Food and Drug Administration, HHS

§ 610.42

Plasma, that test reactive by a screening test for syphilis as required under paragraph (i) of this section if, consistent with §640.5 of this chapter, the donation is further tested by an adequate and appropriate test which demonstrates that the reactive screening test is a biological false positive. You must label the blood or blood components with both test results.

(vii) You may use Source Plasma from a donor who tests reactive by a screening test for syphilis as required under §610.40(i) of this chapter, if the donor meets the requirements of §640.65(b)(2) of this chapter.

(i) Syphilis testing. In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a), and 640.65(b)(2) of this chapter.

§ 610.40 Test requirements.

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(h) * * * *

(ii) * * * *

(B) You must appropriately label such blood or blood components as required under §606.121 of this chapter, and with the “BIO-HAZARD” legend;

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(i) Syphilis testing. In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a), and 640.65(b)(1) and (b)(2) of this chapter.

§ 610.41 Donor deferral.

(a) You, an establishment that collects human blood or blood components, must defer donors testing reactive by a screening test for evidence of infection due to a communicable disease agent(s) listed in §610.40(a) or reactive with a serological test for syphilis under §610.40(i), may serve as an autologous donor under §610.40(d).

(b) A deferred donor subsequently may be found to be suitable as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by FDA. Such a donor is considered no longer deferred.

(c) You must comply with the requirements under §§610.46 and 610.47 when a donor tests reactive by a screening test for HIV or HCV required under §610.40(a) and (b), or when you are aware of other reliable test results or information indicating evidence of HIV or HCV infection.

§ 610.42 Restrictions on use for further manufacture of medical devices.

(a) In addition to labeling requirements in subchapter H of this chapter, when a medical device contains human