

Drugs of Abuse Integrated Strip/Card/Device/Cup(Urine)

Package Insert for testing of any combination of the following drugs:
ACE/AMP/BAR/BUP/BZO/COC/COT/EDDP/ETG/FYL/HMO/K2/KET/LS/D/6-MAM/MDMA/MET/
MOP/MPD/MQL/MTD/OPI/OXY/PCP/PPX/TCA/THC/TRA/ZOL

CLIA Waived/INTENDED

INTENDED USE

Drug Tests (Strip/Card/Device/Cup) is a rapid visual immunoassay for the qualitative, presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-off (ng/mL)
ACE	Acetaminophen	5000
AMP	d-Amphetamine	1000/500/300
BAR	Secobarbital	300
BUP	BUP-3-D-Glucuronide	10/5
BZO	Oxazepam	300/200/100
COC	Benzoylcegonine	300/200/150/100
COT	(-)-Cotinine	600/300/200
EDDP	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300/100
ETG	Ethyl Glucuronide	500
FYL	Norfentanyl/Fentanyl	200/10
HMO	Hydromorphone	250
K2	JWH-073/JWH-018	50/25
KET	Ketamine	1,000
LS/D	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	50
6-MAM	6-Monoacetylmorphine	10
MDMA	3,4-Methylenedioxy-MET	1000/500
MET	Methamphetamine	1000/500/300
MOR	Morphine	300/200/100
MPD	Methylphenidate	300
MQL	Methaqualone	300
MTD	Methodone	300
OPI	Morphine	2000/1000
OXY	Oxycodone	300/100
PCP	Phencyclidine	25
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-9-COOH	200/150/50/25
TRA	Tramadol	300/100
ZOL	Zolpidem	50
ALC	Alcohol	0.02%

The Integrated Split Specimen Cup (Urine) can also come with adulteration strips listed below:

Adulteration (StripA)	Oxidants / Specific Gravity / PH
Adulteration (StripB)	Nitrite / Glutaraldehyde / Creatinine

PRINCIPLE

Drug Tests (Strip/Card/Device/Cup) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the corresponding drug strip. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as Creatinine, pH, and Specific Gravity and to detect the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine. A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

Nitrite (NIT): Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH. Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLUT): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening results by disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in urine; therefore, detection of Glutaraldehyde in a urine specimen is generally indicates adulteration.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate that the specimen has been altered.

Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant. Normal human urine should not contain Oxidants or PCC.

MATERIALS

Materials Provided

Test strip/card/device/cup
Package insert

Materials Required but Not provided

Timer
Centrifuge
Positive and negative controls

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all **specimens** as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Drugs of Abuse Integrated Cup(Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

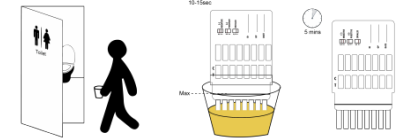
For Drug Test Strip:

- Equilibrate the test strip, urine specimens or external controls to room temperature (15-30°C) prior to testing.
- Remove the test strip from the sealed pouch and dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
- Place the test strip on a flat dry surface.
- Read the results at 5 minutes. Do not interpret the result after 10 minutes.



For Drug Test Card:

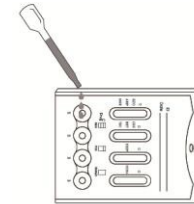
- Equilibrate the test card, or the test strip, urine specimens or external controls to room temperature(15-30°C) prior to testing.
- Removing the test card from the sealed pouch and dip the card into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip(s) of the test card just below the top line of the wave line on the test strips; do not dip the card above the top line.
- Place the test card or the test strip on a flat dry surface.
- Read the adulteration strips between 3 to 5 minutes (when applicable) by comparing the colors in the adulteration pads to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommended not to interpret the drug test results and suggest you to retest the urine by using another specimen.
- Read the results at 5 minutes. Do not interpret the result after 10 minutes.



