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.

(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:

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

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

§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 of relevant cell-associated communicable diseases, including:

(i) Human T-lymphotropic virus, type I; and

(ii) Human T-lymphotropic virus, type II.

(2) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue for evidence of infection...
due to cytomegalovirus (CMV), to ade-
quately and appropriately reduce the
risk of transmission. You must estab-
lish and maintain a standard operating
procedure governing the release of an
HCT/P from a donor whose specimen
tests reactive for CMV.

(c) Donors of reproductive cells or tis-
sue. In addition to the communicable
disease agents for which testing is re-
quired under paragraphs (a) and (b) of
this section, as applicable, and except
as provided under §1271.90, you must
test a specimen from the donor of re-
productive cells or tissue to adequately
and appropriately reduce the risk of
transmission of relevant communicable
disease agents of the genitourinary
tract. Such testing must include testing
for the communicable disease agents
listed in paragraphs (c)(1) and (c)(2) of
this section. However, if the re-
productive cells or tissues are recov-
ered by a method that ensures freedom
from contamination of the cells or tis-
sue by infectious disease organisms
that may be present in the genito-
urinary tract, then testing for the com-
unicable disease agents listed in
paragraphs (c)(1) and (c)(2) of this sec-
tion is not required. Communicable
disease agents of the genitourinary
tract for which you must test include:
(1) Chlamydia trachomatis; and
(2) Neisseria gonorrhoea.

(d) Retesting anonymous semen donors.
Except as provided under §1271.90 and
except for directed reproductive donors
as defined in §1271.3(l), at least 6
months after the date of donation of
semen from anonymous donors, you
must collect a new specimen from the
donor and test it for evidence of infec-
tion due to the communicable disease
agents for which testing is required
under paragraphs (a), (b), and (c) of
this section.

(e) Dura mater. For donors of dura
mater, you must perform an adequate
assessment designed to detect evidence
of transmissible spongiform encephalopathy.

§1271.90 Are there exceptions from
the requirement of determining
donor eligibility, and what labeling
requirements apply?

(a) Donor-eligibility determination not
required. You are not required to make
a donor-eligibility determination under
§1271.50 or to perform donor screening
or testing under §§1271.75, 1271.80 and
1271.85 for:
(1) Cells and tissues for autologous
use; or
(2) Reproductive cells or tissue do-
nated by a sexually intimate partner of
the recipient for reproductive use; or
(3) Cryopreserved cells or tissue for
reproductive use, other than embryos,
originally exempt under paragraphs
(a)(1) or (a)(2) of this section at the
time of donation, that are subse-
quently intended for directed donation,
provided that
(i) Additional donations are unavail-
able, for example, due to the infertility
or health of a donor of the cryopreserved
reproductive cells or tissue; and
(ii) Appropriate measures are taken
to screen and test the donor(s) before
transfer to the recipient.

(4) A cryopreserved embryo, origi-
nally exempt under paragraph (a)(2) of
this section at the time of
cryopreservation, that is subsequently
intended for directed or anonymous do-
nation. When possible, appropriate
measures should be taken to screen and
test the semen and oocyte donors be-
fore transfer of the embryo to the re-
cipient.

(b) Required labeling. As applicable,
you must prominently label an HCT/P
described in paragraph (a) of this sec-
tion as follows:
(1) “FOR AUTOLOGOUS USE
ONLY,” if it is stored for autologous
use.
(2) “NOT EVALUATED FOR INFEC-
TIOUS SUBSTANCES,” unless you
have performed all otherwise applica-
tble screening and testing under
§§1271.75, 1271.80, and 1271.85. This para-
graph does not apply to reproductive
cells or tissue labeled in accordance
with paragraph (b)(6) of this section.
(3) Unless the HCT/P is for
autologous use only, “WARNING: Ad-
vise recipient of communicable disease
risks;”

(i) When the donor-eligibility deter-
mination under §1271.50(a) is not per-
formed or is not completed; or
(ii) If the results of any screening or
testing performed indicate: