Food and Drug Administration, HHS

§ 864.7400 Hemoglobin A<sub>2</sub> assay.

(a) Identification. A hemoglobin A<sub>2</sub> assay is a device used to determine the hemoglobin A<sub>2</sub> content of human blood. The measurement of hemoglobin A<sub>2</sub> 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).

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