§ 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 60621, Sept. 12, 1980]

§ 864.7470 Glycosylated hemoglobin assay.

(a) Identification. A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobin (HbA1a, HbA1b, and HbA1c) 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 60622, Sept. 12, 1980]

§ 864.7490 Sulfhemoglobin assay.

(a) Identification. A sulfhemoglobin assay is a device consisting of the reagents, calorimeters, 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 60623, Sept. 12, 1980]