

§ 864.7360

(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 A₂ assay.

(a) *Identification.* A hemoglobin A₂ assay is a device used to determine the hemoglobin A₂ content of human blood. The measurement of hemoglobin A₂ 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]

21 CFR Ch. I (4-1-10 Edition)

§ 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