

## §610.41

## 21 CFR Ch. I (4-1-01 Edition)

### §610.41 History of hepatitis B surface antigen.

A person known to have previously tested positive for hepatitis B surface antigen, testing positive, or both, may not serve as a donor of human blood, plasma, or serum, except that under §640.120 of this chapter, such a donor may serve as a source of hepatitis B surface antigen for the manufacture of hepatitis B vaccine or the preparation of a diagnostic product for laboratory tests, or a person known to have previously tested positive for hepatitis B surface antigen may serve as a source of antibody to hepatitis B surface antigen for the preparation of a biological product or a diagnostic product for laboratory tests.

[48 FR 23182, May 24, 1983, as amended at 57 FR 10814, Mar. 31, 1992]

### §610.45 Human Immunodeficiency Virus (HIV) requirements.

(a) *Testing requirements.* (1) Each donation of human blood or blood components intended for use in preparing a product shall be tested for antibody to HIV by a test approved for such use by FDA, except as otherwise approved in writing by FDA. When the test for antibody to HIV is required, blood and blood products may be issued before the results of the test for antibody to HIV are available only in dire emergency situations or as otherwise approved in writing by FDA and, provided the test required by this paragraph is performed as soon as possible after issuance of the blood or blood product.

(2) Tests approved by FDA for the screening of blood and blood components for evidence of HIV may only be used in place of a test for antibody to HIV to satisfy the requirements of this section and related sections if so specified by FDA.

(b) *Testing responsibility.* The test for antibody to HIV shall be performed by the collection facility, by personnel of an establishment licensed to manufacture blood or blood derivatives under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or by a clinical laboratory which meets the standards of the Clinical Laboratory Improvement Act of 1967 (CLIA) (42 U.S.C. 263a), provided the establish-

ment or clinical laboratory is qualified to perform the test.

(c) *Restrictions on use.* (1) Blood, plasma, or other blood components that are repeatedly reactive to a test for antibody to HIV or that were collected from a donor whose blood is known to be repeatedly reactive to a test for antibody to HIV, shall not be shipped or used to prepare any product, including products not subject to licensure; except that such blood and blood components shall be shipped or used only for purposes and under conditions specifically approved in writing by FDA.

(2) The restrictions on use contained in this paragraph shall not apply in the following cases:

(i) Blood and blood components testing repeatedly reactive or from a donor whose blood is known to be repeatedly reactive that are shown to be negative for evidence of HIV infection by a method or process approved for such use by FDA;

(ii) The distribution of blood, plasma, or serum samples, except when intended for use in the manufacture of a product;

(iii) The in-house use of blood and blood components for research purposes; or

(iv) The distribution of blood and blood components for research purposes, if not distributed by sale, barter, or exchange.

(d) For a donor whose test results for antibody to HIV are repeatedly reactive or otherwise determined to be unsuitable when tested in accordance with paragraph (a) of this section, the blood establishment shall comply, as applicable, with §§610.46 and 610.47.

[53 FR 116, Jan. 5, 1988, as amended at 61 FR 47423, Sept. 9, 1996]

### §610.46 "Lookback" requirements.

(a) *Quarantine and notification.* (1) All blood and plasma establishments are required to take appropriate action when a donor of Whole Blood, blood components, Source Plasma and Source Leukocytes tests repeatedly reactive for antibody to human immunodeficiency virus (HIV), or otherwise is determined to be unsuitable when tested in accordance with §610.45. For Whole Blood, blood components, Source Plasma and Source Leukocytes