

CLIAwaived, Inc. CLIA X Multiple Drug Cup Test

URINE SCREENING TEST /HOME TESTING KITS

Results in 5 Minutes

CLIA-Waived

Instructions



INTENDED USE

This CLIA-X Multiple Drug Cup Test - is intended for professional use as the first step in a 2-step process to provide information concerning the presence or absence of the below stated drugs in a urine sample.

CLIA-X Multiple Drug Cup Test is used to detect the possible use of the drugs listed below at or above the concentrations listed:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE	AMP	1000 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
METHAMPHETAMINE	MET	1000 ng/ml
MORPHINE	MOR	2000 ng/ml
MORPHINE*	MOR	300 ng/ml
BENZOYLECGONINE	BEG	300 ng/ml
BARBITURATES	BAR	300 ng/ml
BENZODIAZEPINE	BZD	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
OXYCODONE	OXY	100 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

*MOR 300 ng/ml not CLIA Waived

Important Note: There are no uniformly recognized cutoff levels for drugs of abuse testing for Benzodiazepine, Oxycodone, Tricyclic Antidepressant, and Barbiturates. The test is not intended to screen or monitor individuals who are prescribed these drugs by a physician; the test may yield positive results for individuals taking such drugs, as prescribed.

For professional and in vitro diagnostic use only

Before You Begin: Read all the information in this instruction booklet before performing the test. first, make sure you are familiar with the test kit contents shown on the following page. it is very important to send the urine sample to the laboratory to confirm a positive result because certain foods, food supplements, beverages or medicine can cause potential interferences. Laboratory tests using GC/MS (HPLC for TCA), are the most reliable way to confirm drugs of abuse tests.

STORAGE AND STABILITY

Store at room temperature 15 - 30°C (59 - 86°F), or refrigerated 2 - 8°C (35 - 45°F) in the sealed pouch, away from direct sunlight. Do not freeze. Do not use after the expiration date that is stamped on the package and foil pouch containing the CLIA-X Multiple Drug Cup Test.

MATERIALS PROVIDED

- One (1) CLIA-X Multiple Drug Cup Test reaction urine cup and one (1) moisture absorbent packet in sealed pouch (this packet should be discarded).
- One (1) instruction booklet
- One (1) plastic sealable bag

MATERIALS REQUIRED BUT NOT PROVIDED

1. Stopwatch or Clock.
2. Control materials to be used periodically (see Quality Control section)
3. One (1) confirmation identification label
4. One (1) pre-addressed mailing box

SUMMARY AND EXPLANATION OF THE TEST

CLIA-X Multiple Drug Cup Test is a convenient specimen collection cup with a built-in strip holder which allows 11 individual determinations within one container. The test is easy and fast allowing the user to visually read the screen for drugs of abuse without the need for any other instrumentation to determine results. The

tester will obtain a result in five minutes. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. This test is the first step in determining whether there are drugs in the urine. If the CLIA-X™ result shows 1 line (preliminary positive) you should send the sample for laboratory testing.

CLIA-X Multiple Drug Cup Test is not for legal or medical diagnostic purposes. For diagnostic and treatment purposes, consult with a healthcare or substance abuse professional.

A **Negative** specimen produces two distinct rose/pink color lines in both the control and test regions

A **Preliminary Positive** specimen produces only one rose/pink color line in the control region.

Note: There is no meaning corresponding to shades of color or the intensity of either the test line or the control line.

COLLECTING THE URINE SAMPLE

All tests for drugs of abuse are only as good as the sample being tested. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected and tested soon after for test results to be accurate. It is recommended that the CLIA-X Multiple Drug Cup Test be used with a fresh and warm urine sample. The testing should not be performed with chilled/refrigerated samples.

CAUTION: Urine sample may be potentially infectious. Wash hands with soap and warm water before and after collecting the urine sample and performing the CLIA-X Multiple Drug Cup Test.

