Food and Drug Administration, HHS

§ 866.3830

Treponema pallidum nontreponemal 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).

§ 866.3830

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 II (performance standards).