

ToxCup® Drug Screen Cup

Quick Reference Guide

The ToxCup® II Drug Screen Cup is a preliminary screening test that detects drugs-of-abuse in urine at specified detection levels. For a quantitative analytical result or to confirm preliminary positive results, a more specific method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

This is a CLIA-Waived Test. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA Waived. This Instruction Sheet provides a brief summary of the testing procedure. For more information see the Product Insert that is provided with the product.

Warnings and Precautions

- For *in vitro* diagnostic use only (not for internal use).
- Store ToxCup® Drug Screen Cup at room temperature 59°F to 86°F (15°C to 30°C).
- Keep the ToxCup® Drug Screen Cup in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the ToxCup® Drug Screen Cup after the expiration date printed on the pouch.
- Be careful with urine because it may contain infectious diseases. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test will work properly the testing instructions must be followed. Failure to do so may result in inaccurate screening results.
- Do not use this test if you are color-blind.

Limitations of the Test

- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.
- The ToxCup® Drug Screen Cup should give negative results when testing the urine of a normal healthy person. The ToxCup® device will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. See the Expected Results section of the enclosed Package Insert.

Detection Levels

The ToxCup® Drug Screen Cup may not detect drug amounts lower than the detection levels.

Abbr.	Drug Test	Detect. Level
AMP	d-Amphetamine	1000 ng/mL
BAR	Barbiturates	300 ng/mL
BZO	Benzodiazepines	300 ng/mL
COC	Cocaine	300 ng/mL
MDMA	3,4-Methylenedioxymethamphetamine	500 ng/mL
MET 1000	d-Methamphetamine	1000 ng/mL
MET 500	d-Methamphetamine	500 ng/mL
MTD	Methadone	300 ng/mL
OPI 2000	Opiates	2000 ng/mL
OPI 300	Opiates	300 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
THC	Tetrahydrocannabinol	50 ng/mL

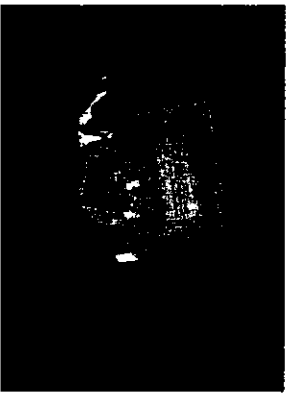
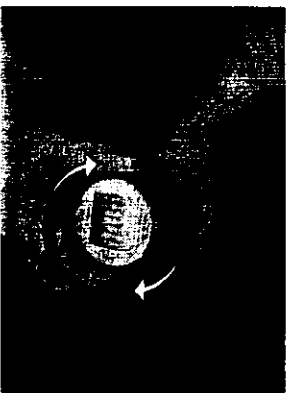
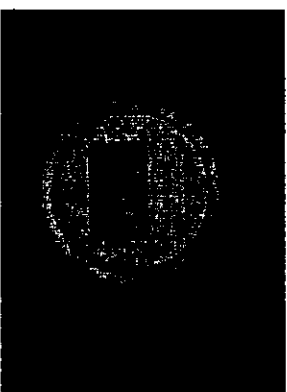
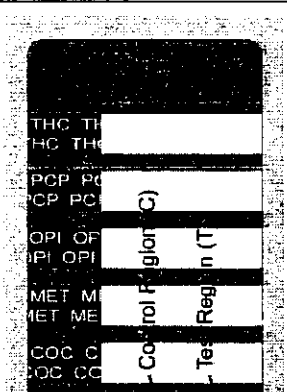
Quality Control

An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer's recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

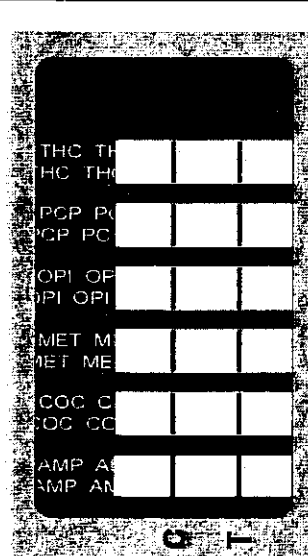
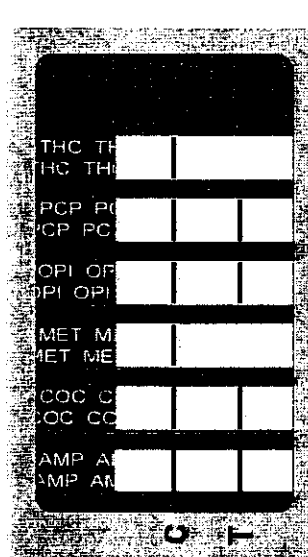
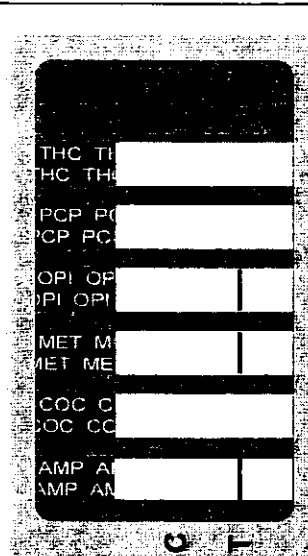
The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at Branam Medical Corporation at 1-866-468-3287 or email to info@branammedical.com for the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the ToxCup® Drug Screen Cup.

