§ 864.7060  Antithrombin III assay.

(a) Identification. An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

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

[45 FR 60610, Sept. 12, 1980]

§ 864.7100  Red blood cell enzyme assay.

(a) Identification. Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible for a patient’s hereditary hemolytic anemia.

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

[45 FR 60610, Sept. 12, 1980]

§ 864.7140  Activated whole blood clotting time tests.

(a) Identification. An activated whole blood clotting time test is a device, used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.

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

[45 FR 60611, Sept. 12, 1980]

§ 864.7250  Erythropoietin assay.

(a) Identification. A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.

(b) Classification. Class II. The special control for this device is FDA’s “Document for Special Controls for Erythropoietin Assay Premarket Notification (510(k)s).”


§ 864.7275  Euglobulin lysis time tests.

(a) Identification. A euglobulin lysis time test is a device that measures the length of time required for the lysis (dissolution) of a clot formed from fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysis enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

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

[45 FR 60612, Sept. 12, 1980]

§ 864.7280  Factor V Leiden DNA mutation detection systems.

(a) Identification. Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems are devices that consist of different reagents and instruments which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection of the Factor V Leiden mutation aids in the diagnosis of patients with suspected thrombophilia.

(b) Classification. Class II (special controls). The special control is FDA’s guidance entitled “Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.” (See §864.1(d) for the availability of this guidance document.)

[69 FR 12273, Mar. 16, 2004]

§ 864.7290  Factor deficiency test.

(a) Identification. A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor
deficiency such as hemophilia and the corresponding normal gene).

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

[45 FR 60613, Sept. 12, 1980]

§ 864.7300 Fibrin monomer paracoagulation test.

(a) **Identification.** A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).

(b) **Classification.** Class II. The special control for this device is FDA’s “In Vitro Diagnostic Fibrin Monomer Paracoagulation Test.”


§ 864.7320 Fibrinogen/fibrin degradation products assay.

(a) **Identification.** A fibrinogen/fibrin degradation products assay is a device used to detect and measure fibrinogen degradation products (protein fragments produced by the enzymatic action of plasmin on fibrinogen and fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).

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

[45 FR 60615, Sept. 12, 1980]

§ 864.7340 Fibrinogen determination system.

(a) **Identification.** A fibrinogen determination system is a device that consists of the instruments, reagents, standards, and controls used to determine the fibrinogen levels in disseminated intravascular coagulation (nonlocalized clotting within the blood vessels) and primary fibrinolysis (the dissolution of fibrin in a blood clot).

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

[45 FR 60615, Sept. 12, 1980]

§ 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.

(a) **Identification.** An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultraviolet kinetics.

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

[45 FR 60616, Sept. 12, 1980]

§ 864.7375 Glutathione reductase assay.

(a) **Identification.** A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.

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

[45 FR 60616, Sept. 12, 1980]

§ 864.7400 Hemoglobin A\textsubscript{2} assay.

(a) **Identification.** A hemoglobin A\textsubscript{2} assay is a device used to determine the hemoglobin A\textsubscript{2} content of human blood. The measurement of hemoglobin A\textsubscript{2} is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chains).

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

[45 FR 60617, Sept. 12, 1980]