# Policy and Procedure

# McMinnville Free Clinic

## LABORATORY TESTING

BOARD APPROVAL 8/1/16
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INITIALLY APPROVED: 4/1/13

**Policy**

McMinnville Free Clinic performs clinical laboratory testing under the Clinical Laboratory Improvement Amendments (CLIA). We operate under a CLIA Certificate of Waiver. Only testing that has been designated as CLIA Waived can be performed in the clinic. This policy outlines the quality management plan for performing laboratory tests.

**Organization and Procedures**

McMinnville Free Clinic is committed to quality laboratory testing. The laboratory is under the direction of the clinic medical director. The clinic utilizes volunteers to provide laboratory testing to patients. Oversight of the Laboratory Quality Management Plan is assigned to the QA Committee.

Laboratory policies are reviewed on a regular schedule, along with other clinic policies. The laboratory uses current product inserts provided with each test kit. Product inserts serve as procedures for specimen collection and test performance.

1. Facilities and Safety: The laboratory operates as part of the triage area of the clinic. Volunteers are trained about the clinic facilities and safety before they begin working. Volunteer training covers biohazard training and the chemical hazard plan.

2. Personnel: Laboratory testing personnel must meet the minimum requirements and qualifications as set forth in CLIA. A high school diploma (or equivalent) is required for volunteers who perform laboratory testing.

3. Assessments: Prior to performing testing, volunteers are trained, and competency is assessed and documented. Competency to perform testing is assessed by verbal exam and direct

observation of patient testing. Either performing quality control or performing initial patient testing under direct observation is an effective way to assess volunteer competency. Records of competency assessment are maintained in the volunteers file. Volunteers that do not routinely perform laboratory testing or have industry experience should train alongside of an experienced volunteer for at least one clinic prior to performing laboratory testing without observation.

4. Purchasing and Inventory: When inventory of lab items runs low, the designated lab personnel will notify the clinic coordinator, who is responsible for making sure supplies are ordered.

5. Quality Control: External quality control uses known samples or reagents to test kits in a manner that is similar to patient testing. External controls are used to verify that tests and test kits are performing according to manufacturers' specifications. A separate positive and negative external quality control will be performed on kits at box opening or if there are concerns about temperature at storage area (eg. extremely hot or cold temperatures).

   Many kits contain internal quality control monitors to ensure that the kit is operating correctly with each patient test. Internal controls ensure that an adequate quantity of sample was used and that other variables perform correctly. When applicable, internal controls are monitored each time that the test is performed.

   If quality control testing does not perform as expected, test results are invalid. For external quality control, testing can be repeated on another test from the same lot. If after two attempts quality control does not perform as expected, the test kits should be discarded, and a new box or lot should be tested. If the internal control fails, patient results are not valid, and testing should be repeated.

6. Procedures: Each test kit comes with a package insert and manufacturer's instructions for specimen collection and performing the test. Prior to performing patient testing, volunteers should be familiar or review the package insert. Package inserts are used as the procedure for each individual test.

7. Documents and Records: Laboratory records should be kept whenever patient testing is performed. Records should allow for traceability and identify that the laboratory quality management plan was followed when patient testing occurs. Records must identify the test, including kit and lot identification information for each test performed. A laboratory log book will be maintained that will allow for the collection of this information.

Laboratory records are reviewed by the QA committee or designee on an ongoing basis. Records must be retained for at least 2 years.

8. Information Management: The triage record is the primary source of communication between the provider and the laboratory. The triage record will be used to identify testing that needs to be performed. Patient results are recorded directly on the clinic triage record. The triage record is then maintained in the patient chart.

9. Nonconforming Event Management and Continuous Improvement: As part of the laboratory log, volunteers can record issues or concerns from the clinic day. Nonconforming events, or deviations from established practice, are documented on the log. Prior to beginning testing, volunteers should review the notes from the log. In this manner, communication can be passed from clinic to clinic. Notes from the log are reviewed by the QA committee to determine significant trends for improvement.