Chemtrue® Drugs of Abuse Cup Tests

TRAINING



Chemtron Biotech, Inc. 9245 Brown Deer Road, Suite B San Diego, CA 92121 USA Telephone: 858-450-0044

Fax: 858-450-0046

Training and Certification

This training document is intended to educate test administrators in the use of the Chemtrue[®] DOA Cup Tests. This document will include training for both Chemtrue[®] DOA Cup Tests with and without adulteration. Please read the training information thoroughly and a multiple-choice test will be given once the training has been completed.

Intended Use

The Chemtrue[®] Multi-Panel DOA Cup Tests are rapid immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine/Opiates 300, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL
Barbiturates (BAR)	Secobarbital /Pentobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Ecstasy (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR/OPI300)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Marijuana (THC)	11-nor-Δ ⁹ -THC-9-COOH	50 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

Summary and Explanation

The Chemtrue $^{\circledR}$ Multi-Panel DOA Cup Tests are rapid, visual immunoassays that can be used for the simultaneous, qualitative detection of Amphetamine, Benzoylecgonine, Methamphetamine, Phencyclidine, 11-nor- Δ 9-tetrahydrocannabinol-9-carboxylic acid, Benzodiazepines, Barbiturates, Buprenorphine, MDMA (Ecstasy), Methadone, Morphine 300, Opiates (Morphine/Codeine) 2000, Oxycodone and Tricyclic Antidepressants in urine. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency of use, amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet. Each drug is detected and cleared by the body at different rates. Please refer to the table below:

Drug of Abuse	Detection Times	Clearance Rates
AMP	Within 4 to 6 hours after use	For 2 to 3 days after use
BAR	Within 2 to 6 hours after use	For 1 day after use, 2 to 3 weeks for chronic abusers.
BZO	Within 4 to 6 hours after use	For 3 days after use, 4 to 6 weeks for chronic abusers.
BUP	Within 2 to 4 hours after use	For 2 to 7 days after use
COC	Within 2 to 6 hours after use	For 2 to 3 days after use
MDMA	Within 1 to 6 hours after use	For 2 to 3 days after use
MET	Within 4 to 6 hours after use	For 2 to 3 days after use
MTD	Within 2 to 6 hours after use	For 2 to 6 days after use
MOR/OPI300	Within 2 to 6 hours after use	For 1 to 3 days after use
OPI	Within 2 to 6 hours after use	For 1 to 3 days after use
OXY	Within 2 to 6 hours after use	For 2 to 3 days after use
PCP	Within 4 to 6 hours after use	For 7 to 14 days after use
ТНС	Within 1 to 3 hours after use	For 3 to 10 days after use, 10 to 20 days for chronic abusers
TCA	Within 8 to 12 hours after use	For 2 to 10 days after use
K2	Within 1 to 3 hours after use	For 3 to 10 days after use, 10 to 20 days for chronic abusers

Warning and Precautions

This test is only the first step in a two-step process for determining the presence of drugs of abuse in urine. You must consult your health care provider or refer all "preliminary" results produced by this product to the reference laboratory in order to obtain a confirmed result. Judgment should be applied to any drugs of abuse test result, particularly when initial results are "preliminary". Remember, without confirmation testing, you cannot accept any preliminary positive test result as final. The test provides a screening result only. It is not designed to determine the actual concentration of a drug and it is not to be used for definitive sample analysis.

- Keep test device in the sealed pouch until use. Discard the test device if the pouch foil is ripped or torn.
- Don't reuse the device and don't use expired devices.

Chemtrue® Multi-Panel Drugs of Abuse Cup



Chemtrue® Multi-Panel DOA Cup Tests with Adulteration

Adulteration of urine samples may cause erroneous results and adulterants may interfere with the drug screening test and/or destroy the drugs in the urine. The simplest and most common urine adulteration method is diluting the urine with water. Bleach, Drano, Visine, vinegar, sodium bicarbonate, sodium nitrite, and hydrogen peroxide are some examples of adulterants used to adulterate the urine sample. Chemtrue tests for the following:

Creatinine (**Cr**): Testing for sample dilution. Creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The color intensity is directly proportional to the concentration of creatinine.

Nitrite (Ni): Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium which couples with an indicator to yield a pink-red/purple color complex.

Glutaraldehyde (Gl): Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

pH: Testing for the presence of acidic/alkaline adulterant. The pH determination of urine sample is based on color change of indicator in different acidic or basic medium. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range.

Bl: Testing for the presence of bleach in urine. Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents.

S.G.: Testing for sample dilution. The S.G. test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors changes from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

Specimen Collection and Handling

The urine specimen must be collected in a clean and dry container. The sample can be collected and tested at any time of the day. Fresh urine does not require any special handling or pretreatment and must be collected directly into the drug cup device.