For Drug Test Device:

Allow the test device, urine specimen, and/or controls to equilibrate to room temperature(15-30°C) prior to testing.

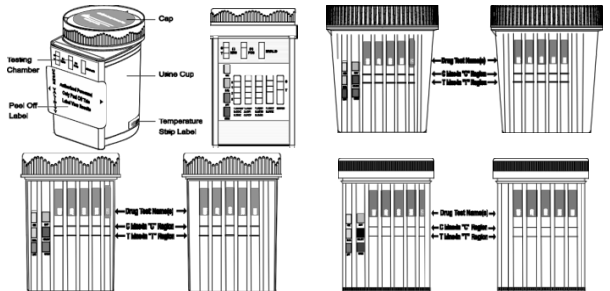
- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. The result should be read at 5. Do not interpret the result after 10 minutes. It is important that the background is clear before the result is read.



For Drug Test Cup :

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use if stored at refrigerated temperatures. Remove the cup from sealed pouch and use it as soon as possible.

- Donor dates and initials body label.
- Donor provides a urine specimen in the cup and screws cap on to it. Start timer immediately.
- Operator checks the cap for tightness.
- Remove the peel-off label.
- Check the temperature strip label at 2-4 minutes after specimen collection for the fresh urine specimen. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
- Drug test results are indicated by the presence or absence of colored band(s) in the result area of the test strips. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
- Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.
- For the adulteration, compared with the color card, and the results should be read at 2 minutes, do not interpret the result after 5 minutes.



C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Drug Tests (Strip/Card/Device/Cup) identified positive results at 5 minutes.

Acetaminophen 5000 related compounds			
		Mephentermine hemisulfate salt	15,625
Acetaminophen	5,000	Methadone	50,000
Acetophenetidine	7,500	D-Methamphetamine	12,500
Amphetamine 1000 related compounds			
d-Amphetamine	1,000	3,4-Methylenedioxyethylamphetamine	25,000
l-Amphetamine	>100,000	Nordoxepin hydrochloride	25,000
d-methamphetamine	>100,000	Phencyclidine	5,000
l-methamphetamine	>100,000	Promazine	8,000
3,4-Methylenedioxyamphetamine	1,250	Promethazine	25,000
3,4-Methylenedioxy-methamphetamine	>100,000	LSD 50 related compounds	
3,4-Methylenedioxyethylamphetamine	>100,000	Lysergic acid diethylamide	50
3,4-Methylenedioxyethylamphetamine	>100,000	K2 25 related compounds	
Paramethoxyamphetamine	625	JWH-018-5-Pentanoic acid	25
Phentermine	1,250	JWH-073-4-Pentanoic acid	25
Tyramine	>100,000	Ecstasy 500 related compounds	
Amphetamine 500 related compounds			
d-Amphetamine	500	3,4-Methylenedioxy-methamphetamine	500
l-Amphetamine	50,000	d-Amphetamine	>100,000
3,4-Methylenedioxyamphetamine	625	l-Amphetamine	>100,000
Phentermine	1,250	d-methamphetamine	>100,000
Paramethoxyamphetamine	625	l-methamphetamine	>100,000
Tyramine	>100,000	3,4-Methylenedioxyamphetamine	2,500
Amphetamine 300 related compounds			
d-Amphetamine	300	3,4-Methylenedioxyethylamphetamine	156
l-Amphetamine	50,000	Paramethoxyamphetamine	50,000
Mephentermine hemisulfate salt	>100,000	Paramethoxymethamphetamine	10,000
3,4-Methylenedioxyamphetamine	625	Ecstasy 1000 related compounds	
Phentermine	625	3,4-Methylenedioxy-methamphetamine	1,000
Paramethoxyamphetamine (PMA)	625	d-Methamphetamine	1,000
Paramethoxymethamphetamine (PMA)	>100,000	Chloroquine	25,000
Tyramine	>100,000	Fenfluramine	12,500
Barbiturates 300 related compounds			
		Mephentermine hemisulfate salt	31,250
Secobarbital	300	3,4-Methylenedioxyethylamphetamine	50,000
Allobarbital	1,250	3,4-Methylenedioxy-methamphetamine	313
Alphenal	625	Paramethoxymethamphetamine	625
Amobarbital	625	(-)-Ephedrine	4,000
Aprobarbital	188	Methamphetamine 500 related compounds	
Butabarbital	94	d-Methamphetamine	500
Butalbital	2,500	Chloroquine	12,500
Butethal	200	Fenfluramine	12,500
Cyclopentobarbital	400	l-Methamphetamine	3,125
Pentobarbital	1,000	Mephentermine hemisulfate salt	25,000
Phenobarbital	300	MDEA	12,500
Buprenorphine 10 related compounds			
Buprenorphine	10	MDMA	1875
Buprenorphine-3-β-D-Glucuronide	10	PMMA	625
		(-)-Ephedrine	2,000
Norbuprenorphine	50	Methamphetamine 300 related compounds	
Norbuprenorphine-3-β-D-Glucuronide	100	d-Methamphetamine	300
Buprenorphine 5 related compounds			
Buprenorphine	5	Chloroquine	7,500
Buprenorphine-3-β-D-Glucuronide	5	Fenfluramine	12,500
Norbuprenorphine	25	l-Methamphetamine	10,000
Norbuprenorphine-3-β-D-Glucuronide	50	Mephentermine hemisulfate salt	31,250
		MDEA	50,000
Benzodiazepines 300 related compounds			
		MDMA	313

