

THE COLLECTION, PROCESSING, AND STORAGE OF CITRATED WHOLE BLOOD,
BLOOD PLASMA, AND RELATED PRODUCTS

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Each blood bank must be manned by adequately trained personnel, under the direction of a physician, preferably a pathologist or a physician trained in blood bank techniques. All technical procedures must be carried out in conformity with accepted technique as set forth in the most recent revisions of the National Institute of Health Publications; MINIMUM REQUIREMENTS: Citrated Whole Blood (Human) (1st Revision, February 25, 1948) and MINIMUM REQUIREMENTS: Normal Human Plasma (7th Revision, May 15, 1950) or other established published procedures. This shall apply to the selection of donors; the collection of blood; the preparation of rubber tubing, glassware, and fluids to insure a pyrogen free product; culturing for sterility; methods of preparation, bottling, and storage of the final product.

The following shall be considered by the Arkansas State Board of Health as minimum requirements for the operation of a blood bank, the details of procedure to be carried out as stipulated in accordance with accepted technique.

Section I. Collection of Blood

A. The bleeding must be done in an adequately equipped blood donor room under the immediate supervision of a qualified doctor of medicine, assisted by the necessary trained personnel.

B. Only those persons may serve as a source for citrated whole blood or plasma who are certified by a qualified doctor of medicine as being free of disease transmissible by blood transfusion (particularly malaria, other protozoan diseases, syphilis, infectious hepatitis within six months, and acute upper respiratory disease) as far as can be determined from the donor's personal history and from such physical examinations and clinical tests as appear necessary for each donor on the day upon which blood is obtained from the individual. The blood donor must be in such physical condition that the taking of the desired amount of blood will not endanger his health. The donor should have not less than 12.5 grams of hemoglobin per 100 ml. of blood (Sp. Gravity of 1.053 or greater by the copper sulphate technique).

C. An acceptable serological test for syphilis shall be made in a qualified laboratory on a specimen of blood taken at the time of bleeding. Serologically positive blood shall be so labeled but it is safe to use and blood containing spirochetes is safe to administer after 96 hours storage at 4° to 6° C. Serologically positive blood will transfer a passive reagent to the recipient's blood which can be detected for 21 days after administration.

D. The method employed for the removal of blood from the donor shall conform to the accepted standards of aseptic surgery and shall be made in a closed system. (A closed system is defined as an apparatus which will permit nothing to be drawn into the system at any point except the liquid under transfer and the air required for replacement when negative or positive pressure is applied at the proper place. All air for replacement must first pass through a suitable anti-bacterial filter.) The anticoagulant shall be a pyrogen free ACD Solution with the formula specified by the National Institute of Health for 21 day storage of blood, or another formula possessing no less anticoagulant and red-cell preserving properties. Solutions should be tested for pyrogens by standard methods.

E. All glassware coming in contact with the blood or plasma must be clear glass and of good quality (preferably high quality ampoule glass). All rubber stoppers must be of high grade, "Sulphur free," nonoxidizing rubber, suitable for stoppering biological products having a high protein content. Each piece of equipment coming in contact with blood or plasma must have been made scrupulously clean by washing in suitable cleaning solutions followed by adequate rinsing with pyrogen free distilled water or physiological solution of sodium chloride. All exposed parts must be adequately covered by suitable wrappings or inserted into stoppered test tubes. All equipment coming in contact with the blood or plasma must have been sterilized in the autoclave at 121.5° C. (15 pounds pressure for at least 20 minutes) i.e., each part of the material to be sterilized must attain this temperature for at least the full 20 minutes.

Section II. Storage, Typing, And Administration of Whole Blood

A. Blood shall be stored at temperatures between 4° and 10° C., preferably at 4° to 6° C. for a period not to exceed 21 days. Tests for sterility other than gross inspection are not desirable on whole blood.

B. Two sterile, stoppered pilot tubes (Wassermann) shall be attached to each bottle. Blood remaining in the tubing at the expiration of the bleeding of each donor shall be divided between these tubes. One will be used for serologic tests. The other will be used for blood typing. Grouping by the ABC system (preferably by two methods) and Rh typing (for at least the D antigen) will be done and the results recorded legibly on the bottle label. Accepted techniques with appropriate controls for grouping, typing and cross-matching will be used.

C. Blood will be administered only on the order and under the supervision of a qualified doctor of medicine. Except in extreme emergency, compatibility will be determined by cross-matching before administration. Blood which has been frozen or allowed to stand at room temperature or which is obviously hemolyzed or contaminated will be discarded.

Section III. Preparation of Plasma

A. The requirements noted in Section I A, B, C, D, E, and Section II A will be observed in preparing plasma.

B. Plasma may be separated from freshly drawn blood by centrifugation. Blood which has stood in the refrigerator may be used to prepare plasma provided it is not excessively hemolyzed. The

period of refrigeration should not exceed 28 days. A plasma hemoglobin content of less than 50 mg. per cent is considered safe. After several days refrigeration it is better not to mix the blood since the cells do not centrifuge out well but to draw off the plasma separated by sedimentation.

C. If a preservative is to be added it should be added after the aspiration of the sample for the sterility test. In general it is not necessary or advisable to add a bacteriostatic agent. It is better to follow a strictly aseptic technique.

D. In order to dilute high titer antibodies it is desirable to pool plasma from 8 to 10 units of blood into sterile 2000 ml. pool bottles containing 50 ml. of sterile 50% dextrose. The dextrose lessens fibrin formation. Sterility tests are made on the pooled plasma as noted in the next section.

Section IV. Testing For Sterility

A. The pool must stand at room temperature for 24 hours before sterility tests are made.

B. The medium for sterility tests shall be a medium designated as "Fluid Thioglycollate Medium" prepared by a recognized standard formula.

C. Forty cc. of plasma shall be withdrawn from each pool for sterility tests.

D. Ten cc. of plasma shall be inoculated into each of four tubes containing the thioglycollate medium in amounts of at least 20 cc. of medium per tube.

E. These control cultures shall be held for 10 days, two tubes at room temperature and two tubes in the incubator at 37° c.

F. If any sterility tests are made after a preservative has been added, the dilution of the plasma in the culture medium shall be such that the preservative contained in the plasma will no longer prevent bacterial growth.

G. If no growth occurs in the control tubes within 10 days, the pool may be released for distribution into the final containers.

Section V. Filling the Final Containers

Filling the final containers must be done through a closed system into accepted sterile containers.

Section VI. Frozen Plasma

A. The final containers must be frozen in a special freezing cabinet at a temperature range of minus 15-20° C.

B. Frozen plasma must be stored in the frozen state.

C. Frozen plasma must be thawed in a water bath at 37° C. to prevent excess fibrin formation and then treated as liquid plasma.

Section VII. Dried Plasma

A. Drying of plasma shall be accomplished by a method which is not deleterious to the plasma constituents and which will result in a readily soluble and sterile product.

B. Pyrogen free distilled water in proper amount for dilution shall be provided as a diluent.

Section VIII. Liquid Plasma

A. If the plasma is kept in the liquid state it may be stored at room temperature.

B. The expiration date must be given on the label.

Section IX. By-Products

Red cell suspensions or other by-products of the preparation of plasma must be prepared and distributed in conformity with National Institute of Health regulations.

Section X. Records and Directions for Use

A. Record must be kept of each pool of blood plasma, and pools must be properly labeled.

B. Explicit instructions must accompany each unit of plasma distributed, including directions explaining the necessity of administering all plasma through a suitable filter.

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