

8.15.1 LABORATORY SERVICES

Policy: Montana Title X clinic's laboratory services must be 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.
6. Refer to the Laboratory Services Manual (Directory of Services) published on-line by the MTPHL for further information:
<http://dphhs.mt.gov/publichealth/LaboratoryServices/PublicHealthLabTesting>.

References:

Clinical Laboratory Improvement Amendments (CLIA):

www.cms.hhs.gov/clia

Occupational Safety and Health Act (OSHA): Occupational Exposure to Bloodborne pathogens -

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

Board of Clinical Laboratory Science Practitioners:

http://bsd.dli.mt.gov/license/bsd_boards/cls_board/board_page.asp