

**§ 862.1050**

**21 CFR Ch. I (4–1–10 Edition)**

(b) *Classification*. Class II.

**§ 862.1050 Alkaline phosphatase or isoenzymes test system.**

(a) *Identification*. An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification*. Class II.

**§ 862.1055 Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.**

(a) *Identification*. A newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry is a device that consists of stable isotope internal standards, control materials, extraction solutions, flow solvents, instrumentation, software packages, and other reagents and materials. The device is intended for the measurement and evaluation of amino acids, free carnitine, and acylcarnitine concentrations from newborn whole blood filter paper samples. The quantitative analysis of amino acids, free carnitine, and acylcarnitines and their relationship with each other provides analyte concentration profiles that may aid in screening newborns for one or more inborn errors of amino acid, free carnitine, and acyl-carnitine metabolism.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry." See § 862.1(d) for the availability of this guidance document.

[69 FR 68255, Nov. 24, 2004]

**§ 862.1060 Delta-aminolevulinic acid test system.**

(a) *Identification*. A delta-aminolevulinic acid test system is a device intended to measure the level of delta-aminolevulinic acid (a precursor of porphyrin) in urine. Delta-

aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including delta-aminolevulinic acid).

(b) *Classification*. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

**§ 862.1065 Ammonia test system.**

(a) *Identification*. An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification*. Class I.

**§ 862.1070 Amylase test system.**

(a) *Identification*. An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification*. Class II.

**§ 862.1075 Androstenedione test system.**

(a) *Identification*. An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Androstenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(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.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

**§ 862.1080 Androsterone test system.**

(a) *Identification*. An androsterone test system is a device intended to