Performing the Test

1. Remove the CLIA-X Multiple Drug Cup Test from its protective foil wrapper.
2. Open the cap of the cup and urinate into the cup so that the sample level falls above the minimum urine level marks printed on the label. (If you collect the urine sample in another clean and dry glass or plastic container, just open the cap of the cup and pour the urine sample into the cup).
3. Secure the lid tightly to the filled specimen collection cup.
4. Peel label indicated with "TAB" to view results.
5. Read each individual test strip result within five (5) minutes after the urine is added to the cup.

IMPORTANT: Refer to the green color as indicated on the temperature label. If the test cup is cold, allow cup to equilibrate to room temperature before you begin.

READING THE RESULTS

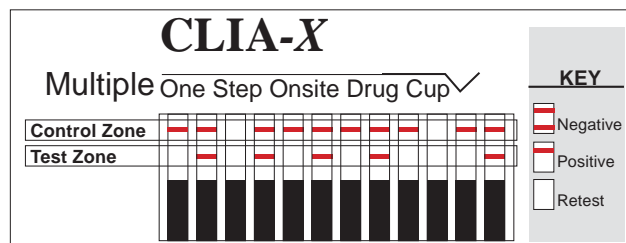
Each target drug that is being tested for has its own test strip. Each strip should be read individually and independently of one another using the illustration below as a guideline.

Preliminary Positive: A *rose-pink* band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

Negative: A *rose-pink* band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

1. Each reaction strip has its own procedural built-in quality control indicator. If, after performing the test, no line is visible on a specific strip, the strip may have deteriorated. The assay for the specific drug of abuse will have to be repeated using a new device or a strip specific for that particular drug. Re-read the instructions carefully or call our USA Local distributor for assistance.

2. External controls (positive and negative) should be run with each new lot, each new shipment and each new operator (or operator who has not performed the test recently) to check that tests are working properly. External controls should also be run when problems are suspected or identified, monthly as a check on storage conditions, and/or if otherwise required by your laboratories standard QC procedure. Commercial controls from Biorad, Quantimetrix (800-624-8380), Utak (www.utak.com), Biochemical Diagnostic (800-223-4835) and Alltech (www.utak.com) are available for validation of device functionality.

3. Manufacturer recommends that for drugs of abuse screening, the controls should contain the drug of abuse analytes at levels near reagent cutoff value.

AFTER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal and/or storage may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** CLIA-X Drug Screen Test Cup Device has been designed to have detection sensitivity as in the following table. The sensitivity study was performed by serial diluting high concentration of determined drug with drug free human urine with 3 different lots of reaction strips.

Table 1-Sensitivity

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE	AMP	1000 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
METHAMPHETAMINE	MET	1000 ng/ml
MORPHINE	MOR	2000 ng/ml
BENZOYLECGONINE	BEG	300 ng/ml
BARBITURATES	BAR	300 ng/ml
BENZODIAZEPINE	BZD	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
OXYCODONE	OXY	100 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

2. Effect of prolonged exposure to test devices

In order to determine if there was any effect on the specimen by prolonged exposure to the test devices a study on CLIA-X Multiple Drug cups was performed using the in-house urine control with GC/MS value. The test specimens were subjected to a time zero (0) GC/MS evaluation. The test specimens were then aliquot to the CLIA-X Multiple Drug cup such that the fluid level was midway between urine level marks and moderately shaken for a period of 10 minutes. The CLIA-X Multiple Drug cup devices with the test specimens were stored for 12 hours at room temperature (15-30°C) followed by 48 hours of incubation at room temperature (15- 30°C).

Samples for GC/MS analysis were taken at times 0, 12, 36 and 60 hours. Statistically there is no significant change in the concentrations reported for any of the analyte at any time period. Based upon the GC/MS data it may safely be concluded that there was no significant change in the specimens that could be related to the device or the test strips contained in the device.

3. Cutoff Characterization

The expected results evaluated at cutoff and 25 % below, 50 % below, 25 % above and 50 % above the determined cutoff values list in the table matched that of the observed results. See table below.

