high mortality rate for infants before or after birth.

(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.


§ 866.3360 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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.


§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.

(a) Identification. Mycobacterium tuberculosis immunofluorescent reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to 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 genitalia, 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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.


§ 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). The device is exempt from the premarket notification procedures in
§ 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 viruses. It 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).

§ 866.3395 Norovirus serological reagents.

(a) Identification. Norovirus serological reagents are devices that consist of antigens and antisera used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis. The detection of these antigens aids in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis. The detection of these antigens aids in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Norovirus Serological Reagents.” See §866.1(e) for the availability of this guidance document.


§ 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 (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.


§ 866.3402 Plasmodium species antigen detection assays.

(a) Identification. A Plasmodium species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae, and aids in the differential diagnosis of Plasmodium falciparum infections from other less virulent Plasmodium species. The device is intended for use in conjunction with other clinical laboratory findings.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Plasmodium species Antigen Detection