

ToxCup[®] Drug Screen Cup

(with and without Adulteration Tests)

Training and Certification Program

ToxCup[®] Drug Screen Cup

ToxCup[®] Drug Screen Cup with Adulteration Tests

Training and Certification for Test Administrators

The information provided is intended to educate test administrators on the use of the ToxCup[®] Drug Screen Cup. This information will include ToxCup[®] with and without adulteration tests. Please read the following information carefully. A multiple-choice test will be administered once the material has been reviewed.

Intended Use

The ToxCup[®] Drug Screen Cup is a one-step immunochromatographic test for the rapid detection of various drugs-of-abuse and their metabolites in human urine. This assay is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only preliminary analytical qualitative drug test results. For a quantitative analytical result or to confirm presumptive positive results obtained by ToxCup[®], a more specific alternative chemical method must be used. The Substance Abuse Mental Health Sources Administration (SAMHSA), formerly the National Institute on Drug Abuse (NIDA), has established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Specific Test Cut Concentration

AMP	Amphetamine	1000 ng/ml
COC	Cocaine (Benzoylecgonine)	300 ng/ml
OPI	Opiates (Morphine)	300 & 2000 ng/ml
MET	Methamphetamine	500 & 1000 ng/ml
PCP	Phencyclidine (PCP)	25 ng/ml
THC	Tetrahydrocannabinol (11-nor- Δ 9-tetrahydrocannabinol-9-carboxylic acid)	50 ng/ml

Warnings and Precautions

- For *in vitro* diagnostic use only.
- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if package is ripped or torn.
- Do not use the test device beyond the expiration date indicated on the pouch.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new ToxCup[®] container for each urine sample.
- The ToxCup[®] Drug Screen Cup should be stored at room temperature (15-30°C or 59-86°F).

ToxCup[®] Drug Screen Cup



Test Principle

The ToxCup[®] Drug Screen Cup is based on the principal of highly specific immunochemical reactions between antigens and antibodies that are used for the analysis of specific substances in urine.

The cup device contains membrane strips onto which drug conjugates are pre-coated at specific regions known as test regions.

Colored antibody-colloidal gold conjugates are coated onto a pad and placed on one end of each membrane. During testing the urine sample is added to the sample well and allowed to migrate across the membrane by capillary action.

If any drug is present in the urine sample, it will compete with the drug conjugate for limited antibody binding sites on the colored colloidal gold conjugate. When a sufficient amount of drug is present above the cut-off level, the drug will saturate the antibody binding sites and the colored colloidal gold cannot bind to the drug conjugate on the membrane. This results in no formation of a band.

If no drug is present, the colored colloidal gold conjugates will bind to the antibody binding sites on the membrane to form visible bands at the test region. Any **presence of a band** regardless of color intensity at the test region indicates a **negative result**.

The absence of a color band at the test region indicates a **presumptive positive result for the particular test**. In either case, the control band must be present for the test to be valid.

ToxCup[®] Drug Screen Cup with Adulteration Tests

The validity of Drugs-of-Abuse (DAU) screening depends on the integrity of the urine samples. Contaminated or adulterated samples may cause erroneous results leading to significant consequences. Hence, it is important to ensure that the samples are intact and unadulterated prior to DAU testing.

CR (Creatinine)	Creatinine is a normal urine constituent. Although the ranges are affected by age, sex, diet, muscle mass and local population distribution, the Department of Transportation (DOT) guideline states that urine specimens with creatinine levels less than 20mg/dl may be indications of dilution or substitution.
OX (Oxidants)	Normal urine specimen should be free of any oxidizing (Ox) agents. A positive 'Ox' detection in the urine suggests adulteration. Bleach and/or other oxidizing compounds are found in commercially available adulterant products. When present in the urine, oxidizing agents such as bleach, nitrate and pyridinium chlorochomate will form a blue to brown-black color on the OX test pad.
PH	The normal urine pH ranges from 4-9. An abnormal 'pH' result (below pH 4 or above 10) indicates adulteration with acidic or alkaline adulterants added to the urine.
NI (Nitrite)	Although nitrite is not a normal component of urine, nitrite levels of up to 10 mg/dl may be found in some urine specimens. A nitrite level of greater than 50 mg/dl is considered beyond the clinical level and is suspiciously abnormal. Nitrite pad changes from no color to pink (normal) to dark purple (abnormal) above 50 mg/dl (≥ 50 mg/dl)

Adulterant testing is a screening method; any abnormal results should be confirmed by an alternate method.

