Food and Drug Administration, HHS

§ 866.3050 Beta-glucan serological assays.

(a) Identification. Beta-glucan serological assays are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.” See §866.1(e) for the availability of this guidance document.

[69 FR 56936, Sept. 23, 2004]

§ 866.3060 Blastomyces dermatitidis serological reagents.

(a) Identification. Blastomyces dermatitidis serological reagents are devices that consist of antigens and antiserum used in serological tests to identify antibodies to Blastomyces dermatitidis in serum. The identification aids in the diagnosis of blastomycosis caused by the fungus Blastomyces dermatitidis. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(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]

§ 866.3065 Bordetella spp. serological reagents.

(a) Identification. Bordetella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify Bordetella spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Bordetella and provides epidemiological information on these diseases. Bordetella spp. cause whooping cough (Bordetella pertussis) and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(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 the limitations in §866.9.


§ 866.3085 Brucella spp. serological reagents.

(a) Identification. Brucella spp. serological reagents are devices that consist of antigens and antiserum 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 antiserum 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 diseases caused by these microorganisms.

(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]