§ 862.1020 Acid phosphatase (total or prostatic) test system.

(a) Identification. An acid phosphatase (total or prostatic) test system is a device intended to measure the activity of the acid phosphatase enzyme in plasma and serum.

(b) Classification. Class II.

§ 862.1025 Adrenocorticotropic hormone (ACTH) test system.

(a) Identification. An adrenocorticotropic hormone (ACTH) test system is a device intended to measure adrenocorticotropic hormone in plasma and serum. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushing’s syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

(b) Classification. Class II.

§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.

(a) Identification. An alanine amino transferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

(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 §862.9.