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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.


§ 866.3140 *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. 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 Thyopericarditis (inflammation of heart tissue).
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§ 866.3205 Echovirus serological reagents.

(a) Identification. Echovirus serological reagents are devices that consist of echovirus antigens and antisera used in serological tests to identify antibodies to echovirus in serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(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.