**Section 490.750 Laboratory Testing**

All laboratory testing shall be performed on a pilot sample specimen of blood taken from the donor at the time of collection of the unit of blood and before the blood or blood components leave the blood bank. The required tests are listed below.

a) Testing for syphilis, blood grouping, Rh factors, and hepatitis B surface antigen shall be performed in accordance with FDA standards (21 CFR 610.40 and 640.5)(1987). Testing for HTLV-1 shall be performed, using a test licensed by the FDA, in accordance with the instructions accompanying the test kit. Blood or blood components intended for transfusion purposes, shall not leave the blood bank unless the tests for HTLV-1, syphilis and hepatitis B surface antigen are negative, unless, an exception is made in accordance with FDA standards (21 CFR 606.121 and 640.2)(1987). The test for HTLV-1 shall be included in the exceptions made in accordance with these FDA standards.

b) HIV Testing

1) All donor blood shall be tested for evidence of infection with the HIV virus by using a test approved by the United States Food and Drug Administration (FDA) (e.g. an enzyme-linked immunosorbent assay (ELISA)). A unit of blood which is found to be reactive by two of three ELISA tests (according to the package insert – product circular) shall not be used for transfusion or for production of components for transfusion or injection and shall be disposed of in accordance with Section 490.330 of this Part. All units of blood which are found to be reactive shall be retested using a confirmatory test approved by FDA or the Department (e.g. Western blot assay or indirect Fluorescent Antibody tests).

2) In the event that blood is transfused before completion of the tests for evidence of HIV infection and if the tests are subsequently confirmed positive, the recipient's physician must be notified within 24 hours either verbally or in writing, by the medical director of the blood bank or the blood bank director or his designate.

3) A donor whose blood has yielded a positive confirmatory result (e.g. Western blot assay or Indirect Fluorescent Antibody tests) shall be notified of that test result in accordance with the following requirements in subsection (b)(4) of this Section.

4) Notification Requirements:

A) The donor shall be advised to contact the blood bank for an appointment to discuss the results of the tests. If initial notification is made by mail, the correspondence must be general in nature (e.g. no references to specific diseases or test procedures shall be made). If the donor does not respond to the initial notification by mail, or if the blood bank chooses not to use such initial notification procedures, the donor shall be advised through certified mail with restricted delivery, messenger or personal visit to contact the blood bank for an appointment to discuss the test results.

B) the medical director of the blood bank or the medical director's designee who is knowledgeable about HIV infection including the possible medical and psychosocial aspects of such infection shall be available for a scheduled appointment with the donor at the earliest possible date requested by the donor and shall present and explain the results of HIV testing only in a person to person interview.

C) If the donor has not contacted the blood bank for an appointment as described in subsection (b)(4)(A) of this Section above or if the donor has failed to follow through with the scheduled appointment, the confirmed test result(s) shall be sent to the donor by certified mail with restricted delivery, messenger or personal visit accompanied by explanatory and referral information which has been provided by the Department;

D) The above-described available test results shall be released to the donor or the donor's physician no later than 55 days after the date of donation;

E) If the donor expressly so requested in writing and provides the name and address of his or her physician, the results shall be sent to the physician by certified mail;

F) HIV test results shall be treated as confidential and shall be disclosed as authorized in writing by the donor or as otherwise authorized by the AIDS Confidentiality and Testing Code, 77 Ill. Adm. Code 697.140.

c) Western Blot Assay Testing Procedure

All laboratories which conduct the Western blot assay shall comply with following requirements.

1) Western blot assay Testing Procedures

A) Western blot assay kits licensed by the United States Food and Drug Administration (FDA) shall be performed on specimens which have been found to be repeatably reactive using the enzyme-linked immunosorbent assay (ELISA) test. The laboratory shall perform a Western blot assay test to determine reactivity with viral polypeptides in accordance with manufacturer's recommendations or package insert.

B) When a Western blot assay kit that is not licensed by the FDA is utilized, the testing procedure must be able to demonstrate and reproduce in a second demonstration at least the viral polypeptides in accordance with recommendations of the Centers for Disease Control, Association of State and Territorial Public Health Laboratory Directors, or American Association of Blood Banks.

C) Western blots must have clear backgrounds and lack non-specific banding; and all banding should be distinct and uniform as well as reproducible.

D) The final blots of non-licensed kits must be examined to determine if the antibodies reacted specifically with HIV polypeptides. Western blot interpretations shall be consistent with the manufacturer's recommendations or package insert.

2) Laboratory Certification and Quality Control

A) The laboratory prior to using any given lot of a non-licensed Western blot kit, shall test all lot material with control sera consisting of negative (no reaction), weakly positive (some reaction but not strong), and positive (strong, very noticeable reaction) sera. The laboratory shall ensure that the reagent lots are correctly identified with the above control sera. Any and all reagents not meeting the laboratory's specified criteria established in accordance with the quality control system methodologies in Subpart K of the Illinois Clinical Laboratory Code (77 Ill. Adm. Code 450 Subpart K) shall not be utilized for testing.

B) The laboratory shall maintain internal viral Western blot quality control for all Western blot assays. All internal Western blot quality control results shall be maintained by the laboratory for review by the Department.

C) The laboratory shall participate in at least one proficiency testing program for ELISA and Western Blot screening and supplemental testing for viral antibodies offered by the College of American Pathologists, the American Association of Bioanalysts, or the Department. A copy of all proficiency testing evaluation reports shall be made available for review by the Department.

d) Records – Quality Control

1) Records shall be maintained concurrently with performance of each laboratory procedure so steps can be clearly traced.

2) All pilot samples shall be stored at 1 to 6 degrees Centigrade for at least seven days after transfusion or expiration date of the blood. When the blood is discarded the pilot tube need not be saved.

3) Equipment

The temperature of water baths, heating blocks, Rh view boxes and incubators shall be checked daily to determine that the temperature meets the requirements set forth in the procedure manual (See 77 Ill. Adm. Code 450, Subpart J). Centrifuges used for serologic testing and for separation of blood components shall be calibrated to determine optimum time and force. (See Subpart E of this Part).

4) Quality Control

All laboratory procedures performed in the blood bank shall meet all applicable requirements of 77 Ill. Adm. Code 450, Subpart K.