Table 2-Cutoff Determination of Single Drug Test Strip in CLIA-X Multiple Drug Screen Test Cup

Drug Test Strip	Total # of Test	Drug Concentration															
		-50% Cutoff				-25% Cutoff				+25% Cutoff				+50% Cutoff			
		+	+/-	-		+	+/-	-		+	+/-	-		+	+/-	-	
AMP	15	0	0	15	0	3	12	15	0	0	15	0	0	15	0	0	
MET	15	0	0	15	0	4	11	15	0	0	15	0	0	15	0	0	
THC	15	0	0	15	0	5	10	15	0	0	15	0	0	15	0	0	
BEG	15	0	0	15	0	4	11	15	0	0	15	0	0	15	0	0	
MOR	15	0	0	15	0	3	12	15	0	0	15	0	0	15	0	0	
PCP	15	0	0	15	0	5	10	15	0	0	15	0	0	15	0	0	

BZD	15	0	0	15	0	4	11	15	0	0	15	0	0
BAR	15	0	0	15	0	3	12	15	0	0	15	0	0
MAD	15	0	0	15	0	6	9	15	0	0	15	0	0
OXY	15	0	0	15	0	4	11	15	0	0	15	0	0
TCA	15	0	0	15	0	2	13	15	0	0	15	0	0

4. Specificity

The CLIA-X Rapid Multiple Abuse Drug Screen Test Cup Device performance at cutoff level is not effect by any urine samples with pH range of 4.0 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for each 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 cutoff result.

Table 3: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

Amphetamine		Marijuana	
d-Amphetamine	1000 ng/ml	Cannabinol	10,000 ng/ml
l-Amphetamine	25,000 ng/ml	11-nor-Δ-8-THC-9-COOH	50 ng/ml
d,l-Amphetamine	10,000 ng/ml	11-nor-Δ-9-THC-9-COOH	50 ng/ml
β-Phenylethylamine	180,000 ng/ml	Δ 8-THC	7500 ng/ml
Tyramine	100,000 ng/ml	Δ 9-THC	10,000 ng/ml
(±) 3,4-Methylene-dioxyamphetamine (MDA)	1200 ng/ml	11-hydroxy-Δ-9-THC	2500 ng/ml
Phencyclidine		Oxycodone	
Phencyclidine	25 ng/ml	Oxycodone-HCL	100 ng/ml
Tenocyclidine	2000 ng/ml	Codeine	700 ng/ml
Methamphetamine		Hydrocodone	500 ng/ml
(+) Methamphetamine	1000 ng/ml	Hydromorphone	1,500 ng/ml
(±)3,4Methylenedioxyamphetamine (MDMA)	1000 ng/ml	Morphine-Sulfate	7,000 ng/ml
Morphine		Morphine-3-b-D-Glucuronide	40,000 ng/ml
Opiate	2000 ng/ml	Norcodeine	40,000 ng/ml
Morphine Sulfate Pentahydrate	2000 ng/ml	Oxymorphone	300 ng/ml
Morphine-3-β-D Glucuronide	2000 ng/ml	Tricyclic Antidepressant-	
Codeine	2000 ng/ml	Amitriptyline	1,000 ng/ml
Heroin	2000 ng/ml	Cyclobenzaprine	1,500 ng/ml
Levorphanol	4000 ng/ml	Clomipramine	5,000 ng/ml
Ranitidine	100,000 ng/ml	Benzoylcegonine	
Benzoylcegonine		Desipramine	600 ng/ml
Cocaine	300 ng/ml	Doxepin	1,000 ng/ml
Benzoyl Ecgonine	300 ng/ml	Imipramine	600 ng/ml
Barbiturates		Notriptyline	1,000 ng/ml
Allobarbitol	600 ng/ml	Nordoxepin	1,000 ng/ml
Amobarbitol	600 ng/ml	Methadone	
Barbitol	300 ng/ml	Methadone	300 ng/ml
Butabarbitol	300 ng/ml	Doxylamine	50,000 ng/ml
Butalbitol	300 ng/ml	EDDP (2 Ethylidene-1,5-dimethy 1-3,3-Diphenylpyrrolidin)	100,000 ng/ml
Pentobarbitol	300 ng/ml	Methadol	25,000 ng/ml
Phenobarbitol	300 ng/ml	Perphenazine	75,000 ng/ml
Secobarbitol	300 ng/ml	Protriptyline	2,000 ng/ml
		Trimipramine	10,000 ng/ml
Benzodiazepine			
Alprazolam	600 ng/ml	Flunitrazepam	300 ng/ml
Bromazepam	100 ng/ml	Flurazepam	150 ng/ml
Chlordiazepoxide	300 ng/ml	Lorazepam	500 ng/ml

