BRANAN MEDICAL CORPORATION

Product Training & Certification

ToxCup®
Drug Screen Cup Test
(with and without Adulteration Test Pads)

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ToxCup® Drug Screen Cup

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

ToxCup® is a one-step test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the concentrations of:

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	Marijuana	50 ng/ml
OXY	Oxycodone	100 ng/ml
MTD	Methadone	300 ng/ml
BZO	Benzodiazepines	300 ng/ml
BAR	Barbiturates	300 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml

Additionally, ToxCup® can include adulteration tests to determine the validity of the urine sample for contamination prior to drugs of abuse testing. The adulteration tests include creatinine, nitrite, pH, specific gravity, glutaraldehyde and oxidizing agents. This assay is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only preliminary screening results for drugs of abuse. For a quantitative result or to confirm positive results obtained by ToxCup®, a more specific alternative method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

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.
- ToxCup® should be stored at room temperature (15-30 °C or 59-86 °F) in the original sealed pouch.

ToxCup® Drug Screen Cup

Test Principle

ToxCup® 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 **positive result for the particular test. In either case, the control band must be present for the test to be valid.**

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.
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.
OX (Oxidizing Agents)	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.
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.
SG	If a urine specimen exhibits a creatinine concentration of <10 mg/dl, then specific gravity should be 1.003 or less which is suspicious of dilution while if specific gravity should be >1.020, this is indicative of substitution.
GL	Glutaraldehyde is not a normal component of urine and its detection is an indication that the urine may have been adulterated. However, in ketoacidosis, starvation, other metabolic abnormalities, ketone and acetone in urine cause an atypical color formation; the color, typical color of brown, as indicated on the color chart is highly suspicious of glutaraldehyde adulteration.

Specimen Collection and Handling

Collection of 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 (32-38 °C). The temperature strip on the ToxCup® can be used as an aid in assessing sample validity. 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.

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

Procedures

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. Remove the test lid from the sealed pouch.
2. Twist the test lid securely onto the specimen cup after collection.
3. Lay the cup on its side to activate testing as shown in **Fig. 1** below.

Fig. 1

4. **Adulteration Tests (if available):** 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.
5. **Drugs of Abuse Tests**: Once the control bands (C) form (in 5 minutes or less) results are ready to interpret. Results are stable and may be interpreted up to 5 minutes after the control bands (C) form. See package insert.

Interpreting Test Results

Adulteration Tests:

Qualitative results are obtained by visually comparing the color of each test pad with the corresponding color blocks on the color chart card (enclosed with each kit box).

Drug Tests:

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. 2** below, the example shown is negative for all drug tests.

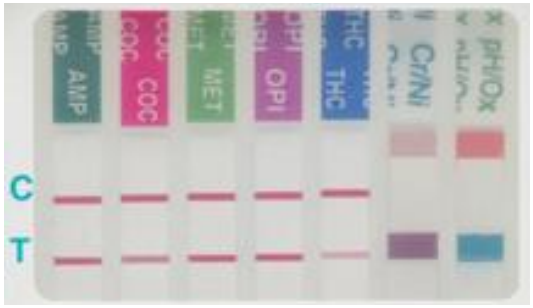


Fig. 2 Example of Negative Test Results

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 positive for that particular drug.

In **Fig. 3** below, the sample is positive for COC and THC because no band is visible in the test region for the COC and THC test.

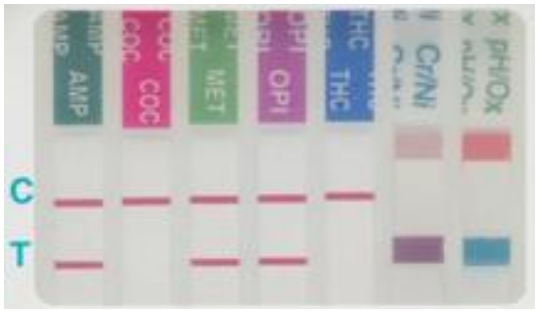


Fig. 3 Example of Positive Test Results

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 4** below, AMP and OPI tests are invalid because there are no colored bands in the control region.

