§ 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 60627, Sept. 12, 1980]

§ 864.7875  Thrombin time test.

(a) Identification. A thrombin time test is a device used to measure fibrinogen concentration and detect fibrin or fibrinogen split products for the evaluation of bleeding disorders.

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

[45 FR 60628, Sept. 12, 1980]

§ 864.7900  Thromboplastin generation test.

(a) Identification. A thromboplastin generation test is a device used to detect and identify coagulation factor deficiencies and coagulation inhibitors.

(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.


§ 864.7925  Partial thromboplastin time tests.

(a) Identification. A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.

(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 (presence in the plasma of functionally defective fibrinogen).

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

[45 FR 60629, Sept. 12, 1980]