§ 866.5230 Colostrum immunological test system.
(a) Identification. A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.
(b) Classification. Class I (general controls).

§ 866.5240 Complement components immunological test system.
(a) Identification. A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C1r, C1s, C2, C3, C4, C5, C6, C7, C8, and C9, 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 C2 inhibitor (inactivator) immunological test system.
(a) Identification. A complement C2 inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C2 inhibitor (a plasma protein) in serum. Complement C2 inhibitor occurs normally in plasma and blocks the action of the C1 component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C2 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 C3b inactivator immunological test system.
(a) Identification. A complement C3b inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C3b inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C3b inactivator aids in the diagnosis of inherited antibody dysfunction.
(b) Classification. Class II (performance standards).

§ 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 the properdin factor B (a plasma protein) in serum. Properdin factor B occurs normally in plasma and is involved in the formation of the properdin membrane attack complex which leads to the destruction of pathogenic cells. Measurement of properdin factor B aids in the diagnosis of certain immune disorders.
(b) Classification. Class II (performance standards).
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§ 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-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.