Food and Drug Administration, HHS § 866.3040

Diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in decisionmaking respecting the treatment of disease.

(b) Classification. Class I (general controls).

§ 866.2900 Microbiological specimen collection and transport device.

(a) Identification. A microbiological specimen collection and transport device is a specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.

(b) Classification. Class I (general controls).

Subpart D—Serological Reagents

§ 866.3010 Acinetobacter calcoaceticus serological reagents.

(a) Identification. Acinetobacter calcoaceticus serological reagents are devices that consist of Acinetobacter calcoaceticus antigens and antisera used to identify this bacterium from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by the bacterium Acinetobacter calcoaceticus and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.3035 Arizona spp. serological reagents.

(a) Identification. Arizona spp. serological reagents are devices that consist of antisera and antigens used to identify Arizona spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Arizona and provides epidemiological information on diseases caused by these microorganisms. Arizona spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.3040 Aspergillus spp. serological reagents.

(a) Identification. Aspergillus spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify antibodies to Aspergillus spp. in serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus Aspergillus. Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball
§ 866.3060 Blastomyces dermatitidis serological reagents.

(a) Identification. Blastomyces dermatitidis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Blastomyces dermatitidis in serum. The identification aids in the diagnosis of blastomycosis caused by the fungus Blastomyces dermatitidis. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) Classification. Class I (general controls).

§ 866.3065 Bordetella spp. serological reagents.

(a) Identification. Bordetella spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Bordetella spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Bordetella and provides epidemiological information on these diseases. Bordetella spp. cause whooping cough (Bordetella pertussis) and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.3085 Brucella spp. serological reagents.

(a) Identification. Brucella spp. serological reagents are devices that consist of antigens and antisera used for serological identification of Brucella spp. from cultured isolates derived from clinical specimens or to identify antibodies to Brucella spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Brucella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus Brucella and provides epidemiological information on diseases caused by these microorganisms.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3110 Campylobacter fetus serological reagents.

(a) Identification. Campylobacter fetus serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify Campylobacter fetus from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium and provides epidemiological information on these diseases. Campylobacter fetus is a frequent cause of abortion in sheep and cattle and is sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

(b) Classification. Class I (general controls).

§ 866.3120 Chlamydia serological reagents.

(a) Identification. Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to chlamydia in serum. Additionally,
some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye used to identify chlamydia directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Chlamydia and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) Classification. Class I (general controls).

§ 866.3125 Citrobacter spp. serological reagents.

(a) Identification. Citrobacter spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Citrobacter spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Citrobacter and provides epidemiological information on diseases caused by these microorganisms. Citrobacter spp. have occasionally been associated with urinary tract infections.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.3135 Coccidioides immitis serological reagents.

(a) Identification. Coccidioides immitis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Coccidioides immitis in serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus Coccidioides and provides epidemiological information on diseases caused by this microorganism. An infection with Coccidioides immitis produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3140 Corynebacterium spp. serological reagents.

(a) Identification. Corynebacterium spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify Corynebacterium spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Corynebacterium and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus, Corynebacterium diphtheriae, causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin, and are either nonpathogenic or have an uncertain role.

(b) Classification. Class I (general controls).

§ 866.3145 Coxsackievirus serological reagents.

(a) Identification. Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to coxsackievirus in serum. Additionally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye that are used to identify coxsackievirus from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(b) Classification. Class I (general controls).
§ 866.3165 Cryptococcus neoformans serological reagents.

(a) Identification. Cryptococcus neoformans serological reagents are devices that consist of antigens used in serological tests to identify antibodies to Cryptococcus neoformans in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify Cryptococcus neoformans directly from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(b) Classification. Class II (special controls).

§ 866.3175 Cytomegalovirus serological reagents.

(a) Identification. Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to cytomegalovirus in serum. The identification aids in the diagnosis of cytomegalovirus infection and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.

(b) Classification. Class II (performance standards).

§ 866.3177 Echinococcus spp. serological reagents.

(a) Identification. Echinococcus spp. serological reagents are devices that consist of Echinococcus spp. antigens and antisera used in serological tests to identify antibodies to Echinococcus spp. in serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus Echinococcus and provides epidemiological information on this disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organisms.

(b) Classification. Class I (general controls).

§ 866.3180 Echovirus serological reagents.

(a) Identification. Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to echovirus in serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 866.3205 Entamoeba histolytica serological reagents.

(a) Identification. Entamoeba histolytica serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Entamoeba histolytica in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to
identify Entamoeba histolytica directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite Entamoeba histolytica and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§866.3235 Epstein-Barr virus serological reagents.

(a) Identification. Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Epstein-Barr virus in serum. The identification aids in the diagnosis of Epstein-Barr virus infections and provides epidemiological information on diseases caused by these viruses. Epstein-Barr viruses are thought to cause infectious mononucleosis and have been associated with Burkitt’s lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

(b) Classification. Class I (general controls).

§866.3240 Equine encephalomyelitis virus serological reagents.

(a) Identification. Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to equine encephalomyelitis virus in serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects, such as mosquitoes and ticks, and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

(b) Classification. Class I (general controls).

§866.3250 Erysipelothrix rhusiopathiae serological reagents.

(a) Identification. Erysipelothrix rhusiopathiae serological reagents are devices that consist of antigens and antisera used in serological tests to identify Erysipelothrix rhusiopathiae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus Erysipelothrix. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§866.3255 Escherichia coli serological reagents.

(a) Identification. Escherichia coli serological reagents are devices that consist of antigens and antisera used in serological tests to identify Escherichia coli from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of Escherichia coli antisera conjugated with a fluorescent dye used to identify Escherichia coli directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium belonging to the genus Escherichia, and provides epidemiological information on diseases caused by this microorganism. Although Escherichia coli constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually non-pathogenic, those strains which are pathogenic may cause urinary tract infections or epidemic diarrheal disease, especially in children.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]
§ 866.3270 Flavobacterium spp. serological reagents.

(a) Identification. Flavobacterium spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Flavobacterium spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Flavobacterium and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. Flavobacterium meningosepticum is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 866.3280 Francisella tularensis serological reagents.

(a) Identification. Francisella tularensis serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Francisella tularensis directly from clinical specimens. The identification aids in the diagnosis of tularemia caused by Francisella tularensis and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3290 Gonococcal antibody test (GAT).

(a) Identification. A gonococcal antibody test (GAT) is an in vitro device that consists of the reagents intended to identify by immunoochemical techniques, such as latex agglutination, indirect fluorescent antibody, or radioimmunoassay, antibodies to Neisseria gonorrhoeae in sera of asymptomatic females at low risk of infection. Identification of antibodies with this device may indicate past or present infection of the patient with Neisseria gonorrhoeae.

(b) Classification. Class III (premarket approval) (transitional device).

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §866.3.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987]

§ 866.3300 Haemophilus spp. serological reagents.

(a) Identification. Haemophilus spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify Haemophilus spp. directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Haemophilus and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by Haemophilus spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

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

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]
§ 866.3305 Herpes simplex virus serological reagents.

(a) Identification. Herpes simplex virus serological reagents are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from an mild infection to a severe generalized disease with a fatal outcome.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §866.3.

§ 866.3330 Influenza virus serological reagents.

(a) Identification. Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 866.3340 Klebsiella spp. serological reagents.

(a) Identification. Klebsiella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify Klebsiella spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Klebsiella and provides epidemiological information on these diseases. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
§ 866.3350 Leptospira spp. serological reagents.

(a) Identification. Leptospira spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Leptospira spp. in serum or identify Leptospira spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify Leptospira spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus Leptospira and provides epidemiological information on this disease. Leptospira infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 866.3355 Listeria spp. serological reagents.

(a) Identification. Listeria spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Listeria spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of Listeria spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Listeria spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus Listeria, and provides epidemiological information on diseases caused by these microorganisms. Listeria monocytogenes, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

(b) Classification. Class I (general controls).

§ 866.3360 Lymphocytic choriomeningitis virus serological reagents.

(a) Identification. Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to lymphocytic choriomeningitis virus in serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infections and provides epidemiological information on diseases caused by these viruses. Lymphocytic choriomeningitis viruses usually cause a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

(b) Classification. Class I (general controls).

§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.

(a) Identification. Mycobacterium tuberculosis immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify Mycobacterium tuberculosis directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. Mycobacterium tuberculosis is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

(b) Classification. Class I (general controls).

§ 866.3375 Mycoplasma spp. serological reagents.

(a) Identification. Mycoplasma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Mycoplasma spp. in serum. Additionally, some of these reagents consist of Mycoplasma spp. antisera conjugated...
with a fluorescent dye (immunofluorescent reagents) used to identify Mycoplasma spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Mycoplasma and provides epidemiological information on diseases caused by these microorganisms. Mycoplasma spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with Mycoplasma pneumoniae range from inapparent infection to mild or severe upper respiratory disease, ear infection, and bronchial pneumonia.

(b) Classification. Class I (general controls).

