§ 866.3332 Reagents for detection of specific novel influenza A viruses.

(a) Identification. Reagents for detection of specific novel influenza A viruses are devices that are intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological information on influenza. These reagents include primers, probes, and specific influenza A virus controls.

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

(1) FDA’s guidance document entitled “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses.” See §866.1(e) for information on obtaining this document.

(2) The distribution of these devices is limited to laboratories with experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and appropriate biosafety equipment and containment.

§ 866.3335 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.

§ 866.3335 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). 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 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). 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