

ToxCup[®] Drug Screen Cup Step-by Step Instructions

The ToxCup[®] Drug Screen Cup is an *in vitro* screening test for the rapid detection of multiple drugs in human urine at or above the following cutoff concentration:

THC	11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
COC	Benzoyllecgonine	150 ng/ml
OPI	Morphine	300 ng/ml
MET	d-Methamphetamine	500 ng/ml
AMP	d-Amphetamine	500 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-Methylenedioxymethamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The ToxCup[®] Drug Screen Cup is available in double drug analyte dip format. It is intended for prescription point-of-care use.

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the ToxCup[®] Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

This is a preliminary screening test that detects drug-of-abuse in urine at specified detection levels. To confirm preliminary positive results, a more specific method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used.



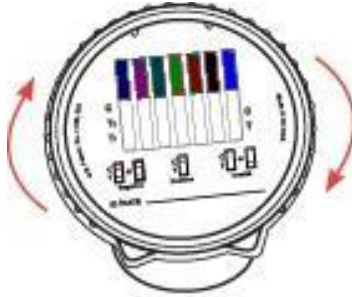
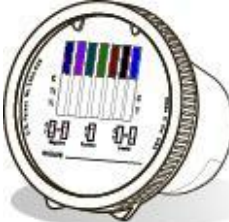

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STORAGE

Store the ToxCup[®] Drug Screen Cup at room temperature 59°F to 86°F (15°C to 30°C).

INSTRUCTION

<p>Step 1. Collect fresh urine in the specimen cup. Make sure the urine is above the minimum line.</p>	 <p>Min. Line →</p>	<p>Open foil pouch. Remove test lid from pouch. Discard desiccant.</p>	
	<p>Step 2. Twist the lid onto the cup. The cup lid must be closed tightly.</p>	<p>Step 3. Tilt the cup on its legs to activate the test. Read test results at 5 minutes. Do not read after 8 minutes.</p> 	 <p>5 minutes</p>

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INTERPRETATION OF RESULTS

Each strip contains two drug tests. C region shows validity of a test result. T1 region shows result for Test 1. T2 region shows result for Test 2.

For C region:

The appearance of a line indicates a valid result.

No line means an **Invalid** result. If a test strip does not have a line in the C region, test results are **Invalid** for both T1 and T2 on that strip.

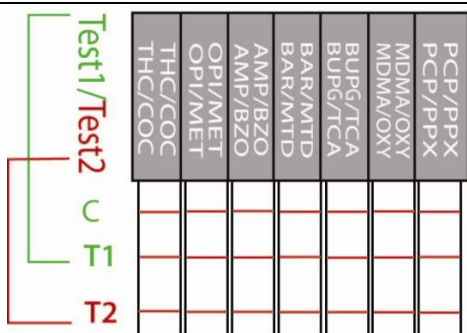
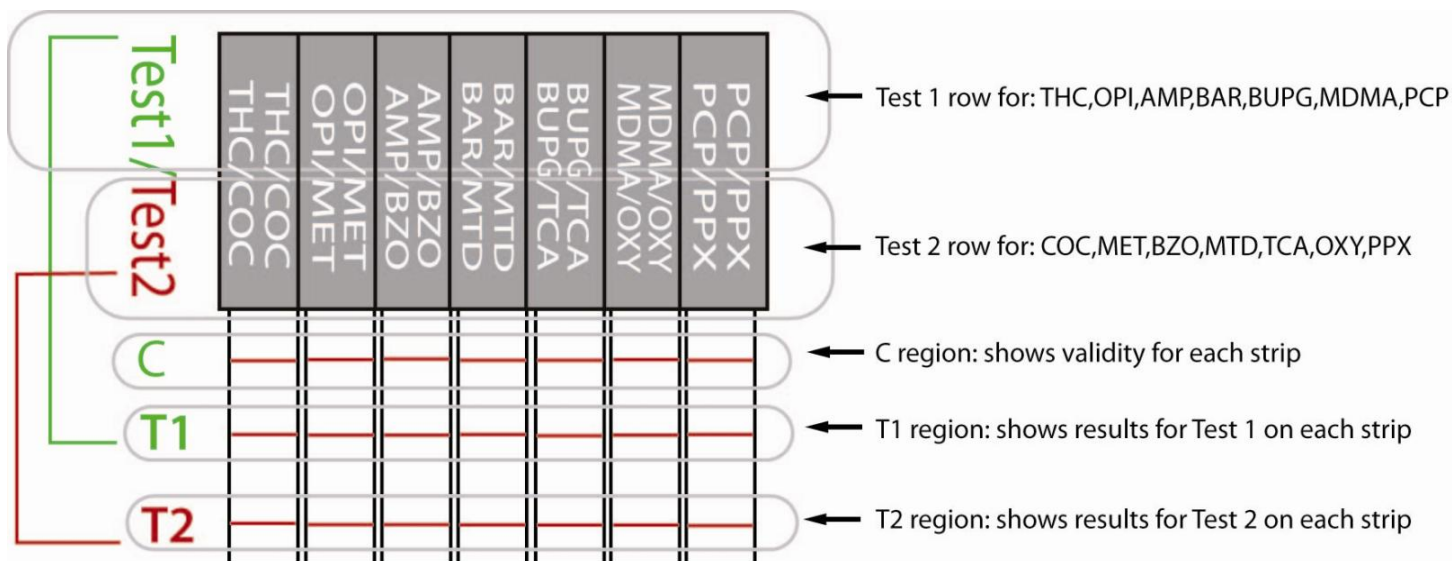
For T1 and T2 regions:

