

Product	Temperature
Fresh Frozen Plasma	-25 °C or colder if expiration is 24 months or -18 to -25 °C if expiration is 3 months.
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Source Plasma	-15 °C or colder.
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PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

3. The authority citation for 21 CFR part 606 continues to read as follows:
Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.
4. Section 606.121 is revised to read as follows:

§ 606.121 Container label.

The container label requirements are designed to facilitate the use of a uniform container label for blood and blood components, including Source Plasma, by all blood establishments.

- (a) [Reserved]
- (b) The label provided by the collecting facility and the initial processing facility must not be removed, altered, or obscured, except that the label may be altered to indicate the proper name, with any appropriate modifiers and attributes, and other information required to identify accurately the contents of a container after blood components have been prepared.
- (c) The container label must include the following information, as well as other specialized information as required in this section for specific products:
- (1) The proper name of the product in a prominent position, with any appropriate modifiers and attributes;
- (2) The name, address, unique facility identifier, and, if a licensed product, the license number of each manufacturer;
- (3) The donor or lot number relating the unit to the donor. If pooled, all donor numbers, all donation numbers, or a pool number that is traceable to each individual unit comprising the pool;
- (4) The expiration date, including the day, month, and year, and, if the dating period for the product is 72 hours or less, including any product prepared in a system that might compromise sterility, the hour of expiration. If Source Plasma intended for manufacturing into noninjectable products is pooled, the expiration date is determined from the collection date of the oldest unit in the pool, and the

- pooling records must show the collection date for each unit in the pool.
- (5) For Whole Blood, Plasma, Platelets, and partial units of Red Blood Cells, the volume of the product, accurate to within ±10 percent; or optionally for Platelets, the volume range within reasonable limits.
- (6) Where applicable, the name and volume of source material.
- (7) The recommended storage temperature (in degrees Celsius).
- (8) If the product is intended for transfusion, the statements:
- (i) “Rx only.”
- (ii) “See Circular of Information for indications, contraindications, cautions, and methods of infusion.”
- (iii) “Properly identify intended recipient.”
- (iv) “This product may transmit infectious agents.”
- (v) The appropriate donor classification statement, i.e., “paid donor” or “volunteer donor,” in no less prominence than the proper name of the product.
- (A) A paid donor is a person who receives monetary payment for a blood donation.
- (B) A volunteer donor is a person who does not receive monetary payment for a blood donation.
- (C) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.
- (9) If the product is intended for transfusion or as is otherwise appropriate, the ABO group and Rh type of the donor must be designated conspicuously. For Cryoprecipitated Antihemophilic Factor (AHF), the Rh type may be omitted. The Rh type must be designated as follows:
- (i) If the test using Anti-D Blood Grouping Reagent is positive, the product must be labeled: “Rh positive.”
- (ii) If the test using Anti-D Blood Grouping Reagent is negative but the test for weak D (formerly Du) is positive, the product must be labeled: “Rh positive.”
- (iii) If the test using Anti-D Blood Grouping Reagent is negative and the test for weak D (formerly Du) is negative, the product must be labeled: “Rh negative.”

- (10) If the product is not intended for transfusion, a statement as applicable: “Caution: For Manufacturing Use Only,” or “Caution: For Use in Manufacturing Noninjectable Products Only,” or other cautionary statement as approved by the Director, Center for Biologics Evaluation and Research (CBER).
- (11) If the product is intended for further manufacturing use, a statement listing the names and results of all the tests for communicable disease agents for which the donation has been tested and found negative.
- (12) The blood and blood components must be labeled in accordance with § 610.40, when the donation is tested and demonstrates evidence of infection due to a communicable disease agent(s).
- (13) The container label may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research (HFB-1).
- (d) Unless otherwise approved by the Director, CBER, the container label must be white and print must be solid black, with the following additional exceptions:
- (1) The ABO and Rh blood groups must be printed as follows:
- (i) Rh positive: Use black print on white background and use solid black or other solid color for ABO.
- (ii) Rh negative: Use white print on black background for Rh and use black outline for ABO.
- (2) The proper name of the product, with any appropriate modifiers and attributes, the donor classification statement, and the statement “properly identify intended recipient” may be printed in solid red or in solid black.
- (3) The following color scheme may be used for differentiating ABO Blood groups:

Blood group	Color of label
O	Blue
A	Yellow
B	Pink
AB	White

(4) Special labels, such as those described in paragraphs (h) and (i) of this section, may be color coded.