Food and Drug Administration, HHS

§ 866.5715 Plasminogen immunological test system.
(a) Identification. A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, other body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

(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.

§ 866.5735 Prothrombin immunological test system.
(a) Identification. A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of blood-clotting disorders.

(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.

§ 866.5750 Radioallergosorbent (RAST) immunological test system.
(a) Identification. A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

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

§ 866.5765 Retinol-binding protein immunological test system.
(a) Identification. A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

(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.

§ 866.5775 Rheumatoid factor immunological test system.
(a) Identification. A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in serum, other body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

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

§ 866.5785 Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test systems.
(a) Identification. The Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test system is an in vitro diagnostic device that consists of the reagents used to measure, by immunochemical techniques, antibodies to S. cerevisiae (baker’s or brewer’s yeast) in human serum or plasma. Detection of S. cerevisiae antibodies may aid in the diagnosis of Crohn’s disease.
(b) **Classification.** Class II (special controls). The special control is FDA’s “Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications.”

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§ 866.5800 Seminal fluid (sperm) immunological test system.

(a) **Identification.** A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.

(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.


§ 866.5820 Systemic lupus erythematosus immunological test system.

(a) **Identification.** A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies in serum and other body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person’s own antibodies).

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

§ 866.5840 Transferrin immunological test system.

(a) **Identification.** A transferrin immunological test system is a device that consists of the reagents used to 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).

§ 866.5860 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 proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.