Food and Drug Administration, HHS

§ 866.3290

Gonococcal antibody test (GAT).

(a) Identification. A gonococcal antibody test (GAT) is an in vitro device that consists of antigens and antisera used in serological tests to identify antibodies to *Francisella tularensis* in serum or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens. The identification aids in the diagnosis of tularemia caused by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

(b) Classification. Class III (premarket approval) (transitional device). (c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §866.3.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987]