§ 864.7490 Sulfhemoglobin assay.
(a) Identification. A sulfhemoglobin assay is a device consisting of the re-
agents, calibrators, controls, and in-
strumentation 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 spectros-
cyopy, colorimetry, spectrophotometry,
or gasometry.
(b) Classification. Class II (performance
standards).
[45 FR 60621, Sept. 12, 1980]

§ 864.7500 Whole blood hemoglobin as-
says.
(a) Identification. A whole blood he-
emoglobin assay is a device consisting
or reagents, calibrators, controls, or
photometric or spectrophotometric in-
strumentation used to measure the he-
moglobin content of whole blood for
the detection of anemia. This generic
device category does not include auto-
mated hemoglobin systems.
(b) Classification. Class II (performance
standards).
[45 FR 60622, Sept. 12, 1980]

§ 864.7525 Heparin assay.
(a) Identification. A heparin assay is a
device used to determine the level of
the anticoagulant heparin in the pa-
tient’s circulation. These assays are
quantitative clotting time procedures
using the effect of heparin on activated
coaulation factor X (Stuart factor) or
procedures based on the neutralization
of heparin by protamine sulfate (a pro-
tein that neutralizes heparin).
(b) Classification. Class II (performance
standards).
[45 FR 60622, Sept. 12, 1980]

§ 864.7660 Leukocyte alkaline phos-
phatase test.
(a) Identification. A leukocyte alka-
line phosphatase test is a device used
to identify the enzyme leukocyte alka-
line phosphatase in neutrophilic
granulocytes (granular leukocytes
stainable by neutral dyes). The
(b) Classification. Class II (performance
standards).
3, 1981]

§ 864.7695 Platelet factor 4
radioimmunoassay.
(a) Identification. A platelet factor 4
radioimmunoassay is a device used to
measure the level of platelet factor 4, a
protein released during platelet activa-
tion by radioimmunoassay. This device
measures platelet activation, which
may indicate a coagulation disorder,
such as myocardial infarction or coro-
nary artery disease.
(b) Classification. Class II (performance
standards).
3, 1981]