§ 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 §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 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 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.


§ 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.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3145 Coxsackievirus serological reagents.

(a) Identification. Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to coxsackievirus in serum. Additionally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye that are used to identify coxsackievirus from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myocarditis (inflammation of heart muscle).