Vol. 4, Issue 11, November 2019

Commission for the Accreditation of Birth Centers

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CLIA Testing: What Birth Centers Need to Know

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Your birth center must have a CLIA certificate if you are doing any labs, including those designed for home use like pregnancy tests or glucose checks.

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regs that oversee all human laboratory testing performed in the US (except some research). Any site that performs lab tests on human specimens must comply if the results may be used by a clinician to make a plan of care. Some states have additional CLIA requirements.

Tests designed for home use like pregnancy tests and glucometer will require a CLIA certificate of waiver. More complex tests, including nitrazine and ferning will likely require a certificate for Provider Performed Microscopy.

Program Audits

When CABC or any auditor reviews a chart and finds a lab result, they should also be able to find the following elements:

- A current CLIA certificate for that level of the test
- A P&P for that test
- Quality control testing performed for that period of time with supplies not expired; equipment that had been checked and calibrated; by personnel who had this in their job description, trained and competency verified
- A provider order
- Parameters for normal and abnormal results
- Notification to the provider
- Notification to the clients of results and plan of care
- Proficiency testing or accuracy validation of ferning or moderate complexity testing
- The assignment of a qualified lab director

Policies & Procedures

The policies can be separate for each test—or one overall document with sections for each test—and signed by the lab director who might be signing laboratory procedures in addition to the clinical director, or whomever signs or writes P&P's at the birth center.

- Follow manufacturer instructions for quality control.
- Document quality control testing on a paper log, or document in your electronic health record and export a log.
- Include instructions for supplies, storage, labeling and handling of a specimen, quality control testing, high and low paraments for expected results, and documentation expectations.

Forms

There are two types of forms that may be used: Quality Control testing logs and Patient logs. These may be separated or combined into one form. It's helpful to have instructions on the log! (i.e., test devices monthly). Results must include date of QC test, lot #s, testing personnel, ordering provider, provider notification of

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results, and parameters or normal results. Those need to either be reported on a log, or on each result reported to the chart.

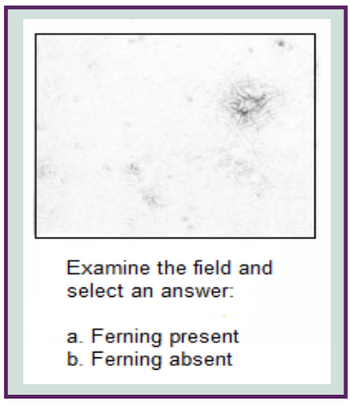
Personnel

At a minimum, some of your staff will be "testing personnel." If you are doing any tests that are moderate complexity or microscopy, you will need to assign "Lab Director" responsibilities to one of your staff, or your consultant. Federal regulations require that the lab director have advance practice licensure or be a physician. Be sure to document the responsibilities of each staff member related to lab testing. For every test you expect staff members to preform, you should document:

◊ Orientation

◊ 6-months after initial competency validation

◊ Annual competency check (must include 6 elements)



Competency Testing

There are 6 required elements:

Direct observation of routine patient testing

Do they explain test to client accurately? Do they label specimen properly?

Direct observation of instrument function and maintenance

Can they do QC testing? Do they know how to clean and maintain microscope?

Monitoring of the recording and reporting of test results

Do records indicate they are accurately recording and reporting results?

Review of intermediate test results, QC records, and preventative maintenance records

Do they know the expected low and high ranges for the urine dipstick results?

Assessment of test performance

Does they know when to suspect a confounding result such as a false positive ferning?

Problem solving skills

Do they know what to do if the pregnancy test doesn't show the "internal quality control" line?

Proficiency Testing

Proficiency testing is external validation that your ***laboratory*** (not person) is accurately testing specimens. While not required for waived testing, it IS required for microscopy and other moderate complexity tests.

♦ If **ferning** is the *only* type of microscopy performed, the birth center may choose accuracy testing in lieu of proficiency testing.

♦ **Wet preps, semen analysis, nitrazine paper, amnisure** and **rapid strep** all require proficiency testing.

Resources

American Academy of Family Practice Guidance for CLIA

CLIA brochure on Competency

CLIA brochure on Proficiency Testing

CDC booklet on Provider Performed Microscopy

CLIA lists of tests by category

FDA website to search complexity of tests

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