

issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in §640.5, the test for hepatitis B surface antigen prescribed in §610.40(a) of this chapter, and a test for antibody to Human Immunodeficiency Virus (HIV) prescribed in §610.45(a) of this chapter have been completed, where such issue is essential to allow time for transportation to ensure arrival of the blood by the time it is needed for transfusion: *Provided*, That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each container of such blood bears the information required by §606.121(h) of this chapter.

(Information collection requirements approved by the Office of Management and Budget under number 0910-0227)

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### §640.3 Suitability of donor.

(a) *Method of determining.* The suitability of a donor as a source of Whole Blood shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability. Such determination shall be made on the day of collection from the donor by means of medical history, a test for hemoglobin level, and such physical examination as appears necessary to a physician who shall be present on the premises when examinations are made, except that the suitability of donors may be determined when a physician is not present on the premises, provided the establishment (1) maintains on the premises, and files with the Center for Biologics Evaluation and Research, a manual of standard procedures and methods, approved by the Director of the Center for Biologics Evaluation and Research, that shall be followed by employees who determine suitability of donors, and (2) maintains records indicating the name and qualifications of the person immediately in charge of the employees who

determine the suitability of donors when a physician is not present on the premises.

(b) *Qualifications of donor; general.* Except as provided in paragraph (f), a person may not serve as a source of Whole Blood more than once in 8 weeks. In addition, donors shall be in good health, as indicated in part by:

- (1) Normal temperature;
- (2) Demonstration that systolic and diastolic blood pressures are within normal limits, unless the examining physician is satisfied that an individual with blood pressures outside these limits is an otherwise qualified donor under the provisions of this section;
- (3) A blood hemoglobin level which shall be demonstrated to be no less than 12.5 gm. of hemoglobin per 100 ml. of blood;
- (4) Freedom from acute respiratory diseases;
- (5) Freedom from any infectious skin disease at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the blood;
- (6) Freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations indicated above; and
- (7) Freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics.

(c) *Additional qualifications of donor; viral hepatitis.* No individual shall be used as a source of Whole Blood if he has—

- (1) A history of viral hepatitis;
- (2) A history of close contact within six months of donation with an individual having viral hepatitis;
- (3) A history of having received within six months human blood, or any derivative of human blood which the Food and Drug Administration has advised the licensed establishment is a possible source of viral hepatitis.

(d) *Therapeutic bleedings.* Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section, shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood.

(e) *Immunized donors.* Blood withdrawn from donors known to have been

§ 640.4

immunized to human blood cell antigens shall not be used for Whole Blood unless the container label conspicuously indicates such information.

(f) *Qualifications; donations within less than 8 weeks.* A person may serve as a source of Whole Blood more than once in 8 weeks only if at the time of donation the person is examined and certified by a physician to be in good health, as indicated in part in paragraph (b) of this section.

[38 FR 32089, Nov. 20, 1973, as amended at 49 FR 23834, June 8, 1984; 50 FR 4138, Jan. 29, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11013, Mar. 26, 1990]

**§ 640.4 Collection of the blood.**

(a) *Supervision.* Blood shall be drawn from the donor by a qualified physician or under his supervision by assistants trained in the procedure. A physician shall be present on the premises when blood is being collected, except that blood may be collected when a physician is not present on the premises, provided the establishment (1) maintains on the premises, and files with the Center for Biologics Evaluation and Research, a manual of standard procedures and methods, approved by the Director of the Center for Biologics Evaluation and Research, that shall be followed by employees who collect blood, and (2) maintains records indicating the name and qualifications of the person immediately in charge of the employees who collect blood when a physician is not present on the premises.

(b) *The donor clinic.* The pertinent requirements of §§ 600.10 and 600.11 of this chapter shall apply at both the licensed establishment and at any other place where the bleeding is performed.

(c) *Blood containers.* Blood containers and donor sets shall be pyrogen-free, sterile and identified by lot number. The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized. In addition, all container and donor set surfaces that come in contact with blood used in the processing of Heparin Whole Blood shall be water repellent.

(d) *The anticoagulant solution.* The anticoagulant solution shall be sterile and pyrogen-free. One of the following

21 CFR Ch. I (4-1-98 Edition)

formulae shall be used in the indicated volumes:

(1) *Anticoagulant citrate dextrose solution (ACD).*

	Solution A	Solution B
Tri-sodium citrate (Na <sub>3</sub> C <sub>6</sub> H <sub>5</sub> O <sub>7</sub> ·2H <sub>2</sub> O) .....	22.0 gm ...	13.2 gm.
Citric acid (C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ·H <sub>2</sub> O) .....	8.0 gm .....	4.8 gm.
Dextrose (C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> ·H <sub>2</sub> O) .....	24.5 gm ...	14.7 gm.
Water for injection (U.S.P.) to make.	1,000 ml ..	1,000 ml.
Volume per 100 ml. blood .....	15 ml .....	25 ml.

(2) *Anticoagulant heparin solution.*

Heparin sodium (U.S.P.) .....	75,000 units.
Sodium chloride injection (U.S.P.) to make.	1,000 ml.
Volume per 100 ml. blood .....	6 ml.

A buffer to maintain stability shall be added, if necessary.

(3) *Anticoagulant citrate phosphate dextrose solution (CPD).*

Tri-sodium citrate (Na <sub>3</sub> C <sub>6</sub> H <sub>5</sub> O <sub>7</sub> ·2H <sub>2</sub> O) ..	26.3 gm.
Citric acid (C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ·H <sub>2</sub> O) .....	3.27 gm.
Dextrose (C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> ·H <sub>2</sub> O) .....	25.5 gm.
Monobasic sodium phosphate (NaH <sub>2</sub> PO <sub>4</sub> ·H <sub>2</sub> O).	2.22 gm.
Water for injection (U.S.P.) to make	1,000 ml.
Volume per 100 ml. blood .....	14 ml.

(4) *Anticoagulant citrate phosphate dextrose adenine solution (CPDA-1).*

Tri-sodium citrate (Na <sub>3</sub> C <sub>6</sub> H <sub>5</sub> O <sub>7</sub> ·2H <sub>2</sub> O) ..	26.3 gm.
Citric acid (C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ·H <sub>2</sub> O) .....	3.27 gm.
Dextrose (C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> ·H <sub>2</sub> O) .....	31.9 gm.
Monobasic sodium phosphate (NaH <sub>2</sub> PO <sub>4</sub> ·H <sub>2</sub> O).	2.22 gm.
Adenine (C <sub>5</sub> H <sub>5</sub> N <sub>5</sub> ) .....	0.275 gm.
Water for injection (U.S.P.) to make	1,000 ml.
Volume per 100 ml blood .....	14 ml.

(e) *Donor identification.* Each unit of blood shall be so marked or identified by number or other symbol as to relate it to the individual donor whose identity shall be established to the extent necessary for compliance with § 640.3.

(f) *Prevention of contamination of the blood.* The skin of the donor at the site of phlebotomy shall be prepared thoroughly and carefully by a method that gives maximum assurance of a sterile container of blood. The blood shall be collected by aseptic methods in a sterile system which may be closed or may be vented if the vent protects the blood against contamination.

(g) *Pilot samples for laboratory tests.* Pilot samples for laboratory tests shall meet the following standards:

(1) One or more pilot samples shall be provided with each unit of blood when