The appearance of a line indicates a **Negative** result.

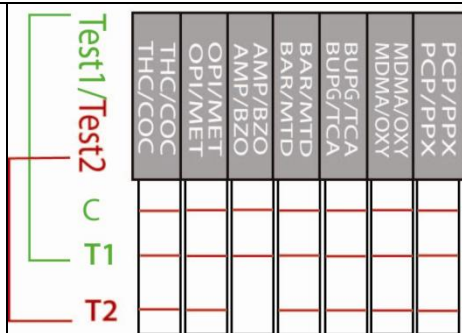
Note: **Any test line, even a very faint test line, is considered a negative result.**

No line indicates a **Preliminary Positive** result.

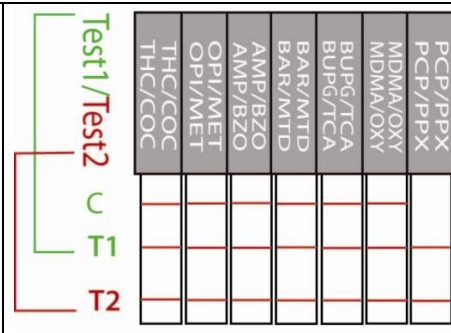
Note: **Any urine with preliminary positive results should be sent to a laboratory for confirmation.**



Example #1: There is a line appearing in both T1 and T2 regions on all test strips. Therefore, it is **Negative** for all tests.



Example #2: There is no line appearing in the T2 region on the third test strip. Therefore, it is **Preliminary Positive** for BZO test. All other tests are **Negative**.



Example #3: There is no line appearing in the C region on the seventh test strip. Therefore, it is **Invalid** for both PCP and PPX tests. All other tests are **Negative**.

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DETECTION LEVEL

Illicit Drug	Identifier	Cut-off Level¹
Marijuana	THC	50 ng/ml
Cocaine	COC	150 ng/ml
Opiates	OPI	300 ng/ml
Methamphetamine	MET	500 ng/ml
Amphetamine	AMP	500 ng/ml
Ecstasy	MDMA	500 ng/ml
Phencyclidine	PCP	25 ng/ml
Propoxyphene	PPX	300 ng/ml

Prescription Drug	Identifier	Cut-off Level¹
Benzodiazepines	BZO	300 ng/ml
Barbiturates	BAR	300 ng/ml
Methadone	MTD	300 ng/ml
Buprenorphine	BUPG	10 ng/ml
Tricyclic Antidepressants	TCA	1000 ng/ml
Oxycodone	OXY	100 ng/ml

¹ Cut-off level is the lowest drug concentration in the urine that can be detected by the ToxCup[®] Drug Screen Cup.

WARNINGS AND PRECAUTIONS

- ❖ For *in vitro* diagnostic use only (not for internal use).
- ❖ The test is for one time use only. It is not reusable.
- ❖ Do not use ToxCup[®] Drug Screen Cup after the expiration date printed on the pouch.
- ❖ Keep the ToxCup[®] Drug Screen Cup lid in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- ❖ Certain foods or medications may cause the test to give false results.
- ❖ Contaminated or tainted urine sample may give false results.
- ❖ Send specimen with preliminary positive or uncertain results to a laboratory for confirmation.
- ❖ Urine may contain infectious diseases. Always wear gloves and wash hands with soap after handling.
- ❖ Do not use this test if you are color-blind.

