§ 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 II (performance standards).

§ 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).