§ 866.3850 Trichinella spiralis serological reagents.

(a) Identification. Trichinella spiralis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Trichinella spiralis* in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) Classification. Class I (general controls).

§ 866.3870 Trypanosoma spp. serological reagents.

(a) Identification. *Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Trypanosoma* spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma*. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) Classification. Class II (special controls).

§ 866.3900 Varicella-zoster virus serological reagents.

(a) Identification. Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient’s body.

(b) Classification. Class II (performance standards).

§ 866.3930 Vibrio cholerae serological reagents.

(a) Identification. *Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(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.

§ 866.3940 West Nile virus serological reagents.

(a) Identification. West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.

(b) Classification. Class II (special controls). The special control is FDA’s guidance entitled “Class II Special
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§ 866.4070 RNA Preanalytical Systems.

(a) Identification. RNA Preanalytical Systems are devices intended to collect, store, and transport patient specimens, and stabilize intracellular RNA from the specimens, for subsequent isolation and purification of the intracellular RNA for RT–PCR used in in vitro molecular diagnostic testing.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification System for RT–PCR Used in Molecular Diagnostic Testing).” See §866.1(e) for the availability of this guidance document.

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