

5.8 Testing of Donor Blood

5.8.1 Determination of ABO Group for All Collections

The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A1 and B reagent red cells.

5.8.2 Determination of Rh Type for All Collections

The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, the blood shall be tested using a method designed to detect weak D. When either test is positive, the label shall read "Rh POSITIVE." When the tests for both D and weak D are negative, the label shall read "Rh NEGATIVE."

5.8.3 Detection of Unexpected Antibodies to Red Cell Antigens for Allogeneic Donors

5.8.3.1 Serum or plasma from donors shall be tested for unexpected antibodies to red cell antigens.

5.8.3.2 Methods for testing shall be those that demonstrate clinically significant red cell antibodies.*

5.8.3.3 A control system appropriate to the method of testing shall be used. Standard 5.1.3 applies.

5.8.4 Red Blood Cell Antigens Other than ABO and RhD

Units may be labeled as antigen negative, without testing the current donation, if units from two previous separate donations were tested by the collection facility and found to be concordant.

5.8.5 Tests Intended to Prevent Disease Transmission by Allogeneic Donations

A sample of blood from each allogeneic donation shall be tested for HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, and syphilis by a serologic test. Each donor shall be tested at least once for antibodies to *Trypanosoma cruzi* (*T. cruzi*). Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative, except in the case of a test for syphilis that has been shown to have a

*21 CFR 606.151(d).