

**§ 866.5250**

a device that consists of the reagents used to measure by immunochemical techniques complement components C<sub>1q</sub>, C<sub>1r</sub>, C<sub>1s</sub>, C<sub>2</sub>, C<sub>3</sub>, C<sub>4</sub>, C<sub>5</sub>, C<sub>6</sub>, C<sub>7</sub>, C<sub>8</sub>, and C<sub>9</sub>, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

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

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988]

**§ 866.5250 Complement C<sub>1</sub> inhibitor (inactivator) immunological test system.**

(a) *Identification*. A complement C<sub>1</sub> inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C<sub>1</sub> inhibitor (a plasma protein) in serum. Complement C<sub>1</sub> inhibitor occurs normally in plasma and blocks the action of the C<sub>1</sub> component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C<sub>1</sub> inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

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

**§ 866.5260 Complement C<sub>3b</sub> inactivator immunological test system.**

(a) *Identification*. A complement C<sub>3b</sub> inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C<sub>3b</sub> inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C<sub>3b</sub> inactivator aids in the diagnosis of inherited antibody dysfunction.

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

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**§ 866.5270 C-reactive protein immunological test system.**

(a) *Identification*. A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

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

**§ 866.5320 Properdin factor B immunological test system.**

(a) *Identification*. A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and other body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and other body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermatitis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

(b) *Classification*. Class II (special 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 63 FR 59227, Nov. 3, 1998]

**§ 866.5330 Factor XIII, A, S, immunological test system.**

(a) *Identification*. A factor XIII, A, S, immunological test system is a device

that consists of the reagents used to measure by immunochemical techniques the factor XIII (a bloodclotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.

(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. This exemption does not apply to factor deficiency tests classified under § 864.7290 of this chapter.

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

**§ 866.5340 Ferritin immunological test system.**

(a) *Identification*. A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an iron-storing protein) in serum and other body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

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

**§ 866.5350 Fibrinopeptide A immunological test system.**

(a) *Identification*. A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and other body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

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

**§ 866.5360 Cohn fraction IV immunological test system.**

(a) *Identification*. A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha*- and *beta*- globulins, used as a raw material for the production of pure *alpha*- or *beta*- globulins. Measurement of specific *alpha*- or *beta*- globulins aids

in the diagnosis of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of *alpha*-1-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders, and kidney 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; 47 FR 56846, Dec. 21, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

**§ 866.5370 Cohn fraction V immunological test system.**

(a) *Identification*. A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

(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]

**§ 866.5380 Free secretory component immunological test system.**

(a) *Identification*. A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis or repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures