**Section 460.140 Donors and Donor Blood/Identification of Donor Blood**

a) Routine Labeling

The following information shall appear in clear, readable letters on a label firmly attached to the container:

1) Name of component

2) The amount of blood and the kind and amount of anticoagulant

3) The serological test used for syphilis and the result.

4) The required storage temperature

5) The identification number

6) The expiration date

7) The ABO and Rh types in conspicuous lettering. Subsections (b) and (c) of this Section shall be followed.

8) The results of tests for significant unexpected antibodies (see subsection (d) of this Section).

9) The nonreactive results of an FDA approved test for Hepatitis B antigen.

10) The name and address of the facility which conducted the tests.

11) The following instructions and cautions:

A) The requirement for administration only to recipients who have been demonstrated capatible by crossmatch.

B) The need for a filter.

C) No medication shall be added to the blood prior to or during a transfusion.

D) A statement of the possible presence of the agent of viral hepatitis (see Section 450.830 (c)(10)(A))

E) Federal law prohibits dispensing without a prescription.

F) Mix thoroughly before transfusion.

G) Do not vent plastic containers.

b) Determination of ABO type

ABO type shall be determined by testing the red blood cells with anti/A and anti/B serums which meet United States Food and Drug Administration (FDA) standards (21 CFR 600-680)(1986), and by testing the serum or plasma for expected antibodies with a pool of known type A (or single subtype A 1 ) and known type B cells. The blood shall not be released unless the tests are in agreement.

c) Routine determination of Rh type

The Rh type shall be determined with anti/Rh o (D) typing serum which meets FDA standards (21 CFR 600-680)(1986). If the blood is typed as Rh o (D) negative, it shall be tested using a technique designed to detect Rh o variants (D u). Routine testing for additional blood types is not recommended. The label shall indicate:

1) Rh positive when the red cells are reactive for Rh o (D) or Rh o variants (D u).

2) Rh negative when the red cells are nonreactive for Rh o (D) and Rh o variants (D u).

d) Test for detecting antibodies

1) All donor blood shall be tested for both expected and unexpected antibodies. This shall be done with Reagent Red Blood Cells that meet FDA standards (21 CFR 600-680)(1986), and are intended for this use.

2) Methods of testing for unexpected antibodies shall be those that will demonstrate hemolyzing, agglutinating, and coating antibodies.

3) Blood in which significant unexpected antibodies have been detected should not be used unless transfused as Red Blood cells. (see Section 450.848(b))

e) HIV Testing

1) All donor blood shall be tested for evidence of infection with HIV 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 or 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. 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.

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 Section 450.840 (e)(4).

4) Notification Requirements:

A) The donor shall be advised to contact the facility which conducted the testing for an appointment to discuss the results of the tests. If initial notification is made by mail, the correspondance 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 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 facility which conducted the testing for an appointment to discuss the test results.

B) The medical director of the facility which conducted the testing 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 facility which conducted the testing for an appointment as described in Section 450.840 (e)(4)(A) above or if the donor has failed to follow through with the scheduled appointment, the confirmed test results(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 or equivalent information;

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.

f) Serological test for syphilis

An FDA approved serological test for syphilis shall be made on a specimen of the blood (21 CFR 600-680)(1986). The blood shall not be used for transfusion unless the test is negative. Blood may be issued in an emergency situation without performing a serological test for syphilis provided the label and the records so indicate. An emergency situation is one which requires the transfusion of blood in order to preserve life prior to the completion of the required tests. If the test is subsequently positive, the recipient's physician shall be notified.

g) Test for Hepatitis B antigen (HB Ag)

All donor blood shall be tested for HB Ag using reagents and technics specified by FDA (21 CFR 600-680)(1986). The unit of whole blood or blood component shall not be used for transfusion unless the test is nonreactive. In an emergency, blood may be transfused before completion of the test for Hepatitis B antigen. An emergency situation is one which requires the transfusion of blood in order to preserve life prior to the completion of the required tests. If the test is subsequently positive, the recipient's physician shall be notified. The medical director shall be responsible for notification of the donor and/or the donor's physician of a positive test for Hepatitis B antigen.

h) Repeat testing

Determination of the ABO and Rh types shall be repeated whenever the facility performing the compatibility test is not affiliated with the collecting facility. Discrepancies shall be resolved before issue of the blood for transfusion purposes. The other tests required by this section do not have to be repeated.

i) Previous records

A donor's previous record of ABO and Rh types shall not serve for identification of units of blood subsequently given by the same donor; new determinations shall be made for each collection.

j) Retention of blood samples

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.

k) Laboratory records

The actual results observed with each test as well as the final interpretation shall be recorded.

l) Control of serologic testing

1) Equipment

The temperature of water baths, heating blocks, Rh view boxes and incubators should be checked daily. Centrifuges used for serologic testing and for separation of blood components shall be calibrated periodically to determine optimum time and force required to produce desired results. (See Subpart E of this Part).

2) Reagents

All antisera and test cells of each lot of each shipment shall be evaluated periodically to demonstrate their capacity to detect the corresponding antigens and antibodies. (See Subpart K of this Part).

(Source: Amended at 12 Ill. Reg. 9998. effective May 27, 1988)