

15.10 LABORATORY SERVICES

Policy: Montana Title X clinics must maintain quality laboratory services that are in compliance with the Clinical Laboratory Improvements Amendments of 1988 (CLIA), the Occupational Safety and Health Administration (OSHA) rules, in particular, the rules on Occupational Exposure to Bloodborne Pathogens, the Board of Clinical Laboratory Science Practitioners rules and regulations, Title X Program Requirements, QFP and applicable state laws. These laws, rules and regulations include issues of safety, equipment, personnel, and quality assurance.

Websites for the references mentioned above are located at the end of this policy.

Procedure:

1. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method and may be provided for the maintenance of health status and/or diagnostic purposes either on-site or by referral:

On-Site laboratory tests include, but are not limited to:

- a. Anemia assessment – microhematocrits, hemocue
- b. Urine pregnancy tests
- c. Vaginal wet mounts
- d. Urinalysis
 - i. Dip stick
 - ii. Microscopic analysis
 - iii. Culture, as indicated
- e. HIV rapid test
- f. Hepatitis C rapid test

Off-site laboratory tests include but are not limited to:

- a. Pap tests
- b. Sexually transmitted infection (STI) screening
 - i. Chlamydia (CT)
 - ii. Gonorrhea (GC)
 - iii. Hepatitis B
 - iv. Hepatitis C
 - v. Syphilis
 - vi. Herpes Simplex Virus (HSV)
 - vii. Human immunodeficiency virus (HIV)
- c. Serum pregnancy tests
- d. Urine cultures
- e. Rubella titer
- f. Cholesterol screening
 - a. Recommended for females over 20 years of age
 - b. Strongly recommended for clients who are/have:
 - i. Age over 35
 - ii. Personal history of elevated cholesterol
 - iii. Family history of death of parent or sibling from myocardial infarction under the age of 50
 - iv. Family history of hyperlipidemia
- g. Diabetes screening

2. All clients must be contacted, treated and/or referred for continuing care when their laboratory tests show abnormal findings (e.g. positive tests for GC or syphilis, persistent vaginitis not responding to usual out-patient therapy, abnormal cytology, persistent anemia or negative rubella titer).
3. There must be a site-specific procedure for client notification and follow-up of abnormal lab results.
4. Procedures for the collection and the performance of laboratory tests on site should be written and maintained in a local procedure manual. The test descriptions in the manual should include the following information:
 - a. Name of the test
 - b. Name of the kit or product used
 - c. Background or principles of the test
 - d. The required test materials
 - e. How to prepare and store reagents, standards and controls
 - f. How to prepare equipment for use
 - g. Specimens--collection and storage
 - h. The actual test steps
 - i. Any necessary calculations
 - j. Special requirements
 - k. Test interpretations
 - l. Quality assurance procedures
 - m. Sources of error
 - n. References

Test kits frequently include instructions that may be used for written procedures (e.g., pregnancy tests).

5. To submit laboratory tests to the Montana Public Health Laboratory (MTPHL), follow these procedures:
 - a. Laboratory tests available through the MTPHL include the following:
 - i. Venereal Disease Research Laboratory (VDRL) and Treponemal pallidum particle agglutination assay (TP-PA)
 - ii. Gonorrhea culture and Nucleic acid amplification testing (NAAT) testing
 - iii. Herpes culture, Polymerase chain reaction (PCR) and serology
 - iv. Chlamydia culture and NAAT testing
 - v. Rubella antibody screen
 - vi. HIV, Multisport confirmation, Nucleic Acid Testing (NAT), if indicated
 - b. The MTPHL provides a standard form for submission of laboratory tests. The appropriate form must accompany each test submitted. The lab will provide the forms, preprinted with the account number to ensure proper billing. To request copies of the standard form, please contact the MTPHL at 444-3444.
 - c. Refer to the [Montana Laboratory Services Manual](#) (Directory of Services) published on-line by the MTPHL for further information:
<http://dphhs.mt.gov/publichealth/LaboratoryServices/PublicHealthLabTesting>.

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 lots 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](http://wwwn.cdc.gov/clia/default.aspx) website (<http://wwwn.cdc.gov/clia/default.aspx>) and a [CLIA Waived Tests website](http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx) (<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 [Centers for Medicare & Medicaid Services CLIA website](http://www.cms.hhs.gov/clia) at www.cms.hhs.gov/clia.

The Montana CLIA contact information is as follows:

Division of Quality Assurance
Department of Public Health and Human Services
2401 Colonial Drive, 2nd floor
PO Box 202953
Helena, MT 59620-2953
Phone: 406-444-2099
Fax: 406-444-3456

References:

1. [Clinical Laboratory Improvement Amendments \(CLIA\)](http://www.cms.hhs.gov/clia): www.cms.hhs.gov/clia
2. Occupational Safety and Health Act (OSHA) - [Occupational Exposure to Bloodborne pathogens](http://www.osha.gov/SLTC/bloodborne pathogens/index.html):
<http://www.osha.gov/SLTC/bloodborne pathogens/index.html>
3. [Board of Clinical Laboratory Science Practitioners](http://bsd.dli.mt.gov/license/bsd_boards/cls_board/board_page.asp):
http://bsd.dli.mt.gov/license/bsd_boards/cls_board/board_page.asp