Step-by-Step Testing Instructions

				<p>1. Open the pouch and remove the test lid from the pouch.</p> <p>2. Write the urine sample ID number on the ToxCup® lid.</p> <p>3. Close the cup with the lid; make sure the lid is closed tightly.</p> <p>4. To start the testing, lay the cup on its side. Position the cup so that it rests on its feet (as shown).</p> <p>5. Read test results after 5 minutes. Do not read test results after 1 hour. See Interpretation of Results section below.</p>
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Interpretation of Results

		
<p>Look at each test strip separately</p> <p>Negative (-)</p> <p>The result is negative when there are two color lines, one in the control region (C) and one in the test region (T). This means that the urine does not contain that particular drug, or that the drug level is lower than the detection level.</p> <p>The picture above indicates that all of the tests are negative.</p> <p>Note: Any test line, even a very faint test line, is considered a negative result.</p>	<p>Look at each test strip separately</p> <p>Preliminary Positive (+)</p> <p>The result is preliminary positive when there is a color line in the control region (C) and no color line in the test region (T).</p> <p>The picture above indicates that the MET and THC tests are preliminary positives since there are no color lines at the test region (T) for those particular tests.</p> <p>All urines with preliminary positive results should be sent to a laboratory for confirmation.</p>	<p>Look at each test strip separately</p> <p>Invalid</p> <p>The result is invalid when no line appears at the control region (C). The test is invalid even if there is a line in the test region (T). Do not use this result.</p> <p>If no line appears at the control region (C), the test may not have performed properly.</p> <p>Check testing procedure and repeat the test using a new ToxCup® Drug Screen Cup.</p> <p>The picture above indicates that all of the tests are invalid.</p>

CLIA WAIVED ToxCup[®] Drug Screen Cup Package Insert

This is a **CLIA-Waived Test**. A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read this entire Instruction Sheet carefully before use. If a laboratory modifies the following test instructions including QC, the test will be considered high complexity and no longer considered CLIA Waived.

Intended Use

The ToxCup[®] Drug Screen Cup is a screening device for the detection of drugs and drug metabolites in human urine. The ToxCup[®] Drug Screen Cup is only the first step in a two-step process for detecting drugs of abuse in urine. The first step is screening the urine. The second step is confirming the results.

The ToxCup[®] Drug Screen Cup may include up to seven individual drug tests. The device detects the following drugs or drug metabolites in human urine at or above the detection level listed.

Abbreviation	Drug or Drug Metabolite	Detection Level
AMP	d-Amphetamine	1000 ng/ml †
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoyllecgonine	300 ng/ml †
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET1000	d-Methamphetamine	1000 ng/ml †*
MET500	d-Methamphetamine	500 ng/ml *
MTD	Methadone	300 ng/ml
OPI2000	Morphine	2000 ng/ml †**
OPI300	Morphine	300 ng/ml **
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml †
THC	11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml †

† SAMHSA mandated cut-off concentration

* Methamphetamine test can be provided at either 500 ng/ml or 1000 ng/ml

** Opiates test can be provided at either 300 ng/ml or 2000 ng/ml

The ToxCup[®] Drug Screen Cup provides visual qualitative results and is for *in vitro* diagnostic use only. It is not for over-the-counter sale to non-professionals.

The ToxCup[®] Drug Screen Cup provide only preliminary screening test results. For quantitative analytical results or to confirm positive results obtained by ToxCup[®], a more specific method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA) has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

Summary and Explanation

AMP: Amphetamine is a man-made drug used to control weight, treat narcolepsy and ADHD. Amphetamine can be snorted, taken orally, smoked, or injected. When used, amphetamines will stimulate the central nervous system. Short-term amphetamine use includes increased heart rate and blood pressure, reduced appetite, and feelings of increased energy and power. Long-term use of amphetamine can lead to violent and aggressive behavior, weight loss, insomnia and restlessness. The detection time for amphetamine in urine is 3-5 days after use.