Clobazam	300 ng/ml	Lormetazepam	500 ng/ml
Clonazepam	300 ng/ml	Nitrazepam	250 ng/ml
Clorazepate	200 ng/ml	Nordiazepam	150 ng/ml
Delorazepam	3,000 ng/ml	Oxazepam	300 ng/ml
Diazepam	300 ng/ml	Prazepam	1,500 ng/ml
Estazolam	300 ng/ml	Temazepam	150 ng/ml
Triazolam	200 ng/ml		

A study was conducted with CLIA-X Multiple Drug Screen Test Cup to determine the cross-reactivity of non drug related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances list in the following table.

Table 4: Compounds tested and found not to cross-react with the test at a 100 µg / ml concentrate in urine.

<i>Acetaminophen</i>	<i>Furosemide</i>
<i>Acetone</i>	<i>Glucosamine</i>
<i>Acetyl Salicylic Acid</i>	<i>Guaiacol Glyceryl Ether</i>
<i>Amikacin</i>	<i>Hydrochlorothiazide</i>
<i>Amitriptyline</i>	<i>Hydrocodone</i>
<i>Ampicillin</i>	<i>Ibuprofen</i>
<i>l-Ascorbic Acid (Vitamin C)</i>	<i>Ketamine</i>
<i>Aspartame</i>	<i>Lidocaine</i>
<i>Aspirin</i>	<i>Maprotiline</i>
<i>Atropine</i>	<i>Meperidine</i>
<i>Benzocaine</i>	<i>Methanol</i>
<i>Benzoic Acid</i>	<i>Methylphenidate</i>
<i>(+)- Brompheniramine</i>	<i>Naltrexone</i>
<i>Buprenorphine</i>	<i>(+/-) Naproxen</i>
<i>Buprenorphine-3-β-D-Glucuronide</i>	<i>Nicotine</i>
<i>Caffeine</i>	<i>Nor-Buprenorphine</i>
<i>(+)-Chlorpheniramine</i>	<i>Noscapine Hydrochloride</i>
<i>(+/-)-Chlorpheniramine</i>	<i>Oxalic Acid</i>
<i>Chlorpromazine</i>	<i>Omega-3-Fatty Acid</i>
<i>Cortisone</i>	<i>Penicillin G</i>
<i>(-)-Cotinine</i>	<i>Phenazone</i>
<i>Creatinine</i>	<i>l-Phenylephrine</i>
<i>Dextromethorphan</i>	<i>(+/-)-Phenylpropanolamine</i>
<i>4-Dimethylaminoantipyrine</i>	<i>Promethazine</i>
<i>Diphenhydramine</i>	<i>Pseudoephedrine</i>
<i>5,5-Diphenylhydantoin</i>	<i>Quinine</i>
<i>Dopamine</i>	<i>Quinidine</i>
<i>EDDP</i>	<i>Salicylic Acid</i>
<i>+ Ephedrine</i>	<i>Sulindac</i>
<i>- Ephedrine</i>	<i>Sustiva</i>
<i>(+/-) Epinephrine</i>	<i>Theophylline</i>
<i>Erythromycin</i>	<i>Thioridazine</i>
<i>Ethanol</i>	<i>Tramadol</i>
<i>Fentanyl</i>	<i>d(+)-Trehalose</i>
<i>Fluxetine</i>	<i>Trifluoperazine</i>

In order to examine potential natural occurring interfering substances normally contained in urine. Drug free urine and drug positive urine were spiked with various potential interfering substances. Both aliquots were tested with CLIA-X Multiple Drug Screen Test Cup Device. There is no cross interference by the following substances at the concentration list in the following table. The results are presented below in the following table.

