§ 866.3480 Respiratory syncytial virus serological reagents.

(a) Identification. Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to respiratory syncytial virus in serum. Additionally, some of these reagents consist of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.3490 Rhinovirus serological reagents.

(a) Identification. Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rhinovirus in serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.3500 Rickettsia serological reagents.

(a) Identification. Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rickettsia in serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens. The identification aids in the diagnosis of diseases caused by virus-like bacteria belonging to the genus Rickettsiae and provides epidemiological information on these diseases. Rickettsiae are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.3510 Rubella virus serological reagents.

(a) Identification. Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubella virus in serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person’s immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) Classification. Class II. The special controls for this device are:

(1) National Committee for Clinical Laboratory Standards:

(i) 1/LA6 “Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory, October 1997,”

(ii) 1/LA18 “Specifications for Immunological Testing for Infectious Diseases, December 1994,”

(iii) D13 “Agglutination Characteristics, Methodology, Limitations, and Clinical Validation, October 1993,”

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 23047, June 12, 1989; 66 FR 38792, July 25, 2001]
(iv) EP5 “Evaluation of Precision Performance of Clinical Chemistry Devices, February 1999,” and
(2) Centers for Disease Control’s:
(i) Low Titer Rubella Standard,
(ii) Reference Panel of Well Characterized Rubella Sera, and
(3) World Health Organization’s International Rubella Standard.
§ 866.3520 Rubeola (measles) virus serological reagents.
(a) Identification. Rubeola (measles) virus serological reagents are devices that consist of antigens and antiserum used in serological tests to identify antibodies to rubeola virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.
§ 866.3550 Salmonella spp. serological reagents.
(a) Identification. Salmonella spp. serological reagents are devices that consist of antigens and antiserum used in serological tests to identify Salmonella spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antiserum conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Salmonella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus Salmonella and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever (“enteric fever”), severe diarrhea, and cramps.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.
§ 866.3600 Schistosoma spp. serological reagents.
(a) Identification. Schistosoma spp. serological reagents are devices that consist of antigens and antiserum in serological tests to identify antibodies to Schistosoma spp. in serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus Schistosoma. Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer’s itch), a skin disease marked by intense itching.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.
§ 866.3630 Serratia spp. serological reagents.
(a) Identification. Serratia spp. serological reagents are devices that consist of antigens and antiserum used in serological tests to identify Serratia spp. from cultured isolates. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Serratia and provides epidemiological information on these diseases. Serratia spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in