Food and Drug Administration, HHS

§ 866.3375 Mycoplasma spp. serological reagents.

(a) Identification. Mycoplasma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Mycoplasma spp. in serum. Additionally, some of these reagents consist of Mycoplasma spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Mycoplasma spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Mycoplasma and provides epidemiological information on diseases caused by these microorganisms. Mycoplasma spp. are associated with inflammatory conditions of the urinary and respiratory systems.