BAR: Barbiturates are a class of central nervous system depressants. There are three types of Barbiturates: short acting, short-to-intermediate acting and long acting. Phenobarbital is an example of long acting barbiturate while pentobarbital and secobarbital are examples of short acting barbiturates. The short acting barbiturates are used as anesthetics or sedatives in conjunction with other inhalants. The short-to-intermediate acting barbiturates are used as sleeping pills. Short-to-intermediate acting barbiturates are the most commonly

abused barbiturates; these include amobarbital, butobarbital and secobarbital. Long acting barbiturates are used for treatment of epilepsy, ulcers and high blood pressure. Barbiturate abuse can lead to impaired motor coordination, mental disorder, respiratory collapse, coma and even death. Barbiturates can be detected in urine for 4 to 6 days after use.

BZO: Benzodiazepines are a class of drugs most commonly prescribed and used for panic disorder and other anxiety disorders. Benzodiazepines are also used for age-related sleep problems. Use of Benzodiazepines can result in drowsiness and confusion. The effects of benzodiazepines can be increased when combined with other central nervous system depressants, such as alcohol and pain relievers. Physical dependency of benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by injection. The drug is metabolized in the liver and excreted in the urine as the parent compound or as oxazepam (in the case of chlorodiazepoxide and diazepam). Oxazepam is detectable in the urine for up to 7 days.

COC: Street names for cocaine are coke, blow, snow, and nose candy. Cocaine is derived from the leaves of the coca plant. The white powder form of cocaine can be snorted, or dissolved in water and injected, while "Crack" cocaine, a white chunky material is usually smoked. Cocaine use creates a sense of increased energy and confidence; these effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is highly addictive and can cause lung complications, cardiac arrest or seizures. Cocaine is mainly excreted in urine as benzoylecgonine and can generally be detected for 24–60 hours after use.

MDMA: 3,4-methylenedioxymethamphetamine (MDMA) is a synthetic drug. MDMA has been available as a street drug since the 1980s, however, since the 1990s its use has increased, particularly among teenagers and young adults. The drug has street names that include "Ecstasy, XTC, Clarity, Essence and Adam". The common method of use is oral ingestion, although the powder form can be snorted or smoked. MDMA has properties of both stimulants and hallucinogens. The effects of the drug last up to 6 hours after oral ingestion. MDMA effects include elevated blood pressure, increased heart rate, hypothermia, dehydration, anxiety, paranoia and insomnia. The detection period of MDMA in urine is 1-3 days for single use and up to 5 days for heavy use.

MET: Street names for methamphetamine are speed, glass, ice, and crystal meth. Methamphetamine is usually a white powder that can be inhaled, injected or smoked. When used, methamphetamine causes increased heart rate and blood pressure. Higher doses of methamphetamine lead to a sense of increased energy and power. Methamphetamine can also cause respiratory problems, irregular heartbeat and anorexia. Methamphetamine can be detected in the urine within 4-6 hours after use and for 3-5 days, depending on urine pH level.

MTD: Methadone is a synthetic analgesic drug that is originally used for the treatment of narcotic addiction. Methadone use induces psychological effects such as analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver. The major route of methadone excretion is in the urine. The effects of methadone last up to 24 hours after use and can be detected in the urine up to 14 days. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the user's age, weight, activity and diet.

OPI: Opiates are a group of drugs that include morphine, heroin and codeine. Heroin, morphine and codeine come from a resin taken from the seed pod of the opium poppy. With the exception of heroin, health care professionals use opiates as pain relievers. Inside the body, heroin is quickly converted to morphine. Thus, morphine and morphine metabolites may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. The presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, opiates can be detected in the urine within 2 to 6 hours after use and remains detectable up to 3 days.

OXY: Oxycodone is a synthetic drug. Oxycodone is taken orally for the relief of moderate to severe pain. Long-term use of Oxycodone can lead to physical dependence. Withdrawal symptoms include restlessness, insomnia, vomiting, and muscle and bone pain. The major route of oxycodone excretion is in the urine. The effects of oxycodone last up to 4 hours after use. Oxycodone can be detected in the urine for 2-4 days after use.

PCP: PCP (phencyclidine) was developed in the 1950s as an anesthetic. Use of PCP was ended when patients had psychotic reactions to the drug. PCP is now made illegally and can be found on the street under names such as Angel Dust, Hog and Rocket Fuel. PCP can be eaten, snorted, injected or smoked. Effects of PCP

include sense of well-being, blurred vision, numbness, confusion or anxiety. PCP may be detected in the urine for up to 10 days.

