§ 610.46 Human immunodeficiency virus (HIV) “lookback” requirements.

(a) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and communicable disease agent(s) listed in §610.40(a) may serve as a donor for blood or blood components shipped or used under §610.40(h)(2)(ii);

(3) A deferred donor who showed evidence of infection due to hepatitis B surface antigen (HBsAg) when previously tested under §610.40(a), (b), and (e) subsequently may donate Source Plasma for use in the preparation of Hepatitis B Immune Globulin (Human) provided the current donation tests nonreactive for HBsAg and the donor is otherwise determined to be suitable;

(4) A deferred donor, who otherwise is determined to be suitable for donation and tests reactive for anti-HBc or for evidence of infection due to HTLV, types I and II, may serve as a donor of Source Plasma;

(5) A deferred donor who tests reactive for a communicable disease agent(s) described under §610.40(a) or reactive with a serological test for syphilis under §610.40(l), may serve as an autologous donor under §610.40(d).

(b) FDA may approve an exception or alternative to the statement of warning required in paragraph (a) of this section based on evidence that the reactivity of the human blood or blood component in the medical device presents no significant health risk through use of the medical device.

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