§ 862.3030 Acetaminophen test system.
(a) Identification. An acetaminophen test system is a device intended to measure acetaminophen, an analgesic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.
(b) Classification. Class II.

§ 862.3035 Amikacin test system.
(a) Identification. An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3040 Alcohol test system.
(a) Identification. An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.
(b) Classification. Class II.

§ 862.3050 Breath-alcohol test system.
(a) Identification. A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
(b) Classification. Class I.

§ 862.3080 Breath nitric oxide test system.
(a) Identification. A breath nitric oxide test system is a device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient’s response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. A breath nitric oxide test system combines chemiluminescence detection of nitric oxide with a pneumotachograph, display, and dedicated software.
(b) Classification. Class II (special controls). The special control is FDA’s guidance entitled “Class II Special Controls Guidance Document: Breath Nitric Oxide Test System.” See §862.1(d) for the availability of this guidance document.

§ 862.3030—Breath nitric oxide test system.
[68 FR 40127, July 7, 2003]

§ 862.3100 Amphetamine test system.
(a) Identification. An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3110 Antimony test system.
(a) Identification. An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.
(b) Classification. Class I.

§ 862.3120 Arsenic test system.
(a) Identification. An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements
obtained by this device are used in the diagnosis and treatment of arsenic poisoning.

(b) Classification. Class I.

§ 862.3150 Barbiturate test system.

(a) Identification. A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturate to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3170 Benzodiazepine test system.

(a) Identification. A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, chlorzepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose and in monitoring levels of benzodiazepines to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3200 Clinical toxicology calibrator.

(a) Identification. A clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.). (See also §862.2 in this part.)

(b) Classification. Class II.

§ 862.3220 Carbon monoxide test system.

(a) Identification. A carbon monoxide test system is a device intended to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.

(b) Classification. Class I.

§ 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
§ 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 metabolized primarily by the specific enzyme about which the system provides genotypic information.

(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.

[70 FR 11867, Mar. 10, 2005]

§ 862.3380 Ethosuximide test system.

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

(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 plasma 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. Measurements 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 system is a device intended to measure lidocaine, an antiarrhythmic 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 ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3560 Lithium test system.

(a) Identification. A lithium test system is a device intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive 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 contents. 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 system 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 system.

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

(b) Classification. Class II.

§ 862.3620 Methadone test system.

(a) Identification. A methadone test system is a device intended to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone use or overdose and to determine compliance with regulations in methadone maintenance treatment.

(b) Classification. Class II.

§ 862.3630 Methaqualone test system.

(a) Identification. A methaqualone test system is a device intended to measure methaqualone, a hypnotic and sedative drug, in urine. Measurements obtained by this device are used in the diagnosis and treatment of methaqualone use or overdose.

(b) Classification. Class II.

§ 862.3640 Morphine test system.

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

(b) Classification. Class II.

§ 862.3645 Neuroleptic drugs radioreceptor assay test system.

(a) Identification. A neuroleptic drugs radioreceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of such drugs.

(b) Classification. Class II.

§ 862.3650 Opiate test system.

(a) Identification. An opiate test system is a device intended to measure
any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, mor-
phine glucoronide, heroin, codeine, nalorphine, and meperidine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3660 Phenobarbital test system.
(a) Identification. A phenobarbital test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3670 Phenothiazine test system.
(a) Identification. A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.

(b) Classification. Class II.

§ 862.3680 Primidone test system.
(a) Identification. A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3700 Propoxyphene test system.
(a) Identification. A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3750 Quinine test system.
(a) Identification. A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) Classification. Class I.


§ 862.3830 Salicylate test system.
(a) Identification. A salicylate test system is a device intended to measure salicylates, a class of analgesic, anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3840 Sirolimus test system.
(a) Identification. A sirolimus test system is a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.

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

[69 FR 58259, Sept. 30, 2004]

§ 862.3850 Sulfonamide test system.
(a) Identification. A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide
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overdose and in monitoring sulfonamide levels to ensure appropriate therapy. 
(b) Classification. Class I.

§ 862.3870 Cannabinoid test system.
(a) Identification. A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include delta-9-tetrahydrocannabinol, cannabidiol, cannabinoil, and cannabinochrome. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use. 
(b) Classification. Class II.

§ 862.3880 Theophylline test system.
(a) Identification. A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy. 
(b) Classification. Class II.

§ 862.3900 Tobramycin test system.
(a) Identification. A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy. 
(b) Classification. Class II.

§ 862.3910 Tricyclic antidepressant drugs test system.
(a) Identification. A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy. 
(b) Classification. Class II.

§ 862.3950 Vancomycin test system.
(a) Identification. A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy. 
(b) Classification. Class II.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

Subpart A—General Provisions

Sec. 864.1 Scope.
864.3 Effective dates of requirement for premarket approval.
864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

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864.1850 Dye and chemical solution stains.
864.1860 Immunohistochemistry reagents and kits.

Subpart C—Cell and Tissue Culture Products
864.2240 Cell and tissue culture media and components.
864.2260 Chromosome culture kit.
864.2280 Cultured animal and human cells.
864.2360 Mycoplasma detection media and components.
864.2800 Animal and human sera.
864.2875 Balanced salt solutions or formulations.

Subpart D—Pathology Instrumentation and Accessories
864.3010 Tissue processing equipment.
864.3250 Specimen transport and storage container.
864.3260 OTC test sample collection systems for drugs of abuse testing.
864.3300 Cytocentrifuge.
864.3400 Device for sealing microsections.
864.3600 Microscopes and accessories.