

§ 866.5600

21 CFR Ch. I (4–1–12 Edition)

§ 866.5600 Low-density lipoprotein immunological test system.

(a) *Identification.* A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

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

§ 866.5620 Alpha-2-macroglobulin immunological test system.

(a) *Identification.* An *alpha-2*-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha-2*-macroglobulin (a serum protein) in plasma. Measurement of *alpha-2*-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

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

§ 866.5630 Beta-2-microglobulin immunological test system.

(a) *Identification.* A *beta-2*-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques *beta-2*-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of *beta-2*-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

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

§ 866.5640 Infectious mononucleosis immunological test system.

(a) *Identification.* An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

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

[47 FR 50823, Nov. 9, 1982; 47 FR 56846, Dec. 21, 1982]

§ 866.5660 Multiple autoantibodies immunological test system.

(a) *Identification.* A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in serum and other body fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (disease produced when the body's own tissues are injured by autoantibodies).

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

§ 866.5680 Myoglobin immunological test system.

(a) *Identification.* A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart or renal disease.

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

§ 866.5700 Whole human plasma or serum immunological test system.

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in plasma or serum. Measurements of proteins in plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in