the donor’s relevant medical records for risk factors for and clinical evidence of relevant cell-associated communicable disease agents and diseases, including Human T-lymphotropic virus.

(c) Donors of reproductive cells or tissue. In addition to the relevant communicable disease agents and diseases for which screening is required under paragraphs (a) and (b) of this section, as applicable, and except as provided under §1271.90, you must screen the donor of reproductive cells or tissue by reviewing the donor’s relevant medical records for risk factors for and clinical evidence of relevant cell-associated communicable disease agents and diseases, including Human T-lymphotropic virus.

(c)(1) Chlamydia trachomatis; and

(c)(2) Neisseria gonorrhoeae.

(d) Ineligible donors. You must determine ineligible a donor who is identified as having either of the following:

(1) A risk factor for or clinical evidence of any of the relevant communicable disease agents or diseases for which screening is required under paragraphs (a)(1), (b), or (c) of this section; or

(2) Any communicable disease risk associated with xenotransplantation.

(e) Abbreviated procedure for repeat donors. If you have performed a complete donor screening procedure on a living donor within the previous 6 months, you may use an abbreviated donor screening procedure on repeat donations. The abbreviated procedure must determine and document any changes in the donor’s medical history since the previous donation that would make the donor ineligible, including relevant social behavior.

§ 1271.85 What donor testing is required for different types of cells and tissues?

(a) All donors. To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under §1271.90, you must test a specimen from the donor of cells or tissue, whether viable or nonviable, for evidence of infection due to relevant communicable disease agents, including:

(1) Human immunodeficiency virus, type 1;
(2) Human immunodeficiency virus, type 2;
(3) Hepatitis B virus;
(4) Hepatitis C virus; and
(5) Treponema pallidum.

(b) Donors of viable, leukocyte-rich cells or tissue. In addition to the relevant communicable disease agents for which testing is required under paragraph (a) of this section, and except as provided under §1271.90,

(1) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue to adequately and appropriately reduce the risk of transmission. You must establish and maintain a standard operating procedure governing the release of an

(B) 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:

(1) Blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or
(2) Crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.