

641—11.25(141) Laboratory procedures and procedure manual requirements.

11.25(1) All laboratories shall have written procedures and a procedure manual which encompasses all current aspects of the HIV testing process including, but not limited to:

- a.* Specimen acquisition.
- b.* Specimen and report security.
- c.* Test performance.
- d.* Reporting of results.
- e.* Confirmation of positive test results.
- f.* Confidentiality.

11.25(2) Procedure manuals shall be readily available for review during any on-site inspection.

11.25(3) Positive and negative controls shall be used each time a test is performed.

11.25(4) Laboratories shall develop criteria for the rejection of specimens.