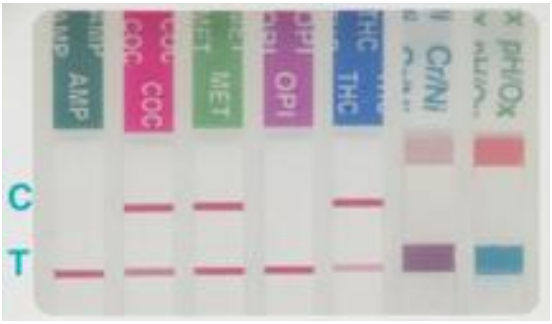


Fig. 4 Example of Invalid Test Results

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. ToxCup® 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 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.
- 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 a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain foods and/or medications.
- If it is suspected that the sample may have been mislabeled or tampered with, 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 results.

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 1-866-468-3287/949-598-7166 OR E-MAIL INFO@BRANANMEDICAL.COM.

ToxCup® Certification Test

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Write your answers on the sheet provided (p. 12).

1. ToxCup® Drug Screen Cup provides

    a. preliminary drug test results
    b. quantitative drug test results
    c. qualitative drug test results
    d. confirmed test results
    e. both a and c are correct

2. The absence of a colored band in the control (C) region indicates that

    a. the test result is invalid.
    b. the test result is negative.
    c. the test result is presumptive positive.
    d. the test should be repeated using a new device.
    e. both a and d are correct.

3. The presence of a colored band at the control (C) region and a colored band at the test region (T) indicates that

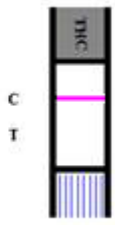
    a. the test is invalid
    b. the test is negative
    c. the test is positive

4. The ToxCup® should be stored

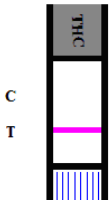
    a. in the freezer.
    b. in the refrigerator.
    c. at room temperature.

5. Interpret the following test:

    a. Invalid
    b. Negative for THC
    c. Presumptive positive for THC

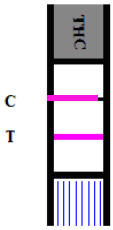


6. Interpret the following test:



   a. Invalid
   b. Negative for THC
   c. Presumptive positive for THC

7. Interpret the following test:



   a. Invalid
   b. Negative for THC
   c. Presumptive positive for THC

8. Once the control band forms in _____ or less, the results are ready to be read.

   a. 2 days
   b. 1 hour
   c. 8 hours
   d. 5 minutes

9. Which of the following are true?

   a. The presence of a band at the test region (T) indicates a presumptive positive result.
   b. Do not compare band intensity of one test to another.
   c. No band at the test region (T) indicates a negative result.
   d. With the appearance of the control band, any test (T) band that can be seen visually, no matter how faint, is a negative result.
   e. Both b and d.

10. Which is false pertaining to adulteration tests?

   a. They ensure the integrity of the urine samples in DAU testing.
   b. Creatinine, Nitrite, Oxidizing Agents, pH, Specific Gravity and Glutaraldehyde are the parameters used to detect adulteration in the ToxCup®.
   c. Adulteration test results may be read in 1 minute.
   d. After 2 minutes reaction colors may fade.
   e. None of the above.

ToxCup® Certification Test Result Sheet

Please enter your answers in the spaces below. Print your name, organization, address, telephone, fax, and e-mail. A certificate will be sent to you if you achieve a score of 80% or higher. Good Luck!

Name _____

Organization _____

Address_____

City, State, Zip Code_____

Telephone_____

Fax_____

E-mail_____

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Answers:

Question 1 _____ Question 6 _____

Question 2 _____ Question 7 _____

Question 3 _____ Question 8 _____

Question 4 _____ Question 9 _____

Question 5 _____ Question 10 _____