§ 864.7720 Prothrombin consumption test.

(a) Identification. A prothrombin consumption test 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 60627, 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.

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

[45 FR 60628, Sept. 12, 1980]

§ 864.7750 Prothrombin time test.

(a) Identification. A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

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

[45 FR 60626, Sept. 12, 1980]

§ 864.7825 Sickle cell test.

(a) Identification. A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell trait or sickle cell diseases.

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

[45 FR 60629, Sept. 12, 1980]

Subpart I—Hematology Reagents

§ 864.8100 Bothrops atrox reagent.

(a) Identification. A Bothrops atrox reagent is a device made from snake venom and used to determine blood fibrinogen levels to aid in the evaluation of disseminated intravascular coagulation (nonlocalized clotting in the blood vessels) in patients receiving heparin therapy (the administration of the anticoagulant heparin in the treatment of thrombosis) or as an aid in the classification of dysfibrinogenemia...