LIMITATIONS OF THE TEST

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances in certain foods and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce positive results, and Interference section for list of compounds that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain foods and/or medications.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, a new specimen should be collected.

For Professional Use

QUALITY CONTROL

Internal control: The ToxCup® Drug Screen Cup test device has built-in internal procedural controls. The appearance of the control band (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed. Additionally, the background color should become clear and provide distinct test result. If the control band (C) does not appear then the test is invalid. The test should be repeated using a new device.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. If external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

PERFORMANCE CHARACTERISTICS

PRECISION

A study was conducted at two laboratory and one physician offices in an effort to determine the precision of ToxCup® Drug Screen Cup over 12 or more consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Methylenedioxymethamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays by operators using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at the concentration of ± 50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

ACCURACY

The accuracy of the ToxCup® Drug Screen Cup was evaluated in comparison to the results from GC/MS or LC/MS analysis. Thirty-six (36) negative drug-free urine samples were collected from volunteer donors and tested with both the ToxCup® Drug Screen Cup and the GC/MS or LC/MS method. Of the 36 negative urine samples tested, all were found negative by both methods. Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC/MS or LC/MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Drug Test	GC/MS Neg.	GC/MS < -50%	GC/MS -50% to Cutoff	GC/MS Cutoff to +50%	GC/MS > +50%	% Agreement w/ GC/MS		
						Neg (-)	Pos (+)	
THC 50	Pos. (+)	0	0	1	6	35	97.7%	100%
	Neg. (-)	36	2	4	0	0		
COC 150	Pos. (+)	0	0	3	3	37	92.7%	97.6%
	Neg. (-)	36	0	2	1	0		
OPI 300	Pos. (+)	0	0	3	7	34	92.5%	100%
	Neg. (-)	36	0	1	0	0		
MET 500	Pos. (+)	0	0	0	5	67	100%	96.0%
	Neg. (-)	36	2	4	3	0		
AMP 500	Pos. (+)	0	0	2	5	36	95.1%	100%
	Neg. (-)	36	1	2	0	0		
BZO 300	Pos. (+)	0	0	3	4	39	92.5%	100%
	Neg. (-)	36	0	1	0	0		

Drug Test	GC/MS Neg.	GC/MS < -50%	GC/MS -50% to Cutoff	GC/MS Cutoff to +50%	GC/MS > +50%	% Agreement w/ GC/MS		
						Neg (-)	Pos (+)	
BAR 300	Pos. (+)	0	0	1	6	33	97.5%	95.1%
	Neg. (-)	36	0	3	2	0		
MTD 300	Pos. (+)	0	0	0	3	36	100%	97.5%
	Neg. (-)	36	0	4	1	0		
BUPG 10	Pos. (+)	0	0	1	4	38	97.5%	97.7%
	Neg. (-)	36	0	3	1	0		
TCA 1000	Pos. (+)	0	0	0	27	11	100%	92.7%
	Neg. (-)	36	0	4	3	0		
MDMA 500	Pos. (+)	0	0	1	3	40	97.5%	97.7%
	Neg. (-)	36	0	3	1	0		
OXY 100	Pos. (+)	0	0	2	6	38	95.2%	100%
	Neg. (-)	36	0	4	0	0		
PCP 25	Pos. (+)	0	0	0	3	36	100%	95.1%
	Neg. (-)	36	0	4	2	0		
PPX 300	Pos. (+)	0	0	2	4	36	95.0%	100%
	Neg. (-)	36	0	2	0	0		

SPECIFICITY

The specificity for the ToxCup® Drug Screen Cup was determined by testing various drugs, drug metabolites, structurally related compounds, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine. The effect of specimens with various pH (4.5–9) and specific gravity (1.005–1.030) ranges was also evaluated and found not to interfere with ToxCup® Drug Screen Cup.

The following compounds produced positive results when tested at or above the concentrations listed below.

AMP 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Amphetamine	500	Phentermine	1,000
l-Amphetamine	20,000	β-Phenylethylamine	80,000
d,l-3,4-MDA	1,500		

BAR 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Allobarbitol	1,500	Butalbital	300
Alphenal	400	Butethal	400
Amobarbital	1,500	Pentobarbital	400
Aprobarbital	400	Phenobarbital	400
Barbital	400	Secobarbital	300
Butabarbital	400		

