

# ToxCup® Drug Screen Cup

## Quick Reference Guide

The ToxCup® Drug Screen Cup is a preliminary screening test that detects drugs-of-abuse in urine at specified detection levels. For a quantitative result or to confirm preliminary positive results, a more specific method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is 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


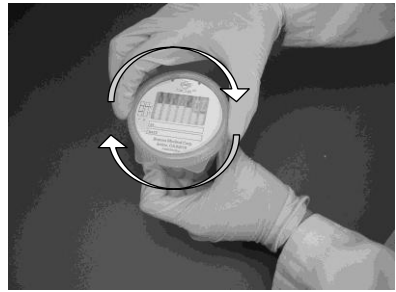
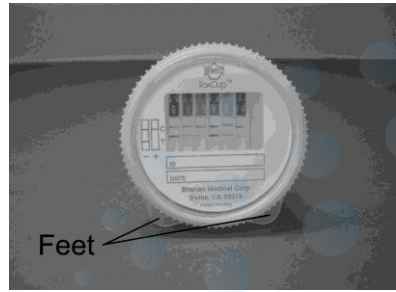
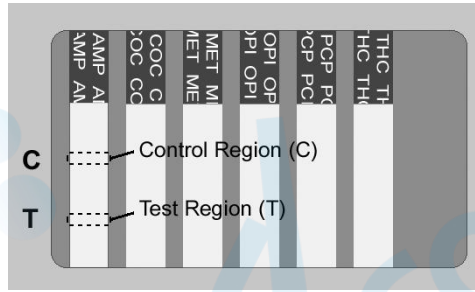
### Quality Control

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.

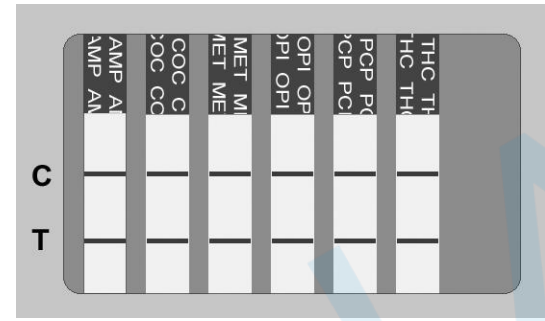
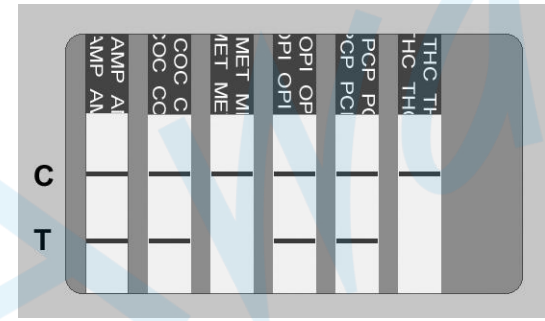
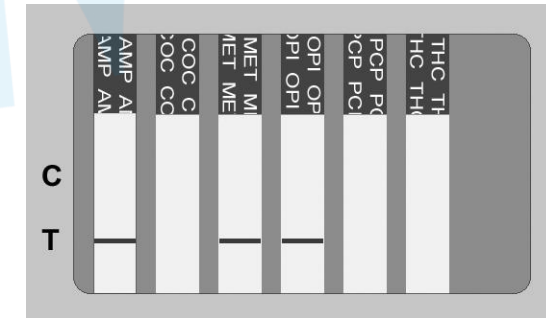
The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality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

			
<ol style="list-style-type: none"> <li>1. Open the pouch and remove the test lid from the pouch.</li> <li>2. Write the urine sample ID number on the ToxCup® lid.</li> </ol>	<ol style="list-style-type: none"> <li>3. Close the cup with the lid; make sure the lid is closed tightly.</li> </ol>	<ol style="list-style-type: none"> <li>4. To start the testing, lay the cup on its side. Position the cup so that it rests on its feet (as shown).</li> </ol>	<ol style="list-style-type: none"> <li>5. Read test results at 5 minutes. See Interpretation of Results section below.</li> </ol>