Oxazepam	300	PMMA	625
Alprazolam	125	(-)-Ephedrine	2,000
Bromazepam	625	Morphine 300 related compounds	
Chlordiazepoxide	2500	Morphine	300
Clobazam	63	Acetylcodeine	150
Clonazepam	2500	Buprenorphine	3,125
Clorazepate	3330	Codeine	250
Desalkflurazepam	250	Diacetyl Morphin	250
Diazepam	250	Dihydrocodeine	586
Estazolam	5000	Ethylmorphine	200
Fentanyl	>100,000	Hydrocodone	12,500
Flunitrazepam	375	Hydromorphone	12,500
Flurazepam	>100,000	6-Monoacetylmorphine	250
Lorazepam	1250	Morphine-3-β-glucuronid	2,500
Lormetazepam	1250	Nalorphine	25,000
Medazepam	>100,000	Thebaine	25,000
Midazolam	>100,000	Morphine 200 related compounds	
Nitrazepam	25000	Morphine	200
Norchlordiazepoxide	250	Acetylcodeine	100
Nordiazepam	500	Buprenorphine	2,000
Prazepam	>100,000	Codeine	170
Temazepam	63	Diacetyl Morphin	168
Triazolam	5000	Dihydrocodeine	395
Benzodiazepines 200 related compounds			
Oxazepam	200	Ethylmorphine	135
Alprazolam	83	Hydrocodone	8,350
Bromazepam	417	Hydromorphone	8,350
Chlordiazepoxide	1,667	6-Monoacetylmorphine	170
Clobazam	42	Morphine-3-β-glucuronid	1,670
Clonazepam	1,667	Nalorphine	16,666
Clorazepate	2,220	Thebaine	16,666
Desalkflurazepam	167	Morphine 100 related compounds	
Diazepam	167	Morphine	100
Estazolam	3,333	Codeine	100
Fentanyl	>100,000	Diacetylmorphine (Heroin)	100
Flunitrazepam	250	Ethylmorphine	100
Flurazepam	>100,000	Hydromorphone	500
Lorazepam	833	Hydrocodone	500
Lormetazepam	833	6-Monoacetylmorphine	100
Medazepam	>100,000	Morphine-3-β-d-glucuronide	2,000
Midazolam	>100,000	Oxycodone	20,000
Nitrazepam	16,667	Oxymorphone	20,000
Norchlordiazepoxide	167	Promethazine	>100,000
Nordiazepam	333	Rifampicine	8,400
Prazepam	>100,000	Thebaine	8,400
Temazepam	42	Trimipramine	20,000
Triazolam	3,333	MPD 300 related compounds	
Benzodiazepines 100 related compounds			
Oxazepam	100	Methaqualone	300
Alprazolam	42	Amitriptyline	50,000
Bromazepam	208	Carbamazepine	20,000
Chlordiazepoxide	833	Nortriptyline	50,000
Clobazam	21	Phenytion	40,000
Clonazepam	833	Theophylline	40,000
Clorazepate	1,110	Methadone 300 related compounds	
Desalkflurazepam	83	Methadone	300
Diazepam	83	(-)-alpha-methadol	2,000
Estazolam	1,667	Opiates 2000 related compounds	
Fentanyl	>100,000	Morphine	2,000
Flunitrazepam	125	Acetylcodeine	1,563
Flurazepam	>100,000	Buprenorphine	25,000
Lorazepam	417	Codeine	500
Lormetazepam	417	Diacetylmorphine (Heroin)	1,250