BZO 300 ng/ml

Compound	ng/ml	Compound	ng/ml
α-Hydroxy Alprazolam	50	Lorazepam	1,500
Alprazolam	150	Lormetazepam	1,000
Bromazepam	800	Medazepam	2,000
Chlordiazepoxide	2,000	Nitrazepam	1,000
Clobazam	200	Nordiazepam	100
Clonazepam	4,000	Oxazepam	300
Delorazepam	6,000	Phenazepam	1,000
Diazepam	150	Prazepam	1,000
Estazolam	300	Temazepam	150
Flunitrazepam	1,000	Triazolam	1,500
Flurazepam	300		

BUPG 10ng/ml

Compound	ng/ml	Compound	ng/ml
Buprenorphine	100	Norbuprenorphine	100
Buprenorphine Glucuronide	10	Norbuprenorphine Glucuronide	100

COC 150 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoyllecgonine	150	Ecgonine	65,000

MDMA 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d,l-3,4-MDA	2,000	d,l-3,4-MDMA	500
d,l-3,4-MDEA	250	d-Methamphetamine	50,000

MET 500 ng/ml

Compound	ng/ml
Ephedrine	10,000
p-Hydroxymethamphetamine	1,750
d,l-3,4-MDMA	1,000
d,l-3,4-MDEA	20,000

MTD 300 ng/ml

Compound	ng/ml
Doxylamine	50,000
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidine	50,000

OPI 300 ng/ml

Compound	ng/ml
6-Acetylmorphine	500
6-Acetylcodeine	600
Codeine	300
Dihydrocodeine	500
Ethyl morphine	300
Heroin	100

OXY 100 ng/ml

Compound	ng/ml
6-Acetylcodeine	15,000
Codeine	5,000
Dihydrocodeine	2,000
Hydrocodone	300

PCP 25 ng/ml

Compound	ng/ml
4-Hydroxy Phencyclidine	500
Metaphit	500

PPX 300ng/ml

Compound	ng/ml
Propoxyphene	300

TCA 1000 ng/ml

Compound	ng/ml
Amitriptyline	1,000
Clomipramine	7,500
Cyclobenzaprine	1,500
Desipramine	750
Doxepin	1,000
Imipramine	750

THC 50 ng/ml

Compound	ng/ml
Cannabidiol	100,000
Cannabinol	50,000
11-nor- Δ^8 -THC-9-COOH	50
11-nor- Δ^9 -THC-9-COOH	50

CONSUMER STUDY

A consumer study was conducted to determine the performance of the device when used by untrained, laypersons following only the instructions in the product labeling. A total of 153 participants read a total of 5460 assays during the study and 5228 of those 5460 assays (95.8%) was interpreted correctly. Each assay was tested by these participants using spiked solutions targeted to 0%, 25%, 50%, 75%, 125%, 150%, and 175% of the assay cutoff level.

INTERFERENCE

The following compounds were found not to cross-react when tested at concentrations up to 100 $\mu\text{g/ml}$ (100,000 ng/ml).

Acetaminophen	Amitriptyline (except TCA assay)
Acetone	Amobarbital (except BAR assay)
Acetylsalicylic acid (Aspirin)	Amoxapine
6-Acetylcodeine (except OPI & OXY assay)	Amoxicillin
6-Acetylmorphine (except OPI assay)	Aprobarbital (except BAR assay)
Albumin	d-Amphetamine (except AMP assay)
Allobarbitol (except BAR assay)	l-Amphetamine (except AMP assay)
Alphenal (except BAR assay)	Ampicillin
Alprazolam (except BZO assay)	Apomorphine
Aspartame	l-Ascorbic Acid (Vitamin C)
Atropine	α -Hydroxy Alprazolam (except BZO assay)

