plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

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

§ 866.5590 Lipoprotein X immunological test system.

(a) Identification. A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochimical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver 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.


§ 866.5600 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 immunochimical 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).

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

§ 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 immunochimical 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).

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