Medazepam	>100,000	Dihydrocodeine	1,563
Midazolam	>100,000	Merperidine	>100,000
Nitrazepam	8,333	Ethylmorphine	800
Norchlordiazepoxide	833	Hydromorphone	25,000
Nordiazepam	167	Hydrocodone	50,000
Prazepam	>100,000	6-Monoacetylmorphine (6-MAM)	1,250
Temazepam	21	Morphine-3-β-d-glucuronide	12,500
Triazolam	1,667	Nalorphine Hydrochloride	>100,000
Cocaine 300 related compounds			
		Oxycodone	>100,000
Benzoylcegonine	300	Oxymorphone	>100,000
Cocaine	1,000	Rifampicine	>100,000
Ecgonine	100,000	Thebaine	50,000
Ecgonine Methyl Ester	>100,000	Opiates 1000 related compounds	
Cocaine 200 related compounds			
		Morphine	1,000
Cocaine 150 related compounds			
		Oxycodone 300 related compounds	
Benzoylcegonine	200	Oxycodone	300
Cocaine	125	Hydrocodone	75,000
Ecgonine	5,000	Hydromorphone	>100,000
Ecgonine Methyl Ester	>100,000	Naloxone	>100,000
Cocaine 100 related compounds			
		Oxymorphone	750
Benzoylcegonine	150	Oxycodone 100 related compounds	
Cocaine	125	Oxycodone	100
Ecgonine	10000	Hydrocodone	25,000
Ecgonine Methyl Ester	>10000	Hydromorphone	50,000
Cotinine 600 related compounds			
		Oxymorphone	250
(-)-Cotinine	600	Phencyclidine 25 related compounds	
Cotinine 300 related compounds			
		Phencyclidine	25
(-)-Cotinine	300	Hydrocodone	>100,000
(-)-Nicotine	9,375	Hydromorphone	>100,000
Cotinine 200 related compounds			
		4-hydroxyphencyclidine	75
(-)-Cotinine 300 related compounds			
		Propoxyphene 300 related compounds	
(-)-Cotinine	200	Propoxyphene	300
(-)-Nicotine	6,250	D-Norpropoxyphene	5,000
EDDP 100 related compounds			
		D-Norpropoxyphene	5,000
EDDP	100	Tricyclic Antidepressants related compounds	
Meperidine	>100,000	Nortriptyline HCl	1,000
Methadone	>100,000	Amitriptyline	1,500
Norfentanyl	>100,000	Clomipramine	>100,000
Phencyclidine	>100,000	Cyclobenzaprine	12,500
Promazine	50,000	Desipramine	188
Promethazine	25,000	Prozine	1,250
Prothipendyl	50,000	Trimipramine	>100,000
Prozine	12,500	6-Monoacetylmorphine 10 elated compounds	
EDDP 300 related compounds			
		6-Monoacetylmorphine	10
EDDP	300	Acetylcodeine	> 10,000
Meperidine	>100,000	Codeine	> 100,000
Methadone	>100,000	Diacetylmorphine	250
Norfentanyl	>100,000	Dihydrocodeine	> 100,000
Phencyclidine	>100,000	Ethylmorphine	> 10,000
Promazine	80,000	Morphine	1,0000
Promethazine	75,000	Morphine-3-glucuronide	1,000
Prothipendyl	80,000	Nalorphine	1,000
Prozine	37,500	Marijuana 200 related compounds	
ETG 500 related compounds			
		11-nor-A9-THC-9-COOH	200
Ethyl Glucuronide	500	Marijuana 150 related compounds	
Fentanyl 10 related compounds			
		11-nor-A9-THC-9-COOH	150
Fentanyl	10	11-nor-A8-THC-9-COOH	90
Norfentanyl	50	Δ8-Tetrahydrocannabinol	45,000
Fentanyl 200 related compounds			
		Δ9-Tetrahydrocannabinol	45,000
Fentanyl	200	Cannabinol	60,000
Norfentanyl	375	Marijuana 50 related compounds	
HMO 250 related compounds			
		11-nor-A9-THC-9-COOH	50
Hydromorphone	250	11-nor-A8-THC-9-COOH	50

