Food and Drug Administration, HHS

(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 Rubéola (measles) virus serological reagents.
(a) Identification. Rubéola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubéola 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 antisera used in serological tests to identify Salmonella spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera 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 II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

§ 866.3560 Schistosoma spp. serological reagents.
(a) Identification. Schistosoma spp. serological reagents are devices that consist of antigens and antisera used 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 antisera 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 subpart E of part 807 of this chapter subject to § 866.9.
§ 866.3660 Shigella spp. serological reagents.

(a) Identification. Shigella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify Shigella spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

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

§ 866.3680 *Sporothrix schenckii* serological reagents.

(a) Identification. *Sporothrix schenckii* serological reagents are devices used to identify antibodies to *Sporothrix schenckii* in serum. The identification aids in the diagnosis of sporotrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporotrichosis is a chronic tumorlike infection primarily of the skin.

(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.

§ 866.3700 *Staphylococcus aureus* serological reagents.

(a) Identification. *Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).

(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.

§ 866.3720 *Streptococcus* spp. exoenzyme reagents.

(a) Identification. *Streptococcus* spp. exoenzyme reagents are devices used to identify antibodies to *Streptococcus* spp. exoenzyme in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(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.

§ 866.3740 *Streptococcus* spp. serological reagents.

(a) Identification. *Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in