measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

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

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(a) Identification. An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(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.


§ 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.

(a) Identification. The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for standalone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: CFTR Gene Mutation Detection System.” See §866.1(e) for the availability of this guidance document.

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Subpart G—Tumor Associated Antigen immunological Test Systems

§ 866.6010 Tumor-associated antigen immunological test system.

(a) Identification. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) Classification. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,” and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.