Food and Drug Administration, HHS

§ 866.5090 Antimitochondrial antibody immunological test system.

(a) Identification. An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochromatographic techniques the antimitochondrial antibodies (autoantibodies) in human serum. These antimitochondrial antibodies are present in patients with primary biliary cirrhosis (degeneration of the liver) and other inflammatory diseases. Measurement of antimitochondrial antibodies may aid in the assessment of the patient’s nutritional status.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]