Barbital (except BAR assay)	p-Hydroxymethamphetamine (except MET assay)
Benzilic acid	11-Hydroxy- Δ^9 -THC (except THC assay)
Benzocaine (Ethyl p-Aminobenzoate)	Ibuprofen
Benzoic acid	Imipramine (except TCA assay)
Benzoylcegonine (except COC assay)	d,l-Isoproterenol
Benzphetamine	Ketamine
Bilirubin	Lidocaine
Bromazepam (except BZO assay)	Lorazepam (except BZO assay)
d-Brompheniramine	Lormetazepam (except BZO assay)
Buprenorphine (except BUPG assay)	Medazepam (except BZO assay)
Butabarbital (except BAR assay)	Meperidine
Butalbital (except BAR assay)	Metaphit (except PCP assay)
Butethal (except BAR assay)	Methadone (except MTD assay)
Caffeine	d-Methamphetamine (except MET & MDMA assay)
Cannabidiol (except THC assay)	l-Methamphetamine (except MET assay)
Cannabinol (except THC assay)	Methaqualone
Chlordiazepoxide (except BZO assay)	Methoxyphenamine
Chloroquine	(1R,2S) N-Methyl-Ephedrine
d,l-Chlorpheniramine	2-Methylamine-Propiophenone
Chlorpromazine	d,l-3,4-Methylenedioxyamphetamine (except AMP & MDMA assays)
Cholesterol	d,l-3,4-methylenedioxyethylamphetamine (except MET & MDMA assays)
Clobazam (except BZO assay)	d,l-3,4-Methylenedioxyamphetamine (except MET & MDMA assays)
Clomipramine (except TCA assay)	e (except MET & MDMA assays)
Clonazepam (except BZO assay)	Methylphenidate
Cocaine	Morphine (except OPI assay)
Codeine (except OPI & OXY assays)	Morphine-3- β -D-Glucuronide (except OPI assay)
Cortisone	Nalidixic acid
l-Cotinine	Nalorphine (except for OPI assay)
Creatine	Naloxone
Creatinine	d-Naproxen
Cyclobenzaprine (except TCA assay)	Niacinamide
Delorazepam (except BZO assay)	Nitrazepam (except BZO assay)
Deoxycorticosterone	Nordiazepam (except BZO assay)
Desipramine (except TCA assay)	Nordoxepin (except TCA assay)
Dextromethorphan	Nicotine, (S)-
Diazepam (except BZO assay)	11-nor- Δ^9 -THC-9-Carboxylic Acid (except THC assay)
Dihydrocodeine (except OPI & OXY assay)	Norepinephrine
4-Dimethylaminoantipyrine	Norethindrone
Diphenhydramine	Norpropoxyphene (except PPX assay)
Dopamine (3-Hydroxytyramine)	Nortriptyline (except TCA assay)
Doxepin (except TCA assay)	Oxalic Acid
Doxylamine (except MTD assay)	Oxazepam (except BZO assay)
Ecgonine (except COC assay)	Oxolinic acid
Ecgonine Methyl Ester	Oxycodone (except OXY assay)
l-Epinephrine	Oxymorphone (except OXY assay)
d,l-Ephedrine (except MET assay)	Papaverine
Erythromycin	Penicillin-G (Benzylpenicillin)
Estazolam (except BZO assay)	Pentazocine
β -Estradiol	Pentobarbital (except BAR assay)
Estrone-3-Sulfate	Perphenazine (except TCA assay)
Ethanol	Phenazepam (except BZO assay)
Ethyl Morphine (except OPI & OXY assay)	Phencyclidine (except PCP assay)
Ethyl-p-aminobenzoate	Phencyclidine Morpholine (except PCP assay)
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidone (except MTD assay)	Pheniramine (except MTD assay)
Flunitrazepam (except BZO assay)	Phenobarbital (except BAR assay)
Flurazepam (except BZO assay)	Phenothiazine (Thiodiphenylamine)
Furosemide	Phentermine (except AMP assay)
Glucose	Phenylephrine
Gentisic acid	β -Phenylethylamine (except AMP assay)
Glutethimide	Prednisolone
Guaiacol Glyceryl Ether	Prazepam (except BZO assay)
Hemoglobin	Procaine (except MET assay)
Heroin (except OPI assay)	Promazine (except TCA assay)
Hippuric acid	Promethazine
Hydrochlorothiazide	Propoxyphene (except PPX assay)
Hydrocodone (except OPI & OXY assays)	Protriptyline (except TCA assay)
Hydrocortisone	d-Pseudoephedrine
Hydromorphone (except OPI & OXY assays)	Pyrrrolidine
4-Hydroxy Phencyclidine (except PCP assay)	Thiamine

Quinidine	Thioridazine
Quinine	Triazolam (<i>except BZO assay</i>)
Ranitidine	Trifluoperazine
Riboflavin	Trimethobenzamide (<i>except MET assay</i>)
Salicylic acid	Trimipramine (<i>except TCA assay</i>)
Secobarbital (<i>except BAR assay</i>)	Tryptamine
Serotonin	d,l-Tryptophan
Sertraline	Tyramine
Sodium Chloride	d,l-Tyrosine
Sulfamethazine	Uric Acid
Sulindac	Verapamil
Temazepam (<i>except BZO assay</i>)	Zomepirac
Tetracycline	
$\Delta 8$ -THC (<i>except THC assay</i>)	
$\Delta 9$ -THC (<i>except THC assay</i>)	
11-nor- $\Delta 8$ -THC-9-Carboxylic Acid (<i>except THC assay</i>)	

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