§ 866.3380 Mumps virus serological reagents.

(a) Identification. Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify antibodies to mumps virus in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

(b) Classification. Class I (general controls).

§ 866.3390 Neisseria spp. direct serological test reagents.

(a) Identification. Neisseria spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify Neisseria spp. from cultured isolates. Additionally, some of these reagents consist of Neisseria spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of Neisseria spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Neisseria, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

(b) Classification. Class II (performance standards).

§ 866.3400 Parainfluenza virus serological reagents.

(a) Identification. Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to parainfluenza virus in serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause a variety of respiratory illnesses ranging from the common cold to pneumonia.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989]

§ 866.3405 Poliovirus serological reagents.

(a) Identification. Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to poliovirus in serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis (polio) and provides epidemiological information on this disease. Poliomyelitis is an acute infectious disease which in its serious form affects the central nervous system resulting in atrophy (wasting away) of groups of muscles, ending in contraction and permanent deformity.
§ 866.3410 Proteus spp. (Well-Felix) serological reagents.

(a) Identification. Proteus spp. (Well-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium Proteus vulgaris used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in serum. Test results aid in the diagnosis of diseases caused by bacteria belonging to the genus Rickettsiae and provide epidemiological information on these diseases. Rickettsia 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. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989]

§ 866.3415 Pseudomonas spp. serological reagents.

(a) Identification. Pseudomonas spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify Pseudomonas spp. from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Pseudomonas. Pseudomonas aeruginosa is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, abscesses, and meningitis (inflammation of brain membranes). Pseudomonas pseudomallei causes melioidosis, a chronic pneumonia.

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

§ 866.3460 Rabiesvirus immunofluorescent reagents.

(a) Identification. Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesvirus in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bites and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

(b) Classification. Class II (performance standards).

§ 866.3470 Reovirus serological reagents.

(a) Identification. Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to reovirus in serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

(b) Classification. Class I. These devices are exempt from premarket notification procedures in subpart E of part 807 of this chapter.

§ 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).

§ 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 antibodies to Salmonella in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Salmonella directly from clinical specimens. The identification aids in the diagnosis of diseases caused by virus-like bacteria belonging to the genus Rickettsia and provides epidemiological information on these diseases. Rickettsia 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).
§ 866.3600  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 schistosomiasis caused by parasitic flatworms of the genus Schistosoma. Schistosomiasis is characterized by 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.

§ 866.3660  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 that consist of antigens and antisera used in serological tests 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).
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. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989]

§ 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 diseases 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 866.3740 Streptococcus spp. serological reagents.

(a) Identification. Streptococcus spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Streptococcus spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases 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 II (performance standards).

§ 866.3780 Toxoplasma gondii serological reagents.

(a) Identification. Toxoplasma gondii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Toxoplasma gondii in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Toxoplasma gondii from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan Toxoplasma gondii and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

(b) Classification. Class II (performance standards).

§ 866.3820 Treponema pallidum nontreponemal test reagents.

(a) Identification. Treponema pallidum nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus Treponema and provides epidemiological information on syphilis.

(b) Classification. Class II (performance standards).

§ 866.3830 Treponema pallidum treponemal test reagents.

(a) Identification. Treponema pallidum treponemal test reagents are devices that consist of the antigens, antiserum
and all control reagents (standardized reagents with which test results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA-ABS), the Treponema pallidum immobilization test (T.P.I.), and other treponemal tests used to identify antibodies to Treponema pallidum directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of Syphilis caused by bacteria belonging to the genus Treponema and provides epidemiological information on syphilis.

(b) Classification. Class II (performance standards).

§ 866.3850 Trichinella spiralis serological reagents.

(a) Identification. Trichinella spiralis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trichinella spiralis in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus Trichinella and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) Classification. Class I (general controls).

§ 866.3870 Trypanosoma spp. serological reagents.

(a) Identification. Trypanosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trypanosoma spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus Trypanosoma. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) Classification. Class I (general controls).

§ 866.3900 Varicella-zoster virus serological reagents.

(a) Identification. Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) Classification. Class II (performance standards).

§ 866.3930 Vibrio cholerae serological reagents.

(a) Identification. Vibrio cholerae serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify Vibrio cholerae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium Vibrio cholerae and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]
Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4100 Complement reagent.
(a) Identification. A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.

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

§ 866.4500 Immunoelectrophoresis equipment.
(a) Identification. Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

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

§ 866.4540 Immunofluorometer equipment.
(a) Identification. Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

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

§ 866.4600 Ouchterlony agar plate.
(a) Identification. Ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.