THC: Tetrahydrocannabinol (THC) is the substance detected in urine from marijuana use. Street names for marijuana are grass, pot, weed and dope. Marijuana is the green leafy material or brown black lump that can be smoked or eaten. Use of marijuana may cause respiratory problems, anxiety, and impaired memory and learning. Long-term marijuana use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea. The detection time of THC in urine is 3-5 days for occasional users and up to 14 days for chronic users.

Test Principle

The test device consists of up to seven individual test strips placed into separate chambers of a plastic lid. On each test strip, a drug conjugate is pre-coated onto specific region known as the test region (T). A colored antibody-colloidal gold conjugate is coated onto a pad and placed at one end of the strip. During testing the urine comes into contact with the sample pads, which allows the urine to move across the strip. If any drug is present in the urine, it competes with the drug conjugate for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the strip.

The absence of a color line at a specific test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible line at the test region. The presence of a color line at the test region indicates a negative result for that particular test.

A control line with a different antigen/antibody reaction is added to the membrane strip at the control region (C) to indicate that the test performed properly. This control line should always appear regardless of the presence of drug or metabolite. The appearance of the control line during testing indicates that the test has completed and the test is valid.

Reagents

Protein conjugate for amphetamine, barbiturate, benzodiazepine, benzoylecgonine, methamphetamine, MDMA, methadone, morphine, oxycodone, phencyclidine, or THC is coated onto the test region of the membrane.

The colored conjugate pad for each test strip contains monoclonal antibodies for amphetamine, barbiturate, benzodiazepine, benzoylecgonine, methamphetamine, MDMA, methadone, morphine, oxycodone, phencyclidine, or THC.

Materials Provided

Each ToxCup[®] Drug Screen Cup Kit contains:

1. 1 Package Insert (directions for use).
2. 25 individually wrapped test lids. Each lid is packaged in a pouch with a desiccant.
3. 25 specimen cups

Warnings and Precautions

- For in vitro diagnostic use only (not for internal use).
- Keep the ToxCup[®] Drug Screen Cup in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Do not use the ToxCup[®] Drug Screen Cup after the expiration date printed on the pouch.
- Be careful with urine because it may contain infectious diseases. Always wear gloves and wash hands with soap and water after handling urine.
- To ensure that the test device will work properly and results are accurate, the testing instructions must be followed.
- Dispose of the ToxCup[®] Drug Screen Cup and used contents according to local, state and federal requirements.
- Do not use this test if you are color-blind.

Product Storage

The ToxCup[®] Drug Screen Cup kit should be stored at room temperature 59°F to 86°F (15°C to 30°C) until the expiration date. Do not open the pouch until ready to perform the test.

Specimen Collection and Handling

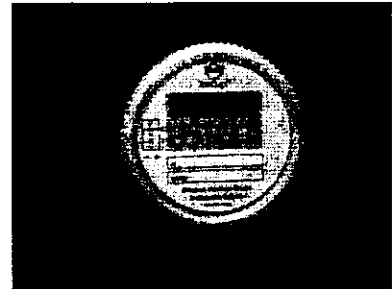
The ToxCup[®] Drug Screen Cup is formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected and tested as soon as possible. Urine samples that have been collected should be refrigerated if testing cannot be performed within the 8-hour workday. Urine samples can be refrigerated up to 3 days and frozen up to 6 months and still obtain accurate test results. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure

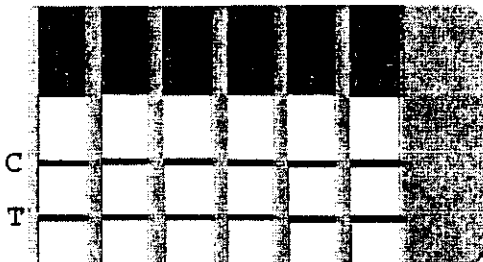
IMPORTANT: If testing refrigerated or frozen urine sample, the sample should be brought to room temperature (15–30°C) before testing. Do not open pouch until ready to perform the test.

1. Collect urine in the cup.
2. Open the pouch and remove the test lid.
3. Write the urine sample ID number on the ToxCup[®] test lid.
4. Close the cup with the test lid; make sure the lid is closed tightly.
5. To start testing, lay the cup on its side. Position the cup so that it rests on its feet.
6. Read test result after 5 minutes. Do not read results after 1 hour.
7. Look at each test strip separately.