Table 5-Natural Occurring Compounds in Urine and the Effect on CLIA-X Multiple Drug Screen Cup

Analyte	Range	Effect	
		Positive*	Negative**
Ascorbic	300 mg/dl		
Bilirubin	1.0 mg/dl	None	None
Creatine	500 mg/dl	None	None
Glucose	1500 mg/dl	None	None
Hemoglobin	300 mg/dl	None	None
Potassium	110 mEq/dl	None	None
Human Serum Albumin	500 mg/dl	None	None
Globulin	1500 mg/dl	None	None
Sodium chloride	6000 mg/dl	None	None
Uric Acid	23 mg/dl	None	None
Cholesterol	500 mg/dl	None	None

*Concentration of Positive Drug Control = Amphetamine 1250 ng/ml, Methamphetamine 1250 ng/ml, Opiates 2500 ng/ml, Cocaine 375ng/ml, THC 63 ng/ml, Phencyclidine (PCP) 32 ng/ml, Benzodiazepine (450 ng/ml), Barbiturate (450 ng/ml), Methadone (450 ng/ml), TCA (1250 ng/ml), Oxycodone (100 ng/ml), Propoxyphene (300 ng/ml). ** Concentration of Drug [Drug Free urine] = 0 ng/ml

5. Precision

Within lot reproducibility

Drug free of human urine demonstrated to be negative for 12 panel of drug (AMP, MET, BEG, THC, MOR, PCP, BZD, MAD, TCA, OXY and BAR) were spike with the drug to the level of 0, 50, 75, 100, 125, and 150 % of the cutoff level for each drug. A single lot of test device were used to test the reproducibility of CLIA-X Multiple Drug Screen Test Cup Device. Fifteen (15) devices per concentration were tested and the result data indicated the result data indicated 100 % precision within lot for each panel of drug on 50 % below (all negative), cutoff and above cutoff level (all positive).

Inter lot reproducibility

To test the inter lot reproducibility, Drug free human urine demonstrated to be negative For 12 panel of drug (AMP, MET, BEG, THC, MOR, PCP, BZD, MAD, TCA, OXY and BAR) were spike with the drug to the level of 0, 50, 75, 100, 125 and 150 % of the cutoff level for each drug. These were used to test three different lots of devices over a period of 15 days. The results of the test demonstrate that there is no appreciable inter lot variation on the drug level of 0, 50, 100, 125 and 150 % of the cutoff level ,when testing both positive and negative spiked samples across three (3) different lots of devices at different day.

4.Accuracy

Banked patient samples were subjected to evaluation involving a comparison between the device, and GC/MS. The summary results of that testing are presented below for all eleven (11) analyte.

Table 6-Summary of Accuracy Results with CLIA-X Multiple Drug Screen Test Cup

CLIA-X Drug Test		GC / MS Negative	GC / MS Negative	GC / MS Positive	GC / MS Positive	% Agreement with GC/MS	
		(0 to <-50% CO)	(-50% to CO)	(+50% to CO)	(>+50% to CO)	Negative (-)	Positive (+)
AMP	P(+)	0	2	5	42	97%	100%
	N(-)	58	3	0	0		
MET	P(+)	0	1	10	31	98%	100%
	N(-)	55	4	0	0		
BEG	P(+)	0	1	17	25	98%	100%
	N(-)	49	4	0	0		
THC	P(+)	0	1	6	36	98%	100%
	N(-)	50	3	0	0		
MOR	P(+)	0	1	17	24	98%	100%
	N(-)	50	4	0	0		
PCP	P(+)	0	4	16	24	93%	100%
	N(-)	50	3	0	0		
BZD	P(+)	0	2	14	28	96%	100%
	N(-)	49	3	0	0		

