Food and Drug Administration, HHS

§ 866.3830
Treponema pallidum treponemal test reagents.

(a) Identification. Treponema pallidum treponemal test reagents are devices that consist of the antigens, antisera and 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 II (performance standards).

§ 866.3820 Treponema pallidum non-treponemal test reagents.

(a) Identification. Treponema pallidum nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus Treponema and provides epidemiological information on syphilis.

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

§ 866.3780 Toxoplasma gondii serological reagents.

(a) Identification. Toxoplasma gondii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Toxoplasma gondii in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Toxoplasma gondii from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan Toxoplasma gondii and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

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

§ 866.3740 Streptococcus spp. serological reagents.

(a) Identification. Streptococcus spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify Streptococcus spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Streptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(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.

§ 866.3730 Treponema pallidum non-treponemal test reagents.

(a) Identification. Treponema pallidum nontreponemal test reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify Streptococcus spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Streptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(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.


§ 866.3720 Toxoplasma gondii serological reagents.

(a) Identification. Toxoplasma gondii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Toxoplasma gondii in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Toxoplasma gondii from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan Toxoplasma gondii and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

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

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