ToxCup® Drug Screen Cup Step-by Step Instructions

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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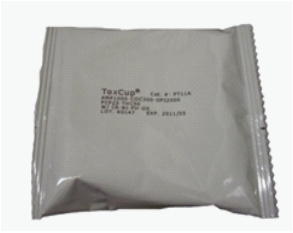
- ✓ 25 Individually Wrapped Test Lids
- ✓ 25 Specimen Cups

Specimen Collection Cup



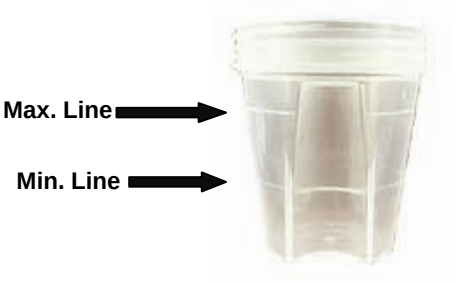
Individually Wrapped Test Lid

STORAGE

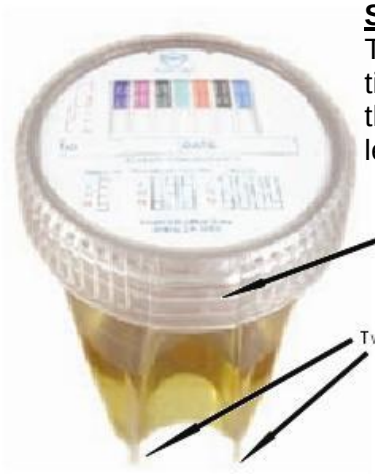
Store the ToxCup® Drug Screen Cup at room temperature 59˚F to 86˚F (15˚C to 30˚C).

INSTRUCTION

Step 1.
Collect fresh urine in the specimen cup. Make sure the urine is **between the minimum and maximum lines**.



Open foil pouch.
Remove test lid from pouch.
Discard desiccant.



Step 2.
Twist the lid onto the cup. Close tightly to align the flat surface on the rim of the lid between the two legs of the specimen cup.

Step 3.
Tilt the cup on its legs to activate the test. **Read test results at 5 minutes. Do not read after 8 minutes.**

5 minutes

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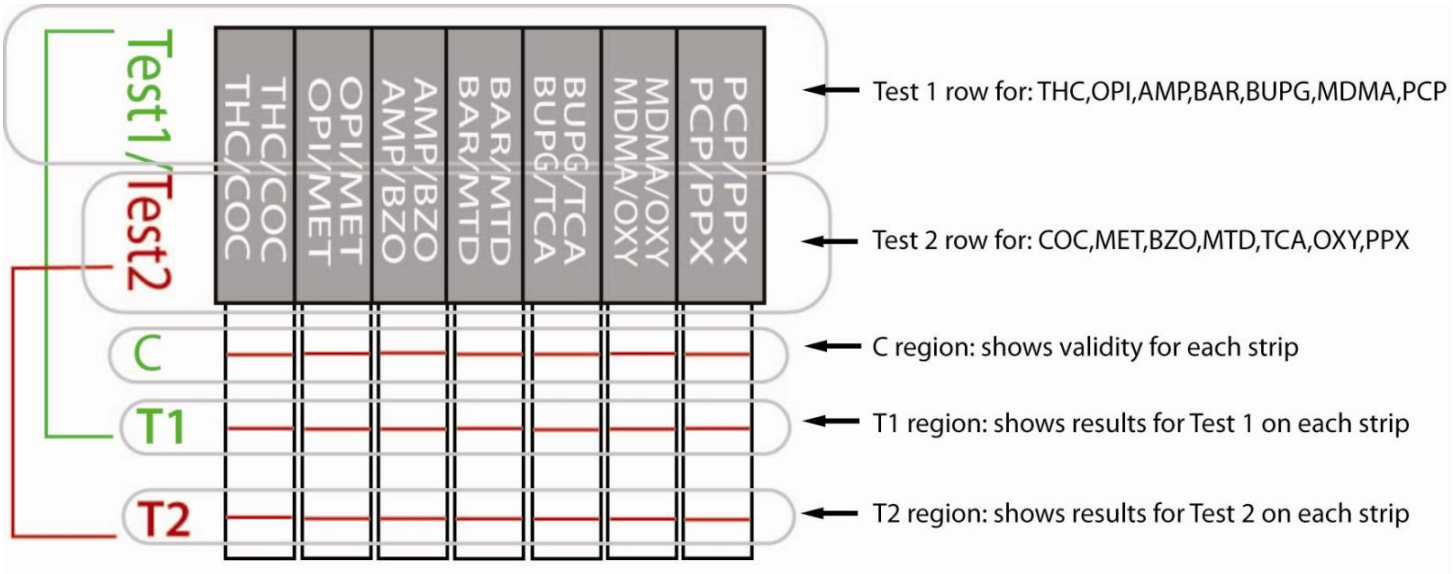
INTERPRETATION OF RESULTS

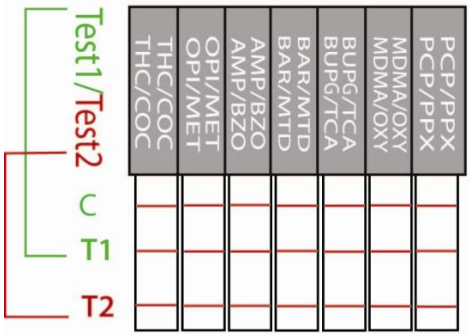
Each strip contains two drug tests. C region shows validity of a test result. T1 region shows result for Test 1. T2 region shows result for Test 2.