Specimen Collection and Handling

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the specimen container provided. Ensure that the sample volume meets the minimum level required as indicated on the side of the collection cup. Freshly voided, unadulterated specimens usually are in the temperature range of 90°-100°F. The temperature strip on the ToxCup[®] can be used as an aid in assessing sample integrity. Urine samples collected should be tested as soon as possible after collection, preferably within the

same day. Specimens that have been refrigerated or frozen must be equilibrated to room temperature and mixed thoroughly prior to testing.

ToxCup[®] Drug Screen Cup Procedure

IMPORTANT: Do not open test lid pouch until ready to perform the test. Allow refrigerated or frozen specimens to warm to room temperature before testing.

1. Collect urine sample from donor using the collection cup provided.
2. Remove the test lid from the sealed pouch.
3. Twist the test lid securely onto the specimen cup after collection.
4. Lay the cup on its side to activate testing as shown in **Fig. a** below.
5. **Drugs of Abuse Tests:** Negative results are ready to interpret once the control bands (C) form. Presumptive positive results can be interpreted once the control bands (C) form and the membrane background clears (in 5 minutes or less). Results are stable and may be interpreted up to 1 hour after the control bands (C) form.
6. If results are to be confirmed, follow standard chain of custody procedures.



Fig. a

ToxCup[®] Drug Screen Cup with Adulteration Tests

1. Collect urine sample from donor using the collection cup provided.
2. Remove the test lid from the sealed pouch.
3. Twist the test lid securely onto the specimen cup after collection.
4. Lay the cup on its side to activate testing as shown in **Fig. b** on the following page.
5. **Drugs of Abuse Tests:** Negative results are ready to interpret once the control bands (C) form. Presumptive positive results can be interpreted once the control bands (C) form and the membrane background clears (in 5 minutes or less). Results are stable and may be interpreted up to 1 hour after the control bands (C) form.
6. **Adulteration Tests:** Read results in 1 minute. Do not read after 2 minutes as reaction colors may fade. For ease of reading the adulteration pads, the cup may be tilted up-right then returned to its side.
7. If results are to be confirmed, follow standard chain of custody procedures.



Fig. b

Interpreting Test Results

Negative Results

For each drug test, two (2) colored bands should be observed in the result window, one band at the control region (C) and a band at the specific test region (T). The color of the test band may be slightly darker or lighter than the control band. Any band that can be seen visually, no matter how faint, is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In **Fig. c** below, the example shown is negative for all drug tests.

Negative



Fig. c Example of Negative Test Results

Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band appears at the specific test region (T), the result is **presumptive positive** for that particular drug.

In **Fig. d** below, the sample is positive for THC **because no band is visible in the test region** for the THC test.

Presumptive Positive



Fig. d Example of Presumptive Positive Test Result

Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the test results. There must be a control band in the control region. If the test is invalid, check testing procedures, and samples. **Repeat the test using a new device.**

In the **Fig e** below, all tests are invalid because there are no colored bands in the control region.

Invalid



Fig. e Example of Invalid Test Results

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

Limitations of the Procedure

- The assay is designed for use with human urine only.
- Presumptive positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that procedural errors as well as other substances in certain foods and/or medications may interfere with the test (s) and cause false results.
- If it is suspected that the sample may have been mislabeled or tampered with, the specimen should be retested, or a new specimen should be collected and the test repeated.
- Abnormal adulteration test results do not indicate the use of a specific adulterant.
- If abnormal results are obtained with any adulteration test, the specimen should be retested and sent to a laboratory for confirmatory analysis.

THIS COMPLETES THE TOXCUP[®] TRAINING PROGRAM. TO BECOME CERTIFIED AS A TEST ADMINISTRATOR FOR THE DEVICE, YOU MUST COMPLETE THE FOLLOWING QUIZ WITH A MINIMUM SCORE OF 80%.

IF YOU HAVE ANY QUESTIONS OR WOULD LIKE TO SPEAK TO CUSTOMER SUPPORT, CALL US AT 1-888-882-7739 OR E-MAIL info@cliawaived.com or FAX:(801) 720-7568