§ 866.3140 Coccidioides spp. serological reagents.

(a) Identification. Coccidioides spp. serological reagents are devices that consist of antiserum conjugated with a fluorescent dye used to identify Coccidioides spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Coccidioides and provides epidemiological information on diseases caused by these microorganisms. 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.

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

§ 866.3145 Cryptococcus neoformans serological reagents.

(a) Identification. Cryptococcus neoformans serological reagents are devices that consist of antigens used in serological tests to identify antibodies to Cryptococcus neoformans in serum. Additionally, some of these reagents consist of antiserum conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify Cryptococcus neoformans directly from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(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.

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

§ 866.3175 Cytomegalovirus serological reagents.

(a) Identification. Cytomegalovirus serological reagents are devices that consist of antigens and antiserum used in serological tests to identify antibodies to cytomegalovirus in serum. The identification aids in the diagnosis of cytomegalovirus infections and provides epidemiological information on diseases caused by these viruses. Cytomegaloviruses 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). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.