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.

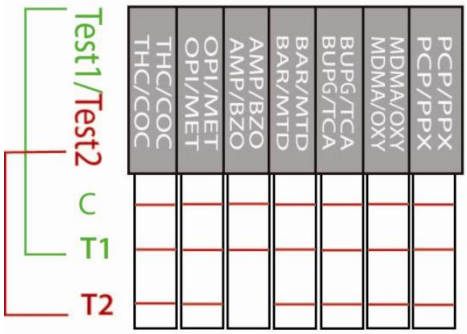
For T1 and T2 regions:
The appearance of a line indicates a **Negative** result.
Note: **Any test line, even a very faint test line, is considered a negative result.**

No line indicates a **Preliminary Positive** result.
Note: **Any urine with preliminary positive results should be sent to a laboratory for confirmation.**

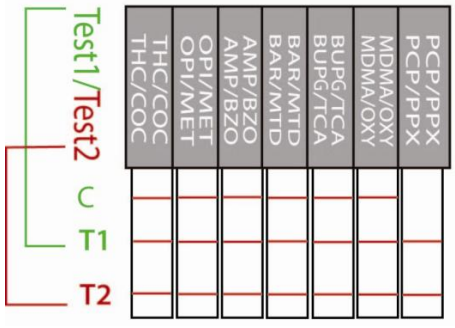




Example #1: There is a line appearing in both T1 and T2 regions on all test strips. Therefore, it is **Negative** for all tests.



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**.

ToxCup® Drug Screen Cup Step-by Step Instructions

DETECTION LEVEL

Illicit Drug	Identifier	Cut-off Level[1]
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
Ecstacy	MDMA	500 ng/ml
Phencyclidine	PCP	25 ng/ml
Propoxyphene	PPX	300 ng/ml

Prescription Drug	Identifier	Cut-off Level[1]
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.

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 CHARACTERISITCS

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		
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
Allobarbital	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
Benzoylecgonine	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	Compound	ng/ml
Ephedrine	10,000	d-Methamphetamine	500
p-Hydroxymethamphetamine	1,750	l-Methamphetamine	25,000
d,l-3,4-MDMA	1,000	Procaine	50,000
d,l-3,4-MDEA	20,000	Trimethobenzamide	75,000

MTD 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Doxylamine	50,000	Methadone	300
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidine	50,000	Pheniramine	75,000

OPI 300 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	500	Hydrocodone	1,000
6-Acetylcodeine	600	Hydromorphone	400
Codeine	300	Morphine	300
Dihydrocodeine	500	Morphine-3-β-D-Glucuronide	500
Ethyl morphine	300	Nalorphine	5,000
Heroin	100		

OXY 100 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylcodeine	15,000	Oxymorphone	3,000
Codeine	5,000	Oxycodone	100
Dihydrocodeine	2,000	Hydromorphone	25,000
Hydrocodone	300	Ethyl Morphine	5,000

PCP 25 ng/ml

Compound	ng/ml	Compound	ng/ml
4-Hydroxy Phencyclidine	500	Phencyclidine	25
Metaphit	500	Phencyclidine Morpholine	50,000

PPX 300ng/ml

Compound	ng/ml	Compound	ng/ml
Propoxyphene	300	Norpropoxyphene	500

TCA 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Amitriptyline	1,000	Nordoxepin	1,000
Clomipramine	7,500	Nortriptyline	1,000
Cyclobenzaprine	1,500	Perphenazine	50,000
Desipramine	750	Promazine	10,000
Doxepin	1,000	Protriptyline	350
Imipramine	750	Trimipramine	1,500

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-Hydroxy-Δ9-THC	2,500
Cannabinol	50,000	Δ-8-Tetrahydrocannabinol	7,000
11-nor-Δ8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ9-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 µg/ml (100,000 ng/ml).

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

Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital *(except BAR assay)*
Serotonin
Sertraline
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam *(except BZO assay)*
Tetracycline
Δ8-THC *(except THC assay)*
Δ9-THC *(except THC assay)*
11-nor-Δ8-THC-9-Carboxylic Acid *(except THC assay)*
Thioridazine
Triazolam *(except BZO assay)*
Trifluoperazine
Trimethobenzamide *(except MET assay)*
Trimipramine *(except TCA assay)*
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

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