

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	Methodone	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


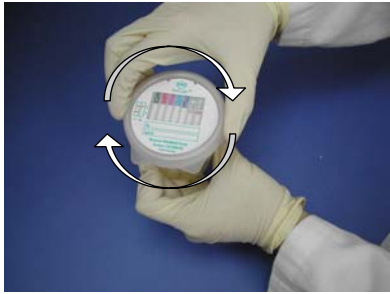

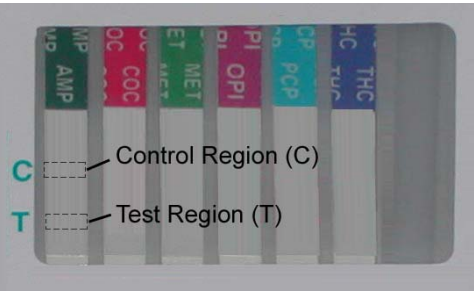
Quality Control

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.



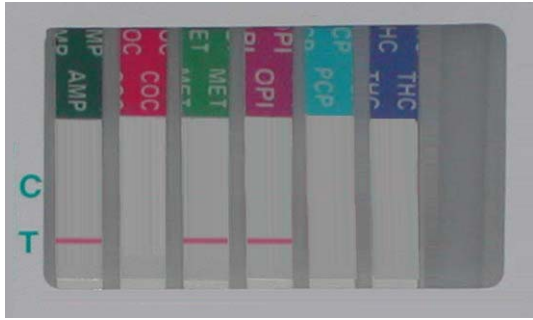
The use of external controls is recommended to verify proper kit performance. Quality Control samples should be tested with each new lot, each new shipment and according to the quality control requirements of the testing facility, and/or applicable federal, state or local guidelines. When testing quality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

Contact the Customer Service Department at CLIAwaived Corporation at 1-888-882-7739 or email to info@cliawaived.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"> 1. Open the pouch and remove the test lid from the pouch. 2. Write the urine sample ID number on the ToxCup® lid. 	<ol style="list-style-type: none"> 3. Close the cup with the lid; make sure the lid is closed tightly. 	<ol style="list-style-type: none"> 4. To start the testing, lay the cup on its side. Position the cup so that it rests on its feet (as shown). 	<ol style="list-style-type: none"> 5. Read test results after 5 minutes. Do not read test results after 1 hour. See Interpretation of Results section below.

Interpretation of Results

		
<p><i>Look at each test strip separately</i></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><i>Look at each test strip separately</i></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><i>Look at each test strip separately</i></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>