

§ 866.5530

immunoglobulin G antibodies in urine, serum, and other body fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

(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 the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other body fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain 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 the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule in serum. Measurement

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of immunoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

(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 the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

§ 866.5550 Immunoglobulin (light chain specific) immunological test system.

(a) *Identification.* An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, other body fluids, and tissues. In some disease states, an excess of light chains are produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

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

§ 866.5560 Lactic dehydrogenase immunological test system.

(a) *Identification.* A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction

(heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

(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]

§ 866.5570 Lactoferrin immunological test system.

(a) *Identification*. A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, breast milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(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]

§ 866.5580 Alpha-1-lipoprotein immunological test system.

(a) *Identification*. An *alpha*-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-1-lipoprotein (high-density lipoprotein) in serum and 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 immunochemical 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.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 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