MAD	P(+)	0	0	9	33	100%	100%
	N(-)	48	4	0	0		
OXY	P(+)	0	1	5	50	98%	100%
	N(-)	39	4	0	0		
TCA	P(+)	0	1	18	23	98%	100%
	N(-)	38	4	0	0		
BAR	P(+)	0	2	19	20	96%	100%
	N(-)	49	3	0	0		

Understanding the Results

This test is the first step in determining whether there are drugs in the urine. If the CLIA-X result shows 1 line at the top (preliminary positive) you should send the sample for laboratory testing. The CLIA-X test device detects any or all of the drugs when they are above the cutoff level for the specific drug. However, a “preliminary positive” test result does not always mean a person took an illegal drug and a negative test result does not always mean a person did not take any illegal drugs. There are a number of factors that influence the reliability of drug tests, such as a doctor’s prescription, diet, over the counter medication, etc. Certain drugs of abuse tests are more accurate than others.

What is meant by a “Preliminary Positive” test results?

CLIA-X Multiple Drug Cup Tests are considered “screening tests”. They are the first step in a two-step process. Screening tests are not as accurate as laboratory tests, and it is possible to get a preliminary positive result when the person has not taken any drugs. For example, some medicines and food may cause the screening tests to incorrectly read positive. Things such as diet pills, inhalers and cough syrup can also cause a positive result.

If you get a preliminary positive test result, you should take the second step and send the sample to a laboratory. There is no additional charge for this confirmation testing. Additional testing by a more sophisticated laboratory technique known as gas chromatography/mass spectroscopy (GC/MS) will be performed. Having the laboratory test the urine is the only way to know for certain if there are drugs in the urine.

What does a negative screening result mean?

This means there is no drug or not enough drugs present in the sample to be considered a preliminary positive test result.

Samples that are negative do not need further testing.

It is possible to get a negative even though the person took drugs. Some reasons this may happen include:

- The urine sample was collected at the wrong time relative to when the person took the drugs (sample was collected before the drug got in the urine or after the drug was no longer in the urine)
- The person took another drug other than the ones being tested for with the CLIA-X Multiple Drug Cup Test.
- The urine sample was adulterated. Bleach and other strong chemicals can degrade drugs in the urine. Also, if other liquids are added to the urine, the urine can get diluted and concentration of the drug may drop below the level where it cannot be detected by the test.
- Reagents may deteriorate if stored improperly

The Substance Abuse and Mental Health Service Agency (SAMHSA), has established “cut-off” levels for testing some drugs of abuse. The CLIA-X Multiple Drug Cup Test is manufactured to conform to those government guidelines. Screening tests may not detect amounts of drugs in a urine sample that are below the cut-off level. In other words, though some level of drugs may be present in a urine sample, the sample would still be considered a NEGATIVE screenings result if the drug level is below the cut-off level.

The CLIA-X Multiple Drug Cup Test Cut-Off Levels

Identifier	Drug Name	Cut-off Level (ng/ml)
AMP	*Amphetamine	1000
MET	*Methamphetamine	1000
COC	*Cocaine	300
THC	*Marijuana	50

OPI	*Opiate	2000
BZD	Benzodiazepine	300
PCP	*Phencyclidine	25
MAD	Methadone	300
OXY	Oxycodone	100
TCA	Tricyclic Antidepressant	1000
BAR	Barbiturates	300

*The cutoff level has been established by SAMHSA

Test Limitations

- For in vitro diagnostic (IVD) use only.
- The CLIA-X Multiple Drug Cup Test can be used one time only.
- Only human urine samples can be used with this test.
- Adulterants, such as bleach, household cleaners, soaps, vinegar, “cleansing” herbs, potions, and teas in a urine sample may produce an incorrect result. If adulteration is suspected, the test should be repeated with fresh urine with a new CLIA-X Multiple Drug Cup Test.
- Drinking large amounts of liquids may dilute the urine so that the drug (if present) cannot be detected.
- Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.
- Some drugs or foods may interfere with the test and cause false positive results. This can happen with any drug, but more so for amphetamine and opiate test results. Therefore confirmation testing is needed.
- Negative results may be obtained if the drug concentration is below the designated test cutoff.

