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aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body’s own tissues).

(b) Classification Class II (performance standards).

§ 866.5130 Alpha-1-antitrypsin immunological test system.

(a) Identification. An alpha-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

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

§ 866.5150 Bence-Jones proteins immunological test system.

(a) Identification. A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom’s macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(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 66 FR 38793, July 25, 2001]

§ 866.5170 Breast milk immunological test system.

(a) Identification. A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(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.


§ 866.5180 Fecal calprotectin immunological test system.

(a) Identification. A fecal calprotectin immunological test system is an in vitro diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for in vitro diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn’s disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

(b) Classification. Class II (special controls). The special control for these devices is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Fecal