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provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and 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]

§ 866.3330 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 (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.


§ 866.3332 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.

[71 FR 14379, Mar. 22, 2006]

§ 866.3340 Leptospira spp. serological reagents.

(a) Identification. Leptospira 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 Leptospira spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Leptospira 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 (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.


§ 866.3350 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