Note about testing for prescription drugs

There are no uniformly recognized cutoff levels for drugs of abuse testing for Benzodiazepine, Oxycodone, Tricyclic Antidepressant, and Barbiturates. The test is not intended to screen or monitor individuals who are prescribed these drugs by a physician; this test and the confirmation test may yield positive results for individuals taking such drugs, as prescribed.

About Confirming the Test Results

Negative samples do not need further testing. You should send “preliminary positive” samples to our laboratory for confirmation. Confirmation testing should be performed on all positive results.

Commonly Asked Questions

1.How common is drug use in America today?

It was reported that an estimated 13 million Americans were currently using illicit drugs, meaning they had used an illicit drug within the month prior to being interviewed by the Washington Post in September of 1996.

2.What does CLIA-X Multiple Drug Cup test do?

CLIA-X Multiple Drug Cup Test indicates if one or more prescription or illegal drugs are present in urine. The test detects the presence of 12 prescription and illegal drugs: Amphetamines(AMP), Benzodiazepine(BZD), Barbiturates(BAR), Methadone(MAD), Phencyclidine(PCP), Opiates(OPI), Tricyclic Antidepressant(TCA), Oxycodone(OXY), Methamphetamine(MET), Marijuana (THC), and Cocaine(COC).

This test is done in two steps. First, do a quick at home test. Second, if the test suggests that drugs may be present, send the sample to a laboratory for additional testing.

3.What is abuse of prescription drugs?

Prescription drugs of abuse are medicines (for example, Oxycodone) that are obtained legally with a doctor’s prescription, but are being taken for non-medical purpose. Non-medical purposes include taking the medication for longer than your doctor prescribed or for a purpose other than what the doctor prescribed. Medications are not considered ‘drugs of abuse’ if they are taken according to your doctor’s instructions.

This test does not distinguish whether a drug is taken according to prescription or is being abused. In addition, the test is a qualitative test and is not intended to determine therapeutic drug levels.

4.What type of test is this?

This is a qualitative test. Results determine that a particular drug may be in the urine, not how much is present in the urine.

5. Why should you perform this test?

You should use this test when you think someone you care about might be abusing prescription or illegal drugs. If you are worried about a specific drug, make sure to check the label to confirm that this test is designed to detect the drug you are trying to detect.

6. How accurate is this test?

The first step of this test is fairly sensitive to the presence of drugs in the urine. (See performance section). You should send the urine sample to the laboratory for second test. It is very important to send the urine sample to the laboratory to confirm a positive result because certain foods, food supplements, beverages, or medicines can affect the results of tests. Laboratory tests are the most reliable way to confirm abuse of drugs.

Note that all amphetamine results should be considered carefully, even those from the laboratory. Some over-the-counter medications cannot be distinguished from illegally-abused amphetamines.

Many things can affect the accuracy of this test, including (but not limited to):

- The way the test is performed
- The way the test or urine is stored
- What the person ate or drank before taking the test
- Any other prescription or over-the-counter drugs the person may have taken before performing the test

7. If I do not see a rose/pink color migration in the viewing window five minutes after I urinate (or pour the urine) into the CLIA-X Multiple Drug Cup Test, what should I do?

The CLIA-X Multiple Drug Cup Test should work if you follow the instructions properly. However, there are always some people who do not add enough urine to the cup (up to the minimum line as the instructions indicated). To compensate for this error, you should add additional urine until it reaches the minimum line indicated and within minutes you should start seeing a rose/pink color migration take place. Read the results after 5 minutes.

8. Within seconds after I add urine sample to the cup, I can see a rose pink color covering the entire window and there are low vertical lines that appear darker than the rest of the window. Does this mean the test is positive?