Interpretation of Results

Negative:

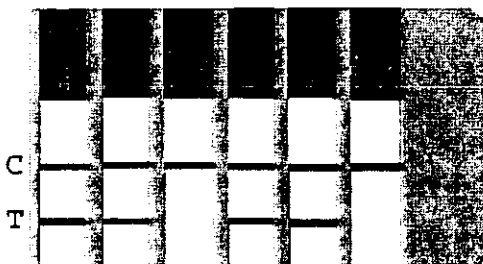


Negative: The result is negative when there are two color lines, one in the control region (C) and one in the test region (T).

The picture to the left indicates that all of the tests are negative.

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

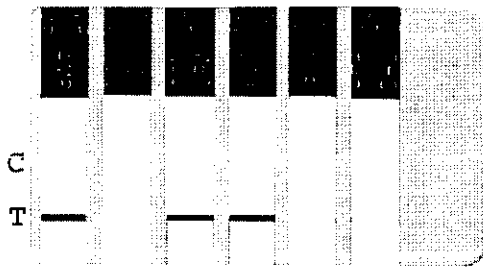
Preliminary Positive:



Preliminary Positive: The result is preliminary positive when there is a color line in the control region (C) and no color line in the test region (T).

The picture to the left indicates that the MET and THC tests are preliminary positives since there are no color lines at the test region (T) for those particular tests.

Invalid:



Invalid: The result is invalid when no line appears at the control region (C). The test is invalid even if there is a line in the test region (T). Do not use this result. Repeat the test using a new device. Contact Branam Medical Corporation if you have any questions.

The picture to the left indicates that all of the tests are invalid.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test lines at the test regions should be considered negative. The ToxCup[®] Drug Screen Cup provides qualitative results for the presence of drug(s) at specified detection concentration(s). It is recommended that samples with questionable test lines and preliminary positive results be confirmed with a more specific method (Gas Chromatography/Mass Spectrometry).

Quality Control

An internal procedural control has been built into the test to ensure that the test performs properly. The appearance of a line in the control region (C) serves as the internal procedural control to verify that the reagents in the test are still working, and that the test is valid. The manufacturer's recommendation for daily quality control is to document the appearance of the control line for the first sample tested each day.

The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality control samples, follow the same testing procedure as for testing urine samples.

Contact the Customer Service Department at Branam Medical Corporation at 1-866-468-3287 or email to info@branammedical.com for the appropriate external controls. Do not use commercially available urine controls since these products may not be compatible with the ToxCup[®] Drug Screen Cup.

Limitations of the Test

- Use the test with human urine only.
- The test is for one time use only; it is not reusable.
- This test is a screening device; it does not detect the actual concentration of a drug.
- Contaminated or tainted urine sample may give false results.
- Certain foods or medications may cause the test to give false results. See Specificity section for the list of substances that will produce either positive results, or that do not interfere with test performance.
- The colors of human urine usually range from amber yellow to very light yellow. Dark urine or urine with a brown or abnormal color should not be tested using this test. Dark urines should be sent to a laboratory for testing.
- Send preliminary positive or uncertain results to a laboratory to confirm results.
- 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, the test should be repeated, and a new specimen should be collected.

Expected Results

The ToxCup[®] Drug Screen Cup should give a negative result when testing the urine of a normal healthy person. The ToxCup[®] device will give a preliminary positive result when the drug or drug metabolite is present in the urine at or above the detection level. The ToxCup[®] Drug Screen Cup is only the first step in a two-step process for detecting drugs of abuse in urine. Any urine specimen that produced a questionable or preliminary positive result should be sent to a laboratory for confirmation testing with a more specific method.

Performance Characteristics

Precision

For each drug test of the ToxCup® device, drug-free normal urine was spiked with the corresponding drug standards to various concentrations (-50%, -25%, cut-off, +25% and +50%). For each concentration prepared, a total of 25 tests were performed to validate the test performance around the cut-off concentration. The results for each drug test in the ToxCup® Drug Screen Cup are summarized below:

Drug Test	Total # of Test / Conc.	Concentration									
		-50%		-25%		Cut-Off		+25%		+50%	
		-	+	-	+	-	+	-	+	-	+
AMP	25	25	0	25	0	21	4	3	22	0	25
COC	25	25	0	25	0	21	4	4	21	0	25
MET1000	25	25	0	25	0	22	3	2	23	0	25
OPI2000	25	25	0	25	0	22	3	5	20	0	25
PCP	25	25	0	23	2	21	4	3	22	1	24
THC	25	25	0	23	2	19	6	4	21	0	25
MDMA	25	25	0	22	3	18	7	5	20	1	24
BAR	25	25	0	23	2	20	5	2	23	0	25
BZO	25	25	0	21	4	21	4	6	19	0	25
MET500	25	25	0	24	1	19	6	5	20	1	24
MTD	25	25	0	21	4	20	5	5	20	1	24
OPI300	25	25	0	25	0	21	4	5	20	2	23
OXY	25	25	0	20	5	18	7	2	23	0	25

