

§ 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. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) *Classification.* Class I (general 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. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989]

§ 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 (performance standards).

§ 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).

§ 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 myopericarditis (inflammation of heart tissue).

(b) *Classification.* Class I (general controls).