Food and Drug Administration, HHS

§ 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. directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus Treponema and provides epidemiological information on syphilis.

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

§ 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).

§ 866.3830 Treponema pallidum treponemal test reagents.

(a) Identification. Treponema pallidum treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which test results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA-ABS), the Treponema pallidum immobilization test (T.P.I.), and other treponemal tests used to identify antibodies to Treponema pallidum directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus Treponema and provides epidemiological information on syphilis.

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