§ 1271.80 What are the general requirements for donor testing?

(a) Testing for relevant communicable diseases is required. To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under §1271.90, if you are the establishment that performs donor testing, you must test a donor specimen for evidence of infection due to communicable disease agents in accordance with paragraph (c) of this section. You must test for those communicable disease agents specified in §1271.85. In the case of a donor 1 month of age or younger, you must test a specimen from the birth mother instead of a specimen from the donor.

(b) Timing of specimen collection. You must collect the donor specimen for testing at the time of recovery of cells or tissue from the donor; or up to 7 days before or after recovery, except:

(1) For donors of peripheral blood stem/progenitor cells, bone marrow (if not excepted under §1271.3(d)(4)), or oocytes, you may collect the donor specimen for testing up to 30 days before recovery; or

(2) In the case of a repeat semen donor from whom a specimen has already been collected and tested, and for whom retesting is required under §1271.85(d), you are not required to collect a donor specimen at the time of each donation.

(c) Tests. You must test using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer’s instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases; however, until such time as appropriate FDA-licensed, approved, or cleared donor screening tests for Chlamydia trachomatis and for
Neisseria gonorrhoea are available, you must use FDA-licensed, approved, or cleared tests labeled for the detection of those organisms in an asymptomatic, low-prevalence population. You must use a test specifically labeled for cadaveric specimens instead of a more generally labeled test when applicable and when available. Required testing under this section must be performed by a laboratory that either is certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

(d) Ineligible donors. You must determine the following donors to be ineligible:

(1) A donor whose specimen tests reactive on a screening test for a communicable disease agent in accordance with §1271.85, except for a donor whose specimen tests reactive on a non-treponemal screening test for syphilis and negative on a specific treponemal confirmatory test;

(2)(i) A donor in whom plasma dilution sufficient to affect the results of communicable disease testing is suspected, unless:

(A) You test a specimen taken from the donor before transfusion or infusion and up to 7 days before recovery of cells or tissue; or

(B) You use an appropriate algorithm designed to evaluate volumes administered in the 48 hours before specimen collection, and the algorithm shows that plasma dilution sufficient to affect the results of communicable disease testing has not occurred.

(ii) Clinical situations in which you must suspect plasma dilution sufficient to affect the results of communicable disease testing include but are not limited to the following:

(A) Blood loss is known or suspected in a donor over 12 years of age, and the donor has received a transfusion or infusion of any of the following, alone or in combination:

(i) More than 2,000 milliliters (mL) of blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(ii) More than 2,000 mL of crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

(3) Regardless of the presence or absence of blood loss, the donor is 12 years of age or younger and has received a transfusion or infusion of any amount of any of the following, alone or in combination:

(A) Blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(B) Crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.