Accuracy

The accuracy of the ToxCup® Drug Screen Cup was evaluated in comparison to the Monitect® single drug predicate kits. Forty (40) negative urine samples obtained from a clinical laboratory were tested by both the ToxCup® Drug Screen Cup and the predicate kits. Of the negative urine samples tested, all were found negatives by both methods (100% agreement). In a separate study, clinical urine samples obtained from clinical laboratories and previously analyzed by GC/MS were blind labeled and tested by ToxCup® Drug Screen Cup devices and the predicate kits. The results are presented below:

Drug Test		GC/MS Neg. (< -25%)	GC/MS Near Neg* (between -25% and C/O)	GC/MS Near Pos* (between +25% and C/O)	GC/MS Pos. (> +25%)	% Agreement w/ GC/MS	
						Neg (-)	Pos (+)
AMP	Pos. (+)	0	0	6	33	100%	98%
	Neg. (-)	2	5	1	0		
COC	Pos. (+)	0	0	7	32	100%	98%
	Neg. (-)	1	4	1	0		
MET1000	Pos. (+)	0	0	6	34	100%	100%
	Neg. (-)	1	4	0	0		
OPI2000	Pos. (+)	0	0	4	36	100%	100%
	Neg. (-)	3	5	0	0		
PCP	Pos. (+)	0	0	5	35	100%	100%
	Neg. (-)	0	4	0	0		
THC	Pos. (+)	0	0	9	30	100%	98%
	Neg. (-)	0	5	1	0		
MDMA	Pos. (+)	0	0	5	34	100%	98%
	Neg. (-)	0	5	1	0		
BAR	Pos. (+)	0	0	4	33	100%	100%
	Neg. (-)	0	4	0	0		
BZO	Pos. (+)	0	0	6	33	100%	98%
	Neg. (-)	0	5	1	0		
MET500	Pos. (+)	0	0	5	34	100%	98%
	Neg. (-)	1	4	1	0		
MTD	Pos. (+)	0	0	4	35	100%	98%
	Neg. (-)	1	4	1	0		
OPI300	Pos. (+)	0	0	5	34	100%	98%
	Neg. (-)	0	4	1	0		
OXY	Pos. (+)	0	0	4	31	100%	100%
	Neg. (-)	0	5	0	0		

*Some near negative and near positive specimens were diluted from more concentrated samples.

CLIA Waiver Performance

Accuracy and Precision

To demonstrate that ToxCup[®] device is a simple test and can be used by untrained users to obtain accurate test results, site studies were conducted at three (3) non-laboratory sites. The participants (untrained users) at these sites are non-laboratory professionals with no training or previous experience with drugs-of-abuse tests or the ToxCup[®] device. The participants are a demographically diverse population that includes a range of ages, educational and regional background and are representative of the users of a CLIA Waived test.

For each specific drug test contained in the ToxCup[®] device, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -20%, +20% and +50%). Each of the concentration was divided into 20 aliquots and each aliquot was blind-labeled with a unique code. A total of 20 tests per concentration were performed at each of the three sites to validate the test performance around the cut-off concentration. The results are summarized below:

Site	Conc.	# of sample per conc. per test	AMP		COC		MET1000		OPI2000		PCP		THC		MDMA		BAR		BZO		MET500		MTD		OPI300		OXY			
			-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
1	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	20	0	19	1	19	1	20	0	19	1	20	0	18	2	20	0	20	0	20	0	20	0	20	0	19	1	19	1
	+20%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	1	19	0	20	0	20	0	20	0	20	0	20	1	19
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
2	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	19	1	19	1	20	0	19	1	19	1	19	1	20	0	20	0	19	1	20	0	19	1	20	0	19	1	20	0
	+20%	20	1	19	0	20	1	19	0	20	1	19	1	19	0	20	0	20	0	20	0	20	1	19	0	20	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
3	-50%	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	-20%	20	19	1	20	0	19	1	20	0	20	0	20	0	19	1	20	0	20	0	19	1	20	0	20	0	20	0	20	0
	+20%	20	0	20	1	19	0	20	0	20	2	18	0	20	1	19	0	20	1	19	0	20	1	19	1	19	0	20	0	20
	+50%	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
Total (-) per test			119		119		119		119		121		120		118		121		120		119		121		120		119		120	
Total (+) per test				121		121		121		121		119		120		122		119		120		120		121		119		120		121

Of the total 160 blind-labeled samples tested per site using ToxCup[®], the study participants at site 1 obtained 91% agreement with the expected negative results and 98% agreement with the expected positive results. The study participants at site 2 obtained 90% agreement with the expected negative results and 94% agreement with the expected positive results. Similarly the study participants at site 3 obtained 95% agreement with the expected negative results and 91% agreement with the expected positive results.