After the urine sample is added, you will see movement of a rose pink colored liquid that starts from the bottom and gradually moves toward the top of the window. You may see a few vertical streaks which should eventually disappear. This is completely normal and the device is working properly. You should never use any vertical streaks in determining test results. Only horizontal lines in the windows can be used to determine the test result.

9. How long after use can drugs be detected in the urine?

Each drug is cleared by the body at different rates. The amount of a drug in the body is dependent on many factors. How often the drug is taken, how the drug was taken (swallowed, inhaled, smoked or injected) as well as user age, weight, diet and metabolic rate all play a part in detection times. The table below shows minimum and maximum times that drugs can be detected in the urine.

Drug	Drug Street Name(s)	Approximate Detection Time	
		Min	Max
Amphetamine (AMP)	Speed, amp, black beauties	4-6 hours	2-3 days
Methamphetamine (MET)	Crystallmeth, speed, glass, Ecstasy	4-6 hours	2-3 days
Benzodiazepine (BZD)	Downers	2-7 hours	1-4 days
Barbiturates (BAR)	Downers, barbs, red devils	2-4 hours	1-3 days
Cocaine (COC)	Coke, snow, blow, candy, crack	2-6 hours	2-3 days
Methadone (MAD)	Done	3-8 hours	1-3 days
Marijuana (THC)	Pot, grass, weed, doobie, joint, roach	1-3 hours	1-7 days
Phencyclidine (PCP)	Angel dust, rocket fuel	4-6 hours	7-14 days
Opiates (OPI)	Heroin, morphine	2-6 hours	1-3 days
Oxycodone (OXY)	--	1-3 hours	1-2 days
Tricyclic Antidepressant (TCA)	--	8-12 hours	2-7 days

10. Do I have to wait the full 5 minutes before reading the test?

Yes. We recommend that you wait the full 5 minutes before reading the result. If you read the result too early, or after 10 minutes, the test results may be incorrect.

11. What if I get an invalid result or I am uncertain about the test result?

If you get an invalid result or are uncertain about the test result, you may not have conducted the test correctly. It is recommended that you retest using another CLIA-X Multiple Drug Cup Test and make sure to follow the instructions carefully. Please call our USA local distributor, TEL #: 858-481-5031, if you have questions about your result.

12. Listed below is a glossary of definitions appropriate to the CLIA-X Multiple Drug Cup Test.

Confirmation – The process of using a second analytical procedure to verify the presence of a specific drug or metabolite, which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test to ensure reliability and accuracy.

Cross reactivity- The degree to which an antibody interacts with antigen other than the one used to produce the antibody. This is a property of nearly all naturally derived antibodies.

Cutoff – The concentration of a target drug in a specimen at or above which the test is called positive and below which it is called negative.

False Positive - A test result which states that a drug or metabolite is present when, in fact, the drug or metabolite is not present, or is present in an amount less than the threshold or cutoff value.

GC/MS – An abbreviation for instrumental technique which couples the powerful separation potential of gas chromatography with the specific characterization ability of mass spectroscopy.

Metabolite – Drug breakdown products.

Screen test – The initial test used to identify those specimens which are negative or positive for the presence of drugs or their metabolites. Negative specimens need no further examination and need not undergo confirmation testing.

13. What commonly abused drugs are not detected by this test?

Buprenorphine
Ketamine
EDDP (a Methadone metabolite)
Nor-Buprenorphine
Ephedrine
Pseudoephedrine
Epinephrine
Tramadol
Fentanyl

14. Where can you get more information and resource about drug abuse and drugs of abuse testing?

The following list of organizations may be helpful to you for counseling support and resources.

National Clearinghouse for Alcohol and Drug Information

www.health.org 1-800-729-6686

Center for Substance Abuse Treatment.

www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence

www.ncadd.org 1-800-NCA-Call

The Parent's Resource Institute for Drug Education, Inc. (PRIDE)

www.pride.org 1-800-677-7433

American Council for Drug Education (ACDE)

www.acde.org 1-800-488-DRUG

MEDLINE plus Health Information: Drug Abuse Back to Consumer Information on Home-Use Tests