§ 866.3320 Haemophilus spp. serological reagents.

(a) Identification. Haemophilus spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify Haemophilus spp. directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Haemophilus and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by Haemophilus spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid, venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

(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.


§ 866.3310 Hepatitis A virus (HAV) serological assays.

(a) Identification. HAV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to hepatitis A virus-specific IgM, IgG, or total antibodies (IgM and IgG), in human serum or plasma. These devices are used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis to determine if an individual has been previously infected with HAV, or as an aid to identify HAV-susceptible individuals. The detection of these antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HAV in conjunction with other clinical laboratory findings. These devices are not intended for screening blood or solid or soft tissue donors.

(b) Classification. Class II (special controls). The special control is "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays." See §866.1(e) for the availability of this guidance document.

[FR 6679, Feb. 9, 2006]

§ 866.3320 Histoplasma capsulatum serological reagents.

(a) Identification. Histoplasma capsulatum serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Histoplasma capsulatum in serum. Additionally, some of these reagents consist of Histoplasma capsulatum antiserum conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Histoplasma capsulatum from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus Histoplasma and provides epidemiological information...