§ 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.

§ 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 1;