§ 866.3402 Plasmodium species antigen detection assays.

(a) Identification. A Plasmodium species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae, and aids in the differential diagnosis of Plasmodium falciparum infections from other less virulent Plasmodium species. The device is intended for use in conjunction with other clinical laboratory findings.

(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. [47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.3405 Poliovirus serological reagents.

(a) Identification. Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to poliovirus in serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis (polio) and provides epidemiological information on this disease. Poliomyelitis is an acute infectious disease which in its serious form affects the central nervous system resulting in atrophy (wasting away) of groups of muscles, ending in contraction and permanent deformity.

(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. [47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

[73 FR 29054, May 20, 2008]

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

(a) Identification. Proteus spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium Proteus vulgaris used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in serum. Test results aid in the diagnosis of diseases caused by bacteria belonging to the genus Rickettsiae and provide epidemiological information on these diseases. Rickettsiae are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(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. [47 FR 50823, Nov. 9, 1982, as amended at 34 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.3415 Pseudomonas spp. serological reagents.

(a) Identification. Pseudomonas spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify Pseudomonas spp. from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Pseudomonas.