§ 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. Chlamydiosis is the causative agent of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) Classification. Class II (special 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 (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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 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.