## Interpretation of Results

		
<p><i>Look at each test strip separately</i></p> <p><b>Negative ( - )</b></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><b>Note: Any test line, even a very faint test line, is considered a negative result.</b></p>	<p><i>Look at each test strip separately</i></p> <p><b>Preliminary Positive ( + )</b></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><i>Look at each test strip separately</i></p> <p><b>Invalid</b></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<sup>®</sup> 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<sup>®</sup> Drug Screen Cup is a screening device for the detection of drugs and drug metabolites in human urine. The ToxCup<sup>®</sup> 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<sup>®</sup> 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- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

\* 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<sup>®</sup> 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<sup>®</sup> Drug Screen Cup provides only preliminary screening test results. For quantitative results or to confirm positive results obtained by ToxCup<sup>®</sup>, a more specific method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is 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, butabarbital 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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**

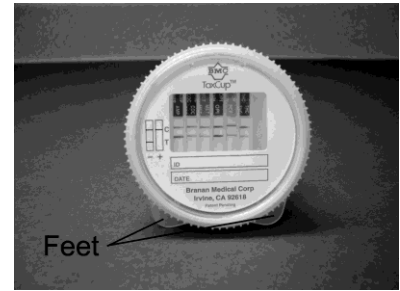
The ToxCup<sup>®</sup> Drug Screen Cup is formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected and tested as soon as possible. Urine samples that have been collected should be refrigerated 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

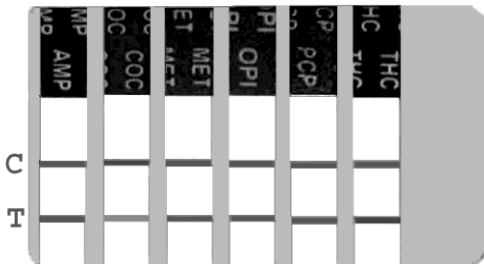
**IMPORTANT:** If testing refrigerated or frozen urine sample, the sample should be brought to room temperature (15–30°C) before testing. Do not open pouch until ready to perform the test.

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 at 5 minutes.
7. Look at each test strip separately.



### Interpretation of Results

#### Negative:

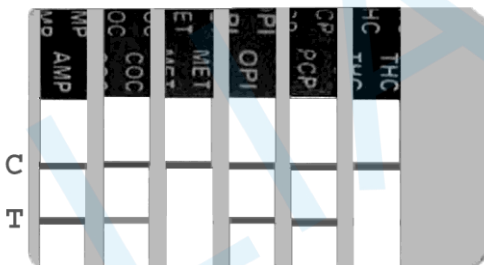


**Negative:** The result is negative when there are two color lines, one in the control region (C) and one in the test region (T).

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.

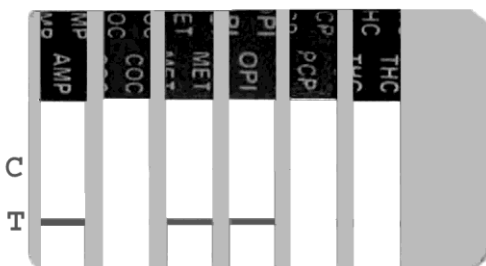
#### Preliminary Positive:



**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 positive 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 Branan 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<sup>®</sup> 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](mailto: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<sup>®</sup> 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, a new specimen should be collected.

### Expected Results

The ToxCup<sup>®</sup> Drug Screen Cup should give a negative result when testing the urine of a normal healthy person. The ToxCup<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Drug Screen Cup are summarized below:

Drug Test	Total # of Test / Conc.	Concentration							
		-50%		-25%		+25%		+50%	
		-	+	-	+	-	+	-	+
AMP1000	25	25	0	25	0	3	22	0	25
BAR300	25	25	0	23	2	2	23	0	25
BZO300	25	25	0	22	3	2	23	0	25
COC300	25	25	0	25	0	0	25	0	25
MDMA500	25	25	0	25	0	0	25	0	25
MET1000	25	25	0	24	1	0	25	0	25
MET500	25	25	0	24	1	0	25	0	25
MTD300	25	25	0	22	3	0	25	0	25
OPI2000	25	25	0	25	0	2	23	0	25
OPI300	25	25	0	25	0	0	25	0	25
OXY100	25	25	0	25	0	0	25	0	25
PCP25	25	25	0	24	1	0	25	0	25
THC50	25	25	0	25	0	0	25	0	25

**Accuracy**

The accuracy of the ToxCup<sup>®</sup> Drug Screen Cup was evaluated in comparison to the results from GC/MS analysis or predicate method using commercially available immunoassay. Forty (40) presumed negative urine samples were collected from volunteer donors and tested with both the ToxCup<sup>®</sup> Drug Screen Cup and the predicate method. Of the 40 presumed negative urine samples tested, all were found negative by both methods.

