

§ 862.3555

21 CFR Ch. I (4–1–11 Edition)

§ 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