Specificity

The ToxCup[®] Drug Screen Cup performance at cutoff level was previously analyzed and found not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for the drug test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

AMP 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Amphetamine	1,000	l-Amphetamine	10,000
(+/-) 3,4-MDA	5,000		

BAR 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Secobarbital	300	Pentobarbital	400
Alphenal	400	Phenobarbital	400
Aprobarbital	400	Allobarbital	1,500
Barbital	400	Amobarbital	1,500
Butobarbital	400	Butalbital	3,000
Butethal	400		

BZO 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Clorazepam	100	Bromazepam	800
Nordiazepam	100	Flunitrazepam	1,000
Alprazolam	150	Lormetazepam	1,000
Diazepam	150	Nitrozapam	1,000
Temazepam	150	Prazepam	1,000
Clobazam	200	Lorazepam	1,500
Estazolam	300	Triazolam	1,500
Flurazepam	300	Medazepam	2,000
Oxazepam	300	Delorazepam	6,000
Chlordiazepoxide	300	Clonazepam	25,000

COC 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoyllecgonine	300	Ecgonine	>100,000
Cocaine	300	Ecgonine Methyl Ester	>100,000

MDMA 500 ng/ml

Compound	ng/ml	Compound	ng/ml
(+/-) 3,4-MDEA	250	(+/-) 3,4-MDA	2,000

MET 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Methamphetamine	1,000	Chloroquine	50,000
(+/-)3,4-MDMA	2,000	(+/-)-Ephedrine	50,000
l-Methamphetamine	5,000	β-Phenylethylamine	50,000
Procaine	10,000	Ranitidine	50,000
d-Amphetamine	50,000		

MET 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Methamphetamine	500	d-Amphetamine	50,000
(+/-)3,4-MDMA	500	(+/-)3,4-MDEA	50,000
l-Methamphetamine	10,000	(+/-)3,4-MDA	100,000
Ephedrine	50,000	l-Amphetamine	> 100,000
Mephentermine	50,000		

MTD 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Methadol	1,000	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	50,000

OPI 2000 ng/ml

Compound	ng/ml	Compound	ng/ml
Morphine	2,000	Nalorphine	5,000
Codeine	2,000	Heroin	10,000
Ethylmorphine	5,000	Hydrocodone	40,000
Morphine-3-glucuronide	5,000	Hydromorphone	50,000

OPI 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Codeine	300	Morphine	300
Ethyl morphine	300	Hydromorphone	400

OXY 100 ng/ml

Compound	ng/ml	Compound	ng/ml
Oxycodone	100	Hydromorphone	2,250
Heroin	500	Morphine	5,000
Hydrocodone	600	Codeine	10,000

PCP 25 ng/ml

Compound	ng/ml
Tenocyclidine	2,000

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
11-nor- Δ -8-THC-9-COOH	50	Δ -9-tetrahydrocannabinol	10,500
11-hydroxy- Δ 9-THC	2,500	Cannabinol	10,000
Δ -8-tetrahydrocannabinol	7,000	Cannabidiol	100,000