Additionally, for each drug test on the ToxCup<sup>®</sup> device, a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Drug Test		GC/MS Negative	GC/MS < -50%	GC/MS -50% to Cutoff	GC/MS Cutoff to +50%	GC/MS > +50%	% Agreement w/ GC/MS	
							Neg (-)	Pos (+)
AMP1000	Pos. (+)	0	0	0	7	28	100%	100%
	Neg. (-)	40	0	5	0	0		
BAR300	Pos. (+)	0	0	1	10	23	98%	100%
	Neg. (-)	40	0	7	0	0		
BZO300	Pos. (+)	0	0	0	9	27	100%	100%
	Neg. (-)	40	0	4	0	0		
COC300	Pos. (+)	0	0	0	7	29	100%	100%
	Neg. (-)	40	0	4	0	0		
MDMA500	Pos. (+)	0	0	0	5	30	100%	100%
	Neg. (-)	40	0	5	0	0		
MET1000	Pos. (+)	0	0	0	4	32	100%	100%
	Neg. (-)	40	0	4	0	0		
MET500	Pos. (+)	0	0	0	4	32	100%	100%
	Neg. (-)	40	0	4	0	0		
MTD300	Pos. (+)	0	0	3	6	28	94%	100%
	Neg. (-)	40	0	4	0	0		
OPI2000	Pos. (+)	0	0	0	7	29	100%	100%
	Neg. (-)	40	0	4	0	0		
OPI300	Pos. (+)	0	0	0	4	32	100%	100%
	Neg. (-)	40	0	4	0	0		
OXY100	Pos. (+)	0	0	0	4	32	100%	100%
	Neg. (-)	40	0	4	0	0		
PCP25	Pos. (+)	0	0	0	7	30	100%	100%
	Neg. (-)	40	0	4	0	0		
THC50	Pos. (+)	0	0	0	10	26	100%	100%
	Neg. (-)	40	0	4	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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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%	20	20	0	19	1	19	1	20	0	19	1	20	0	18	2	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	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
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%	20	19	1	19	1	20	0	19	1	19	1	19	0	20	0	20	0	19	1	20	0	19	1	20	0	19	1	
	+20%	20	1	19	0	20	1	19	0	20	1	19	1	19	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
	+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
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%	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%	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	
	+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
Total (-) per test			119		119		119		119		121		120		118		121		120		119		121		120		119		
Total (+) per test				121		121		121		121		119		120		122		119		120		121		119		120		121	

Of the total 160 blind-labeled samples tested per site using ToxCup<sup>®</sup>, 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<sup>®</sup> 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	Phentermine	3,000
l-Amphetamine	25,000	β-Phenylethylamine	100,000
d,l-3,4-MDA	5,000		

#### 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
Butobarbital	400		

#### BZO 300 ng/ml

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

#### COC 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoylcegonine	300	Ecgonine	100,000

#### 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 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	50,000	d-Methamphetamine	1,000
p-Hydroxymethamphetamine	10,000	l-Methamphetamine	50,000
d,l-3,4-MDMA	1000	Procaine	100,000

#### MET 500 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	10,000	l-Methamphetamine	25,000
p-Hydroxymethamphetamine	1,750	Procaine	50,000
d,l-3,4-MDMA	1000	Trimethobenzamide	75,000
d-Methamphetamine	500		

**MTD 300 ng/ml**

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

**OPI 2000 ng/ml**

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	2,000	Hydrocodone	5,000
Codeine	2,000	Hydromorphone	2,500
Dihydrocodeine	2,000	Morphine	2,000
Ethyl morphine	2,000	Morphine-3-β-D-Glucuronide	5,000
Heroin	2,000	Nalorphine	20,000

**OPI 300 ng/ml**

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

**OXY 100 ng/ml**

Compound	ng/ml	Compound	ng/ml
Codeine	10,000	Hydromorphone	25,000
Hydrocodone	600	Oxycodone	100

