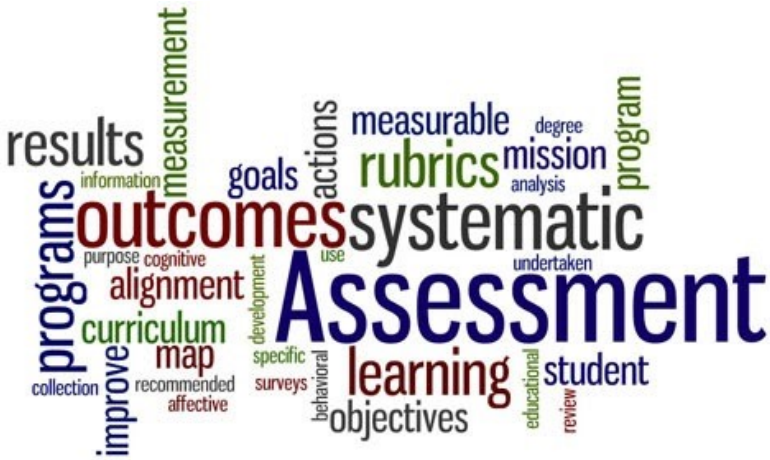
Toxicology	
Alcohol, Blood	Primidone
Blood Lead	Procainamide (and metabolite)
Carbamazepine	Quinidine
Digoxin	Tobramycin
Ethosuximide	Theophylline
Gentamicin	Valproic Acid
Lithium	
Phenobarbital	
Phenytoin	

Hematology
Cell Identification (WBC diff)
Erythrocyte Count
Hematocrit
Hemoglobin
Leukocyte Count
Platelet Count
Fibrinogen
Partial Thromboplastin Time
Prothrombin Time

Immunohematology
ABO Group (excluding subgroups)
D (Rho) Typing
Unexpected Antibody Detection
Compatibility Testing
Antibody Identification

Quality Assessment (QA)

CLIA requires the laboratory to have a written QA policy that includes the four quality systems: general laboratory, pre-analytic, analytic, and post-analytic. The QA policy must include on-going mechanisms to monitor, assess, and when indicated, correct problems identified in the laboratory. In the past, the Iowa CLIA program has seen confusion in hospital laboratories that have developed Quality Improvement plans for critical access requirements. Many times, laboratories try to use the critical access Quality Improvement plans interchangeably with the CLIA QA plans, and they are not the same. Many of the critical access Quality Improvement plans fail to address all four of the CLIA quality systems.



Helpful Hints:

- Review the laboratory's QA plan. Does it include all four of the quality systems?

- Think about weekly, monthly and quarterly reviews. Also, think about activities that are performed every six months, like calibration verification and comparisons between analyzers/methods. These reviews and activities fall under one of the four quality systems and should be documented as part of the laboratory's QA activities. Does the laboratory have a system for documenting these QA reviews and activities?

- Review the laboratory's QA indicators. Has the laboratory performed a study on troponin turn-around-times for the last 5 years? Has the laboratory met its goal? It may be time to find a new QA indicator!

Record Retention

One of the most commonly asked CLIA questions is, "How long do I need to retain my laboratory records?" The CLIA regulations contain specific record retention requirements, which can be found in Subpart J of the CLIA Regulations and Interpretive Guidelines. The majority of laboratory records must be retained for a minimum of two years. This means that for 2020, the laboratory must retain records for 2018 and 2019. Anything from prior to 2018 can be purged! ***CLIA does have more stringent record retention requirements for immunohematology (blood banking) and pathology (cytology and histopathology) testing.***

Helpful Hints:

- Get out the marshmallows, graham crackers, chocolate bars, and roasting sticks; it is acceptable to purge laboratory records!
- ***Refer to the record retention chart on the next page to prevent the laboratory from being burned.***

The beginning of a new year always brings challenges and new adventures. By following the helpful hints provided, the laboratory can ensure a smooth transition and successful CLIA survey!

CONTACT US

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Click on the link below to discover archived CLIA Corner newsletters:

http://www.shl.uiowa.edu/labcert/clia/cliacorner.xml

Type of Record	Specialty/ Subspecialty	Retention Time
Test Requisitions & Authorizations • Including patient's chart or medical record	All	2 years
Test Procedures • Include dates of initial use and discontinuance	All	2 years after procedure has been discontinued
Analytic Systems Records • 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	Immunohematology (Transfusion-related Only)	As specified in FDA 21 CFR 606.160 (b)(3)(ii), (b)(3)(v), & (d): Currently 10 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 • All records, including reporting forms, test records, signed attestation statement, program test reports	All	2 years
Quality Assessments Activities	All	2 years
Test Reports • Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports)	Immunohematology (Transfusion-related Only)	As specified in FDA 21 CFR 606.160 (b)(3)(ii), (b)(3)(v), & (d): Currently 10 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