§ 864.7415 Abnormal hemoglobin assay.

(a) *Identification.* An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.

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

[45 FR 60618, Sept. 12, 1980]

§ 864.7425 Carboxyhemoglobin assay.

(a) *Identification.* A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

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

[45 FR 60619, Sept. 12, 1980]

§ 864.7440 Electrophoretic hemoglobin analysis system.

(a) *Identification.* An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies normal and abnormal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.

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

[45 FR 60620, Sept. 12, 1980]

§ 864.7455 Fetal hemoglobin assay.

(a) *Identification.* A fetal hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells in the maternal circulation or to detect the elevated levels of fetal hemoglobin exhibited in cases of hemoglobin abnormalities such as thalassemia (a hereditary hemolytic anemia characterized by a decreased synthesis of one or more types of hemoglobin polypeptide chains). The hemoglobin determination may be made by methods such as electrophoresis, alkali denaturation, column chromatography, or radial immunodiffusion.

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

[45 FR 60620, Sept. 12, 1980]

§ 864.7470 Glycosylated hemoglobin assay.

(a) *Identification.* A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobins (A_{1a}, A_{1b}, and A_{1c}) in a patient's blood by a column chromatographic procedure. Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient.

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

[45 FR 60621, Sept. 12, 1980]

§ 864.7490 Sulfhemoglobin assay.

(a) *Identification.* A sulfhemoglobin assay is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, or gasometry.

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

[45 FR 60621, Sept. 12, 1980]

§ 864.7500 Whole blood hemoglobin assays.

(a) *Identification.* A whole blood hemoglobin assay is a device consisting or reagents, calibrators, controls, or photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia. This generic device category does not include automated hemoglobin systems.

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

[45 FR 60622, Sept. 12, 1980]

§ 864.7525 Heparin assay.

(a) *Identification.* A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures using the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

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

[45 FR 60623, Sept. 12, 1980]

§ 864.7660 Leukocyte alkaline phosphatase test.

(a) *Identification.* A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occuring in severe infections and polycythemia (increased total red cell mass).

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60623, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.7675 Leukocyte peroxidase test.

(a) *Identification.* A leukocyte peroxidase test is a device used to distinguish certain myeloid cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes, from lymphoid cells of the lymphatic system and erythroid cells of the red blood cell series on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60624, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.7695 Platelet factor 4 radioimmunoassay.

(a) *Identification.* A platelet factor 4 radioimmunoassay is a device used to measure the level of platelet factor 4, a protein released during platelet activation by radioimmunoassay. This device measures platelet activiation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery disease.

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

[45 FR 60625, Sept. 12, 1980; 46 FR 14890, Mar. 3, 1981]

§ 864.7720 Prothrombin consumption test.

(a) *Identification.* A prothrombin consumption tests is a device that measures the patient's capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

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

[45 FR 60625, Sept. 12, 1980]

§ 864.7735 Prothrombin-proconvertin test and thrombotest.

(a) *Identification.* The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.