§ 862.3240 Cholinesterase test system.

(a) Identification. A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) Classification. Class I.

§ 862.3250 Cocaine and cocaine metabolite test system.

(a) Identification. A cocaine and cocaine metabolite test system is a device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.

(b) Classification. Class II.

§ 862.3270 Codeine test system.

(a) Identification. A codeine test system is a device intended to measure codeine (a narcotic pain-relieving drug) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of codeine use or overdose and in monitoring levels of codeine to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3280 Clinical toxicology control material.

(a) Identification. A clinical toxicology control material is a device intended to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various single, and multi-analyte control materials.

(b) Classification. Class I (general controls). Except when used in donor screening, unassayed material is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §862.9.

§ 862.3300 Digitoxin test system.

(a) Identification. A digitoxin test system is a device intended to measure digitoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3320 Digoxin test system.

(a) Identification. A digoxin test system is a device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3350 Diphenylhydantoin test system.

(a) Identification. A diphenylhydantoin test system is a device intended to measure diphenylhydantoin, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3360 Drug metabolizing enzyme genotyping system.

(a) Identification. A drug metabolizing enzyme genotyping system is a device intended for use in testing deoxyribonucleic acid (DNA) extracted from clinical samples to identify the presence or absence of human genotypic markers encoding a drug metabolizing enzyme. This device is used as an aid in determining treatment.
choice and individualizing treatment
dose for therapeutics that are metabo-
lized primarily by the specific enzyme
about which the system provides

(b) Classification. Class II (special
controls). The special control is FDA’s
guidance document entitled “Class II
Special Controls Guidance Document:
Drug Metabolizing Enzyme Genotyping
Test System.” See §862.1(d) for the
availability of this guidance document.

§ 862.3380 Ethosuximide test system.

(a) Identification. An ethosuximide
test system is a device intended to
measure ethosuximide, an antiepileptic
drug, in human specimens. Measure-
ments obtained by this device are used
in the diagnosis and treatment of
ethosuximide overdose and in moni-
toring levels of ethosuximide to ensure
appropriate therapy.

(b) Classification. Class II.

§ 862.3450 Gentamicin test system.

(a) Identification. A gentamicin test
system is a device intended to measure
gentamicin, an antibiotic drug, in
human specimens. Measurements ob-
tained by this device are used in the di-
agnosis and treatment of gentamicin
overdose and in monitoring levels of
gentamicin to ensure appropriate ther-
apy.

(b) Classification. Class II.

§ 862.3520 Kanamycin test system.

(a) Identification. A kanamycin test
system is a device intended to measure
kanamycin, an antibiotic drug, in plas-
ma and serum. Measurements obtained
by this device are used in the diagnosis
and treatment of kanamycin overdose
and in monitoring levels of kanamycin
to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3550 Lead test system.

(a) Identification. A lead test system
is a device intended to measure lead, a
heavy metal, in blood and urine. Meas-
urements obtained by this device are
used in the diagnosis and treatment of
lead poisoning.

(b) Classification. Class II.

§ 862.3555 Lidocaine test system.

(a) Identification. A lidocaine test sys-
tem is a device intended to measure
lidocaine, an antiarrythmic and anticonvulsant drug, in serum and
plasma. Measurements obtained by this
device are used in the diagnosis and
treatment of lidocaine overdose or in
monitoring levels of lidocaine to en-
sure appropriate therapy.

(b) Classification. Class II.

§ 862.3555 Lithium test system.

(a) Identification. A lithium test sys-
tem is a device intended to measure
lithium (from the drug lithium car-
bonate) in serum or plasma. Measure-
ments of lithium are used to assure
that the proper drug dosage is adminis-
tered in the treatment of patients with
mental disturbances, such as manic-de-
pressive illness (bipolar disorder).

(b) Classification. Class II.

§ 862.3580 Lysergic acid diethylamide
(LSD) test system.

(a) Identification. A lysergic acid
diethylamide (LSD) test system is a
device intended to measure lysergic
acid diethylamide, a hallucinogenic
drug, in serum, urine, and gastric con-
tents. Measurements obtained by this
device are used in the diagnosis and
treatment of LSD use or overdose.

(b) Classification. Class II.

§ 862.3600 Mercury test system.

(a) Identification. A mercury test sys-
tem is a device intended to measure
mercury, a heavy metal, in human
specimens. Measurements obtained by
this device are used in the diagnosis and
treatment of mercury poisoning.

(b) Classification. Class I.

§ 862.3610 Methamphetamine test sys-
tem.

(a) Identification. A methamphetamine
test system is a device intended to measure methamphetamine, a cen-
tral nervous system stimulating drug,
in serum, plasma, and urine. Measure-
ments obtained by this device are used
in the diagnosis and treatment of
methamphetamine use or overdose.

(b) Classification. Class II.