Food and Drug Administration, HHS

§ 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

§ 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).

§ 866.3380 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 subpart E of part 807 of this chapter subject to § 866.9.


§ 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.


§ 866.3395 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