Interference

The following compounds were found not to cross-react with the ToxCup[®] Drug Screen Cup when tested at concentrations of 100 μ g/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)	Ibuprofen
Acetone	Imipramine
Acetylsalicylic acid (Aspirin)	(-) Isoproterenol
Albumin	(+/-) Isoproterenol
Aminopyrine	Lidocaine
Amitriptyline	Lorazepam (except BZO assay)
Amobarbital (except BAR assay)	Meperidine
Amoxapine	Methadone
Amoxicillin	(+/-) Methadone
d-Amphetamine (except AMP, MET assays)	Methamphetamine (except MET assay)
d,l-Amphetamine (except AMP, MET assays)	(+) Methamphetamine (except MET assay)
l-Amphetamine (except AMP, MET assays)	(+/-) Methamphetamine (except MET assay)
Ampicillin	Methaqualone
Apomorphine	Methoxyphenamine
l-Ascorbic Acid (Vitamin C)	N-Methyl-Ephedrine
Aspartame	(1R,2S) N-Methyl-Ephedrine
Aspartamine	2-Methylamine-Propiophenone
Atropine (except OPI assay)	(+/-) 3,4- Methylene-dioxymethamphetamine (except MET, MDMA assays)
Benzilic acid	(+/-) 3,4-Methylenedioxyamphetamine (except MET, MDMA assays)
Benzocaine (Ethyl p-Aminobenzoate)	Methylphenidate
Benzoic acid	Morphine (except OPI, OXY assays)
Benzoylcegonine (except COC assay)	Nalidixic acid
Benzphetamine	Naloxone
Bilirubin	(+) Naproxen
(+) Brompheniramine	Niacinamide
Butalbital (except BAR assay)	Nitrazepam (except BZO assay)
Caffeine	Nordiazepam (except BZO assay)
Cannabinol (except THC assay)	(+/-) Norephedrine
Chloralhydrate	(+/-) Norephedrine-(+) Phenylpropanolamine
Chlordiazepam-HCl-Di(H ₂ O)	Norethindrone
Chlordiazepoxide (except BZO assay)	D-Norpropoxyphene
Chloroquine (except MET assay)	Nortriptyline
(+) Chlorpheniramine	Oxalic Acid
(+/-) Chlorpheniramine	Oxazepam (except BZO assay)
l-Chlorpheniramine	Oxolinic acid
Chlorpromazine	Oxycodone (except OXY assay)
Cholesterol	Papaverine
Clobazam (except BZO assay)	Penicillin-G (Benzylpenicillin)
Clomipramine	Penicillin-G Phentermine
Clonazepam (except BZO assay)	Pentazocaine
Cocaine (except COC assay)	Pentobarbital (except BAR assay)
Cortisone	Perphenazine
(-) Cotinine	Phencyclidine
Creatine	Pheniramine
Creatinine	Phenobarbital (except BAR assay)
Cyclobenzaprine	Phenothiazine (Thiodiphenylamine)
Delorazepam	Phentermine
Deoxycorticosterone	Phenylephrine
Desipramine	β -Phenylethylamine (except MET assay)
Desmethyldiazepam	Prednisolone
Dexbrompheniramine	

Dextromethorphan	Prazepam (Ethanol) (except BZO assay)
Diazepam (except BZO assay)	Procaine
4-Dimethylaminoantipyrine	Promethazine
Diphenhydramine	d-Propoxyphene
Dopamine (3-Hydroxytyramine)	Protriptyline
Doxylamine	d-Pseudoephedrine
Ecgonine (except COC assay)	Pyrolidine
Ecgonine Methyl Ester (except COC assay)	Quinidine
(-) Ephedrine	Quinine
(-) Epinephrine	Ranitidine (except MET assay)
(+) Epinephrine	Riboflavin
(+/-) Ephedrine (except MET assay)	Salicylic acid
Erythromycin	Secobarbital (except BAR assay)
Estazolam (except BZO assay)	Serotonin
β-Estradiol	Sodium Chloride
Estrone-3-Sulfate	Sulfamethazine
Ethanol	Sulindac
Ethyl Morphine (except OPI assay)	Temazepam (except BZO assay)
Ethyl-p-aminobenzoate	Tetracycline
2-Ethylidene-1.5-Dimethyl-1-3.3-Diphenyl (except MTD assay)	Δ8-THC (except THC assay)
Flunitrazepam (except BZO assay)	Δ9-THC (except THC assay)
Flurazepam (except BZO assay)	11-Nor-Δ8-THC-9-Carboxylic Acid (except THC assay)
Furosemide	Tetrahydrocortisone
Gentisic acid	Thiamine
Glucose	Thimethobenzamide
Glutethimide	Thioridazine
Guaiacol Glyceryl Ether	Triazolam (except BZO assay)
Hemoglobin	Trifluoperazine
Hippuric acid	Trimethobenzamide
Hydrochlorothizide	Trimipramine Maleate
Hydrocodone (except OPI, OXY assays)	Tryptamine
Hydrocortisone	d,l-Tryptophan
Hydromorphone (except OPI, OXY assays)	Tyramine
3-Hydroxytyramine	d,l-Tyrosine
11-Hydroxy-Δ-9-THC (except THC assay)	Uric Acid
11-Hydroxy-Δ-9-THC-9-COOH (except THC assay)	Verapamil
p-Hydrozymethamphetamine	Zomepirac

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Manufactured by:
 Branan Medical Corporation
 10015 Muirlands Road, Suites E & F
 Irvine, CA 92618

For customer inquiry or technical support contact us at:
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