**PCP 25 ng/ml**

Compound	ng/ml
Phencyclidine	25

**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-Δ-8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ-9-THC-9-COOH	50		

**Interference**

The following compounds were found not to cross-react with the ToxCup<sup>®</sup> Drug Screen Cup when tested at concentrations of 100 μg/ml (100,000 ng/ml):

Acetaminophen (4-Acetamidophenol; APAP; N-Acetyl-p-aminophenol)	Benzoic acid
Acetone	Benzoylecgonine ( <i>except COC assay</i> )
6-Acetylmorphine ( <i>except OPI assay</i> )	Benzphetamine
Acetylsalicylic acid (Aspirin)	Bilirubin
Albumin	Bromazepam ( <i>except BZO assay</i> )
Allobarbitol ( <i>except BAR assay</i> )	d-Brompheniramine
Alphenal ( <i>except BAR assay</i> )	Buprenorphine
Alprazolam ( <i>except BZO assay</i> )	Buprenorphine glucuronide
Amitriptyline	Butabarbital ( <i>except BAR assay</i> )
Amobarbital ( <i>except BAR assay</i> )	Butalbital ( <i>except BAR assay</i> )
Amoxapine	Butethal ( <i>except BAR assay</i> )
Amoxicillin	Caffeine
Aprobarbital ( <i>except BAR assay</i> )	Cannabidiol ( <i>except THC assay</i> )
d-Amphetamine ( <i>except AMP assay</i> )	Cannabinol ( <i>except THC assay</i> )
l-Amphetamine ( <i>except AMP assay</i> )	Chlordiazepoxide ( <i>except BZO assay</i> )
Ampicillin	Chloroquine
Apomorphine	d-Chlorpheniramine
l-Ascorbic Acid (Vitamin C)	d,l-Chlorpheniramine
Aspartame	Chlorpromazine
Aspartamine	Cholesterol
Atropine	Clobazam ( <i>except BZO assay</i> )
Barbital ( <i>except BAR assay</i> )	Clomipramine
Benzilic acid	Clonazepam ( <i>except BZO assay</i> )
Benzocaine (Ethyl p-Aminobenzoate)	Cocaine
	Codeine ( <i>except OPI &amp; OXY assays</i> )