Urine Storage: It is recommended that the collected fresh urine be tested immediately. Fresh urine may be stored at room temperature (25°C) for up to 4 hours or stored refrigerated (2-8°C) for up to 48 hours prior to performing the test. Specimens that have been refrigerated must be brought to room temperature prior to testing. **Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.**

Test Procedure

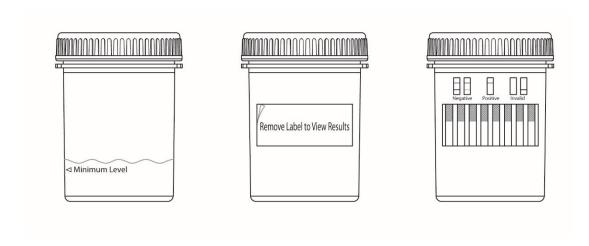
IMPORTANT: The test device should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay. Remove the test device from the sealed pouch and use it as soon as possible.

- 1. Remove the drug cup lid from the test device.
- 2. Collect the urine specimen directly into the Drug Test Cup. Please make sure that enough fresh urine sample is collected and meets the minimum sample level as indicated on the side of the Drug Screen Cup.
- 3. Twist the lid back on and place the cup on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.
- 4. Remove the Peel-Off Label.
- 5. The result(s) should be read at 5 minutes and do not throw away the urine. Urine used may be needed for confirmation testing. Do not interpret the result(s) after 8 minutes.

Positive test results must be confirmed by another test method.

*For adulteration testing, proper read time is critical for optimal results.

Note: All reagent areas may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no value.



Interpretation of Results

Please note: There is no meaning attributed to line color intensity or width. Any evidence of a line should be considered a line. Each test strip is read individually and independently of one another. It is recommended that samples with questionable results or preliminary positives should be confirmed with a more specific method (GC/MS).

NEGATIVE RESULTS:

A colored line appears in the control (C) region and a colored line appears in the test region (T). This negative result indicates that the drug concentration in the urine specimen is below the designated cut-off levels for the drug tested. The color intensity of the line for the drug may be weaker or stronger than that of the control line.



See below for example:



PRELIMINARY POSTIVE RESULTS:

A colored line(s) appears in the control region (C). The absence of a colored line in the test region (T) indicates a positive result.

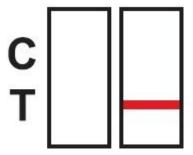


See below for example:



INVALID RESULTS:

No line appears in the control region (C). Under no circumstances should a positive sample be identified until the control line (C) forms in the viewing area. If the control line (C) does not form, the test result is inconclusive and the assay should be repeated with a new device.



See below for example:



Limitations of Procedure

- The assay is designed for use with human urine only.
- A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- There is a possibility that substances may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
- 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 medicines.

THIS CONCLUDES THE CHEMTRON TRAINING PROGRAM. FOR CERTIFICATION, YOU MUST COMPLETE THE QUIZ WITH A MINIMUM SCORE OF 80%.

IF YOU HAVE ANY QUESTIONS OR WOULD LIKE TO SPEAK TO A CUSTOMER SERVICE REPRESENTATIVE, PLEASE CALL US AT 1-866-833-2101.

THANK YOU FOR YOUR TIME AND EFFORTS!

-Chemtron Team

Chemtrue® Multi-Panel Drugs of Abuse Cup Tests

CERTIFICATION TEST

This is a multiple choice test. Please read the questions completely before selecting the best possible answer from the given choices.

1.	The Chemtrue® Drugs of Abuse Tests are rapid immunoassay tests for the qualitative			
	detection of Drugs of Abuse in human			
	a. Urine			
	b. Serum			
	c. Whole Blood			
	d. Saliva			
2.	If the test shows only one control line and no test line appears, the test result should be			
	read as a			
	a. Positive			
	b. Negative			
	c. Invalid			
3.	If the test shows a test line and no control line appears; it is an invalid result and the test should be replaced by using another device. a. True b. False			
4.	If you see a control line and a very light test line appears in the test window, it means that the test result is still a. Negative b. Positive c. Invalid			
5.	If the Chemtrue® Device gives a result for a preliminary positive, the sample must then be sent to a reference laboratory for further confirmation. a. True b. False			

- 6. The Chemtrue® Tests with Adulteration can test for which of the following:
 - a. Creatinine
 - b. Nitrite
 - c. Glutaraldehyde
 - d. pH
 - e. Bleach
 - f. Specific Gravity
 - g. All of the above
- 7. The Chemtrue® Test results should not be interpreted after 8 minutes.
 - a. True
 - b. False
- 8. The Chemtrue® Test shows which result:
 - a. Positive results for all drugs except AMP
 - b. Invalid results for all drugs
 - c. Negative results for all drugs except AMP



- 9. The Chemtrue® Test shows which result:
 - a. Negative results for all drugs except BZO
 - b. Positive results for all drugs
 - c. Negative results for all drugs



- 10. The urine sample must reach the minimum sample level arrow for the test to run properly.
 - a. True
 - b. False

Chemtrue® Test Result Form

Please fill out the form below along with your answers. You must achieve a passing score of 80% or higher to receive a certificate of training. Thank you and good luck!

ANSWERS:

Question 1:	Question 6:
Question 2:	Question 7:
Question 3:	Question 8:
Question 4:	Question 9:
Question 5:	Question 10:

Name	
Company	
Address	
City, State, Zip Code	
Telephone	
Fax	
E-mail	

Mail: Chemtron Biotech, Inc.

9245 Brown Deer Road, Suite B San Diego, CA 92121 USA

Attn: George Chen

Tel: 858-450-0044 Fax: 858-450-0046