Food and Drug Administration, HHS

§ 866.3085 Brucella spp. serological reagents.

(a) Identification. Brucella spp. serological reagents are devices that consist of antigens and antisera used for serological identification of Brucella spp. from cultured isolates derived from clinical specimens or to identify antibodies to Brucella spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Brucella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus Brucella and provides epidemiological information on these diseases. Brucella 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 II (special controls).

§ 866.3110 Campylobacter fetus serological reagents.

(a) Identification. Campylobacter fetus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Campylobacter fetus 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 Campylobacter and provides epidemiological information on diseases caused by these microorganisms. Campylobacter fetus have occasionally been associated with urinary tract infections.

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

§ 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...