Cortisone	Morphine-3-β-D-Glucuronide ( <i>except OPI assay</i> )
l-Cotinine	Nalidixic acid
Creatine	Nalorphine ( <i>except for OPI assay</i> )
Creatinine	Naloxone
Cyclobenzaprine	d-Naproxen
Delorazepam ( <i>except BZO assay</i> )	Naltrexone
Deoxycorticosterone	Niacinamide
Desipramine	Nicotine, (S)-
Dextromethorphan	Nitrazepam ( <i>except BZO assay</i> )
Diazepam ( <i>except BZO assay</i> )	Norbuprenorphine
Dihydrocodeine ( <i>except OPI assay</i> )	Norbuprenorphine glucuronide
4-Dimethylaminoantipyrine	Nordiazepam ( <i>except BZO assay</i> )
Diphenhydramine	Nordoxepin
Dopamine (3-Hydroxytyramine)	d,l-Norephedrine
Doxepin	Norethindrone
Doxylamine ( <i>except MTD assay</i> )	d-Norpropoxyphene
Ecgonine ( <i>except COC assay</i> )	Nortriptyline
Ecgonine Methyl Ester	Oxalic Acid
d,l-Ephedrine ( <i>except MET assay</i> )	Oxazepam ( <i>except BZO assay</i> )
l-Epinephrine	Oxolinic acid
Erythromycin	Oxycodone ( <i>except OXY assay</i> )
Estazolam ( <i>except BZO assay</i> )	Papaverine
β-Estradiol	Penicillin-G (Benzylpenicillin)
Estrone-3-Sulfate	Pentazocaine
Ethanol	Pentobarbital ( <i>except BAR assay</i> )
Ethyl Morphine ( <i>except OPI assay</i> )	Perphenazine
Ethyl-p-aminobenzoate	Phencyclidine ( <i>except PCP assay</i> )
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidone ( <i>except MTD assay</i> )	Pheniramine ( <i>except MTD assay</i> )
Flunitrazepam ( <i>except BZO assay</i> )	Phenobarbital( <i>except BAR assay</i> )
Flurazepam ( <i>except BZO assay</i> )	Phenothiazine (Thiodiphenylamine)
Furosemide	Phentermine ( <i>except AMP assay</i> )
Gentisic acid	Phenylephrine
Glucose	β-Phenylethylamine ( <i>except AMP assay</i> )
Glutethimide	d-Phenylpropanolamine
Guaiacol Glyceryl Ether	Prednisolone
Hemoglobin	Prazepam ( <i>except BZO assay</i> )
Heroin ( <i>except OPI assay</i> )	Procaine ( <i>except MET assay</i> )
Hippuric acid	Promethazine
Hydrochlorothizide	d-Propoxyphene
Hydrocodone ( <i>except OPI &amp; OXY assays</i> )	Protryptiline
Hydrocortisone	d-Pseudoephedrine
Hydromorphone ( <i>except OPI &amp; OXY assays</i> )	Pryrolidine
p-Hydroxymethamphetamine ( <i>except MET assay</i> )	Quinidine
11-Hydroxy-Δ-9-THC ( <i>except THC assay</i> )	Quinine
Ibuprofen	Riboflavin
Imipramine	Salicylic acid
l-Isoproterenol	Secobarbital ( <i>except BAR assay</i> )
d,l-Isoproterenol	Serotonin
Ketamine	Sodium Chloride
Lidocaine	Sulfamethazine
Lorazepam( <i>except BZO assay</i> )	Sulindac
Lormetazepam ( <i>except BZO assay</i> )	Temazepam ( <i>except BZO assay</i> )
Medazepam ( <i>except BZO assay</i> )	Tetracycline
Meperidine	Δ8-THC ( <i>except THC assay</i> )
Methadone ( <i>except MTD assay</i> )	Δ9-THC ( <i>except THC assay</i> )
d-Methamphetamine ( <i>except MET &amp; MDMA assays</i> )	11-nor-Δ8-THC-9-Carboxylic Acid ( <i>except THC assay</i> )
l-Methamphetamine ( <i>except MET &amp; MDMA assays</i> )	11-nor-Δ-9-THC-9-Carboxylic Acid ( <i>except THC assay</i> )
Methaqualone	Thiamine
Methoxyphenamine	Thioridazine
N-Methyl-Ephedrine	Triazolam ( <i>except BZO assay</i> )
(1R,2S) N-Methyl-Ephedrine	Trifluoperazine
2-Methylamine-Propiophenone	Trimethobenzamide
d,l-3,4-Methylenedioxyethylamphetamine	Trimipramine Maleate
d,l-3,4-Methylenedioxyamphetamine ( <i>except AMP &amp; MDMA assays</i> )	Tryptamine
d,l-3,4- Methylenedioxyamphetamine ( <i>except MET &amp; MDMA assays</i> )	d,l-Tryptophan
Methylphenidate	Tyramine
Morphine ( <i>except OPI assay</i> )	d,l-Tyrosine
	Uric Acid
	Verapamil
	Zomepirac

## Bibliography of Suggested Reading

1. Wong, R., The Current Status of Drug Testing in the US Workforce, Am. Clin. Lab., 2002; 21(1): 21-23
2. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
3. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Wong, R., The Effect of Adulterants on Urine Screen for Drugs of Abuse: Detection by an On-site Dipstick Device, Am. Clin. Lab., 2002; 21(3); 14-18
5. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
6. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987.
7. Gilman, A.G., and Goodman, L.S. The Pharmacological Basis of Therapeutics, Eds. MacMillan Publishing, New York, NY, 1980.
8. Ringsrud, K.M and Linne, J.J., Urinalysis and Body Fluids, A color Text and Atlas, Mosby-Year Book, Inc., 1995.
9. U.S Department of Transportation, Drug Testing Procedures Handbook

Manufactured by:  
Branan Medical Corporation  
140 Technology, Suite 400  
Irvine, CA 92618

For customer inquiry or technical support contact us at:  
1-866-468-3287 Domestic U.S.  
Outside the United States contact your local distributor.

Part No.: PI-PT-CLIA Rev: F, 08/2012

CLIA Waived.com