

issued or reissued except as provided in § 640.2(e)(2) and all pilot samples shall be from the donor who is the source of the unit of blood.

(2) All samples for laboratory tests performed by the manufacturer and all pilot samples accompanying a unit of blood shall be collected at the time of filling the final container by the person who collects the unit of blood.

(3) All containers for all samples shall bear the donor's identification before collecting the samples.

(4) All containers for pilot samples accompanying a unit of blood shall be attached to the whole blood container before blood collection, in a tamperproof manner that will conspicuously indicate removal and reattachment.

(5) When CPDA-1 is used, pilot samples for compatibility testing shall contain blood mixed with CPDA-1.

(h) *Phlebotomy for Heparin Whole Blood.* Heparin Whole Blood shall be collected with minimal damage to and minimal manipulation of the donor's tissue, and with a single, uninterrupted, free-flowing venipuncture.

(i) *Storage.* Immediately after collection, unless the blood is to be used as a source for Platelets, it shall be placed in storage at a temperature between 1 and 6 °C unless it must be transported from the donor clinic to the processing laboratory. In the latter case, the blood shall be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a range between 1 and 6 °C until it arrives at the processing laboratory, where it shall be stored at a temperature between 1 and 6 °C. Blood from which Platelets is to be prepared shall be held in an environment maintained at a temperature range 20 to 24 °C until the platelets are separated. The red blood cells shall be placed in storage at a temperature between 1 and 6 °C immediately after the platelets are separated.

[38 FR 32089, Nov. 20, 1973, as amended at 42 FR 59878, Nov. 22, 1977; 43 FR 34460, Aug. 4, 1978; 49 FR 23834, June 8, 1984; 50 FR 4138, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990]

§ 640.5 Testing the blood.

All laboratory tests shall be made on a pilot sample specimen of blood taken

from the donor at the time of collecting the unit of blood, and these tests shall include the following:

(a) *Serological test for syphilis.* Whole Blood shall be negative to a serological test for syphilis.

(b) *Determination of blood group.* Each container of Whole Blood shall be classified as to ABO blood group. At least two blood group tests shall be made and the unit shall not be issued until grouping tests by different methods or with different lots of antisera are in agreement. Only those Anti-A and Anti-B Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the serum is specifically designed to be effective.

(c) *Determination of the Rh factors.* Each container of Whole Blood shall be classified as to Rh type on the basis of tests done on the pilot sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-D Blood Grouping Reagent, is positive, the container may be labeled "Rh Positive". If this test is negative, the results shall be confirmed by further testing which may include tests for the Rh_o variant (D^u) and for other Rh-Hr factors. Blood may be labeled "Rh Negative" if negative to tests for the Rh_o (D) and Rh_o variant (D^u) factors. If the test using Anti-D Blood Grouping Reagent is negative, but not tested for the Rh_o variant (D^u), the label must indicate that this test was not done. Only Anti-Rh Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the serum is specifically designed to be effective.

(d) *Sterility test.* Whole Blood intended for transfusion shall not be tested for sterility by a method that entails entering the final container before the blood is used for transfusion.

(e) *Inspection.* Whole Blood shall be inspected visually during storage and immediately prior to issue. If the color or physical appearance is abnormal or there is any indication or suspicion of microbial contamination the unit of

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Whole Blood shall not be issued for transfusion.

(f) *Test for antibody to HIV.* Whole Blood shall be tested for antibody to HIV as prescribed in §610.45 of this chapter.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 53 FR 12764, Apr. 19, 1988]

§ 640.6 Modifications of Whole Blood.

Upon approval by the Director, Center for Biologics Evaluation and Research, of a supplement to the product license application for Whole Blood a manufacturer may prepare Whole Blood from which the antihemophilic factor has been removed, provided the Whole Blood meets the applicable requirements of this subchapter and the following conditions are met:

(a) The antihemophilic factor shall be removed in accordance with paragraphs (a), (b), and (c) of §640.52.

(b) Although the closed system between the red blood cells and plasma shall be maintained, the red blood cells shall be maintained between 1 and 6° C at all times, including that time when the plasma is being frozen for removal of the antihemophilic factor.

(c) If containers for pilot samples are detached from the blood container during removal of the antihemophilic factor the pilot samples shall be reattached to the unit of Whole Blood Cryoprecipitate Removed as soon as the plasma is returned to the red blood cells. The reattachment of the pilot samples shall be in a tamperproof manner that will conspicuously indicate removal and reattachment.

[38 FR 32089, Nov. 20, 1973, as amended at 49 FR 23834, June 8, 1984; 50 FR 4138, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994]

Subpart B—Red Blood Cells

§ 640.10 Red Blood Cells.

The proper name of this product shall be Red Blood Cells. The product is defined as red blood cells remaining after separating plasma from human blood.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985]

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§ 640.11 General requirements.

(a) *Storage.* Immediately after processing, the Red Blood Cells shall be placed in storage and maintained at a temperature between 1 and 6 °C.

(b) *Inspection.* The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue. The product shall not be issued if there is any abnormality in color or physical appearance or if there is any indication of microbial contamination.

[38 FR 32089, Nov. 20, 1973, as amended at 41 FR 18292, May 3, 1976; 42 FR 59878, Nov. 11, 1977; 50 FR 4139, Jan. 29, 1985]

§ 640.12 Suitability of donor.

The source blood for Red Blood Cells shall be obtained from a donor who meets the criteria for donor suitability prescribed in §640.3.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4139, Jan. 29, 1985]

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in §640.4, except that paragraphs (d)(2), and (g), and (h) shall not apply.

(b) Source blood may also be derived from Whole Blood manufactured in accordance with applicable provisions of this subchapter.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4139, Jan. 29, 1985]

§ 640.14 Testing the blood.

Blood from which Red Blood Cells are prepared shall be tested as prescribed in §§610.40 and 610.45 of this chapter and §640.5 (a), (b), and (c).

[53 FR 117, Jan. 5, 1988]

§ 640.15 Pilot samples.

Pilot samples collected in integral tubing or in separate pilot tubes shall meet the following standards:

(a) One or more pilot samples of either the original blood or of the Red Blood Cells being processed shall be provided with each unit of Red Blood Cells when issued or reissued.

(b) Before they are filled, all pilot sample tubes shall be marked or identified so as to relate them to the donor of that unit of red cells.