and Research or the Director, Center for Drug Evaluation and Research.

(3) **Applicability.** This paragraph applies to diploid and nondiploid cell lines. Primary cell cultures that are not subcultivated and primary cell cultures that are subsequently subcultivated for only a very limited number of population doublings are not subject to the provisions of this paragraph (c).

(d) **Records.** The records appropriate for cultures under this section shall be prepared and maintained as required by the applicable provisions of §§211.188 and 211.194 of this chapter.


**Subpart C—Standard Preparations and Limits of Potency**

§ 610.20 **Standard preparations.**

Standard preparations made available by the Center for Biologics Evaluation and Research shall be applied in testing, as follows:

(a) **Potency standards.** Potency standards shall be applied in testing for potency all forms of the following:

**ANTIBODIES**
- Botulism Antitoxin, Type A.
- Botulism Antitoxin, Type B.
- Botulism Antitoxin, Type E.
- Diphtheria Antitoxin.
- Histolyticus Antitoxin.
- Oedematiens Antitoxin.
- Pertussis Antitoxin.
- Antitoxin Serum.
- Antirabies Serum.
- Sordelli Antitoxin.
- Staphylococcus Antitoxin.
- Tetanus Antitoxin.
- Vibrio Septique Antitoxin.

**ANTIGENS**
- Cholera Vaccine, Inaba serotype.
- Cholera Vaccine, Ogawa serotype.
- Diphtheria Toxin for Schick Test.
- Pertussis Vaccine.
- Tuberculin, Old.
- Tuberculin, Purified Protein Derivative.
- Typhoid Vaccine.

**BLOOD DERIVATIVE**
- Thrombin.

(b) **Opacity standard.** The U.S. Opacity Standard shall be applied in estimating the bacterial concentration of all bacterial vaccines. The assigned value of the standard when observed visually is 10 units. The assigned value of the standard when observed with a photometer is (1) 10 units when the wavelength of the filter is 530 millimicrons, (2) 10.6 units when the wavelength of the filter is 650 millimicrons, and (3) 9 units when the wavelength of the filter is 420 millimicrons.


§ 610.21 **Limits of potency.**

The potency of the following products shall be not less than that set forth below and products dispensed in the dried state shall represent liquid products having the stated limitations.

**ANTIBODIES**
- Diphtheria Antitoxin, 500 units per milliliter.
- Tetanus Antitoxin, 400 units per milliliter.
- Tetanus Immune Globulin (Human), 250 units of tetanus antitoxin per container.

**ANTIGENS**
- Cholera Vaccine, 8 units each of Inaba and Ogawa serotype antigens per milliliter.
- Pertussis Vaccine, 12 units per total human immunizing dose.
- Typhoid Vaccine, 8 units per milliliter.


**Subpart D—Mycoplasma**

§ 610.30 **Test for Mycoplasma.**

Except as provided otherwise in this subchapter, prior to clarification or filtration in the case of live virus vaccines produced from in vitro living cell cultures, and prior to inactivation in the case of inactivated virus vaccines produced from such living cell cultures, each virus harvest pool and control fluid pool shall be tested for the presence of *Mycoplasma*, as follows:

Samples of the virus for this test shall be stored either (1) between 2 and 8 °C for no longer than 24 hours, or (2) at −20 °C or lower if stored for longer than 24 hours. The test shall be performed on samples of the viral harvest pool and on control fluid pool obtained at the time of viral harvest, as follows: No less than 2.0 ml. of each sample...
§ 610.40 Test requirements.

(a) Human blood and blood components. Except as specified in paragraphs (c) and (d) of this section, you, an establishment that collects blood or blood components, must test each donation of human blood or blood component intended for use in preparing a product, including donations intended as a component of, or used to prepare, a medical device, for evidence of infection due to the following communicable disease agents:

1. Human immunodeficiency virus, type I;
2. Human immunodeficiency virus, type II;
3. Hepatitis B virus;
4. Hepatitis C virus;
5. Human T-lymphotropic virus, type I; and
6. Human T-lymphotropic virus, type II.

(b) Testing using one or more approved screening tests. To test for evidence of infection due to communicable disease agents designated in paragraph (a) of this section, you must use screening tests that the Food and Drug Administration (FDA) has approved for such use, in accordance with the manufacturer’s instructions. You must perform one or more such tests as necessary to reduce adequately and appropriately the risk of transmission of communicable disease.

(c) Exceptions to testing for allogeneic transfusion or further manufacturing use—(1) Dedicated donations. (i) You must test donations of human blood and blood components from a donor whose donations are dedicated to and used solely by a single identified recipient under paragraphs (a), (b), and (d) of this section; except that, if the donor makes multiple donations for a single identified recipient, you may perform such testing only on the first donation in each 30-day period. If an untested dedicated donation is made available for any use other than transfusion to the single, identified recipient, then this exemption from the testing required under this section no longer applies.

(ii) Each donation must be labeled as required under § 606.121 of this chapter and with a label entitled “INTENDED RECIPIENT INFORMATION LABEL” containing the name and identifying information of the recipient. Each donation must also have the following label, as appropriate:

<table>
<thead>
<tr>
<th>Donor Testing Status</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tested negative</td>
<td>“DONOR TESTED WITHIN THE LAST 30 DAYS”</td>
</tr>
<tr>
<td>Tested negative within the last 30 days</td>
<td></td>
</tr>
</tbody>
</table>

(38 FR 22056, Nov. 29, 1973, as amended at 63 FR 16683, Apr. 6, 1998)