Acetylcodeine	10,000	11-hydroxy- Δ 9-Tetrahydrocannabinol	50
Thebaine	25,000	Δ 8-Tetrahydrocannabinol	15,000
Nalorphine	12,500	Δ 9-Tetrahydrocannabinol	15,000
Morphine-3-glucuronid	2,500	Cannabinol	20,000
Morphine	5,000	Cannabidiol	>100,000
Hydrocodone	3,100	Marijuana 25 related compounds	
Ethylmorphine	5,000	11-nor- Δ 9-THC-9-COOH	25
Dihydrocodeine	25,000	11-nor- Δ 8-THC-9-COOH	15
Diacetyl Morphin	10,000	Δ 8-Tetrahydrocannabinol	7,500
Codeine	50,000	Δ 9-Tetrahydrocannabinol	7,500
Buprenorphine	10,000	Cannabinol	10,000
6-Monoacetylmorphine	10,000	Tramadol 300 related compounds	
K2 50 related compounds		Tramadol	300
JWH-018-5-Pentanoic acid	50	Tramadol 100 related compounds	
JWH-073-4-Butanoic acid	50	Tramadol	100
Ketamine 1000 related compounds		(+/-)Chlorpheniramine	50,000
Ketamine	1,000	Dimenhydrinate	50,000
Norketamine	1,000	Diphenhydramine	50,000
Dextromethorphan	500	Phencyclidine	50,000
Dextrorphan tartrate	500	(+)-Chlorpheniramine	>100,000
D-Norpropoxyphene	31,250	Zolpidem 50 related compounds	
EDDP	800	Zolpidem	50
Meperidine	12,500		
Doxepin	2,000		
Imipramine	2,500		
Maprotiline	750		
Nortriptyline	3,125		
Nordoxepin	500		
Opipramol	1,563		
Promazine	1,000		
Promethazine	6,250		
Prothipendyl	25,000		
Protryptiline	6,250		

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Drug Tests (Strip/Card/Device/Cup) when tested at concentrations up to 100 μ g/mL.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine
4-Dimethylaminoantipyrene	Dextrorphan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine (Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

LITERATURE REFERENCES

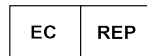
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GLOSSARY OF SYMBOLS

r	Catalog number	8	Temperature limitation
i	Consult instructions for use	L	Batch code
l	<i>In vitro</i> diagnostic medical device	e	Use by
m	Manufacturer	s	Do not reuse



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