§ 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). 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.


§ 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 C\textsubscript{1q}, C\textsubscript{1r}, C\textsubscript{1s}, C\textsubscript{2}, C\textsubscript{3}, C\textsubscript{4}, C\textsubscript{5}, C\textsubscript{6}, C\textsubscript{7}, C\textsubscript{8}, and C\textsubscript{9}, 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\textsubscript{2} inhibitor (inactivator) immunological test system.

(a) Identification. A complement C\textsubscript{1} inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C\textsubscript{1} inhibitor (a plasma protein) in serum. Complement C\textsubscript{1} inhibitor occurs normally in plasma and blocks the action of the C\textsubscript{1} component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C\textsubscript{1} 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\textsubscript{3b} inactivator immunological test system.

(a) Identification. A complement C\textsubscript{3b} inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C\textsubscript{3b} inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C\textsubscript{3b} 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