

### 8.15.2 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

**Policy:** Title X clinics must maintain quality laboratory services that are in compliance with the Clinical Laboratory Improvement Amendments (CLIA) regulations and assure accurate, reliable results.

**Procedure:**

The following laboratory practices must be followed in order to provide quality Title X laboratory tests and procedures (e.g. urine pregnancy, dipstick urinalysis, and rapid HIV tests):

1. Have a current CLIA Certificate of Waiver (COW).
2. Have a provider-performed microscopy procedures (PPMP) certificate in conjunction with the COW if the clinic performs direct microscopic examinations, such as wet mounts.
3. Follow the manufacturer's instructions for performing the test to include all of the instructions in the product insert from "intended use" to "limitations of the procedure." Read the instructions carefully **each time** a new kit is opened to check for changes in procedures or quality control.
4. Sub-recipients must develop a procedural manual for laboratory practices. Information in the manual should include, but is not limited to, the following:
  - a. The manufacturer's instructions for the current testing kit in use. Always use the product insert that comes with the test system that was just opened
  - b. The manufacturer's instructions for specimen collection and handling
  - c. The manufacturer's information about the proper storage requirements for the test kits and specimens collected
  - d. The manufacturer's information regarding the appropriate collection containers for each specimen
  - e. A local policy/procedure that addresses:
    - i. Training new staff on laboratory testing
    - ii. Annual competency testing of personnel that perform CLIA waived tests
    - iii. Proficiency testing for clinicians performing microscopic examinations of specimens
    - iv. Quality control
  - f. Equipment information such as:
    - i. Manufacturer's recommended maintenance, calibration and function checks
    - ii. Cleaning procedures to include how often
5. Notify the state CLIA agency, in writing, before changing to or adding a non-waived test. The Center for Medicare and Medicaid Services (CMS) requires a COW facility to notify the state CLIA agency, in writing, of any change in director, location, and ownership or complete testing termination.
6. A recording tool must be kept to track the lost and expirations dates.
7. Record the client's test results in the proper place, such as the client's chart and in a laboratory log.
  - a. Record the results according to the instructions in the manufacturer's product insert.
  - b. If it is a qualitative test, spell out positive/negative or pos/neg because symbolic representations can be altered (the "-" can be altered to a "+").
  - c. Include the name of the test, date the test was performed, and the initials of the testing personnel in the test record. Include the calendar year in the date.
  - d. If the same test is performed on a client multiple times in one day, include the time of each test.
8. Follow the storage requirements for the test kit. If the kit can be stored at room temperature but this changes the expiration date, write the new expiration date on the kit.
9. Do not mix components of different kits.
10. Be sure to label the client's specimen for testing.

It is recommended that each clinic have the Morbidity and Mortality Weekly Report (MMWR) “*Good Laboratory Practices for Waived Testing Sites.*” This document can be downloaded from the CDC website at <http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>.

CDC maintains a CLIA website (<http://wwwn.cdc.gov/clia/default.aspx>) and a CLIA Waived Tests website (<http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx>) with helpful resources, including the MMWR mentioned above.

Helpful information may also be found on the CLIA website at [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia).

The Montana CLIA contact information is as follows:

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