CLIAwaived™ Inc.

Multi-Drug Screen Test CUP

Package Insert for OTC Use

For *in vitro* diagnostic use only

The CLIAwaived,Inc. Multi-Drug Screen Test Cup offers a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI	Morphine	300
OPI	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

INSTRUCTIONS FOR OTC USE:

BEFORE TESTING

Read the instructions completely.
Check the expiration date on the box. Do not use the test if it is expired. Have a watch, clock or timer ready.

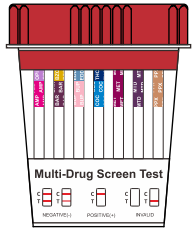
The following items are needed only if you choose to ship samples for confidential confirmation lab testing:

- Pre-addressed shipping box
- Plastic transportation bag
- Identification label

PERFORMING THE TEST

Step 1: Take Out the Test Device

Take the test device from the sealed foil pouch.



Step 2: Apply Urine to the Test Device

If Using a Cup:

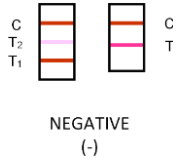
1. Remove the cup from the sealed pouch. Write the donor name or ID in the space provided.
2. **Collect urine** in the cup.

Step 3: Read Result

Read results after 5 minutes. Do not wait longer than 60 minutes.
A red or pink line must appear next to the letter “C” (control) on all of the test strips. The appearance of a red or pink next to the letter “C” on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

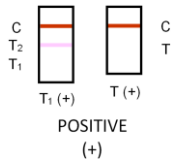
Negative Result:

A red or pink line next to the “T1” or “T2” (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the “T1” or “T2” for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



Preliminary Positive Result:

If NO red or pink line appears next to the "T1" or "T2" under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.



Invalid Result:

A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.

QUESTIONS AND ANSWERS

The CLIAwaived, Inc. IDTC II is user friendly, if you have question about the test or result, please call our helpline at 1-888-882-7739, a 24/7-recorded information service is available, please leave your message and your call will be returned the next business day. In addition, the CLIAwaived, Inc. team is available to answer your question weekdays from 8 am to 5 pm PST

What do my test results mean?

Q. **The drug line is lighter than control line. Does it mean the drug is present in the urine?**

A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. **What does a Preliminary Positive Result mean?**

A. The sample may contain one or more of the drugs being tested for. It is possible to get a "preliminary positive" when someone has not taken the drug. We recommend you send the urine to our laboratory for additional confirmation testing. Additional fees may apply.

- Medicinal such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine. To find more information on false positive results caused by prescription drugs, see www.askdocweb.com/falsepositives.html.

Q. **What does a Negative Result mean?**

A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a

negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. **What does an Invalid Result mean?**

A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact your sales representative.

Laboratory Confirmation Testing:

Q. **How can a Preliminary Positive Result be confirmed?**

A. The urine specimen needs to be sent to our laboratory for confirmation testing. See the shipping instructions in **"Shipping the Urine Sample to the Lab for Confirmation Testing"** section below.

Other Questions:

Q. **When is the best time to take the test?**

A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:

Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/ml	2-7 hours	2-4 days
Cocaine (COC)	150 ng/ml	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/ml	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/ml	2 hours	2-3 days
Marijuana (THC)	50 ng/ml	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/ml	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/ml	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/ml	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/ml	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/ml	1-3 hours	1-2 days
Methadone (MTD)	300 ng/ml	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/ml	2-7 hours	2-4 days
EDDP	300 ng/ml	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/ml	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. **How much urine do I need?**

A. The CLIAwaived, Inc. Multi-Drug Screen Test Cup requites just 30 ml of urine. Fill the collection cup of the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

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

A. Yes, we recommend that you wait the full 5 minutes before reading the result.

Q. **Are there any factors that could affect the drug testing result?**

A. Yes, certain factors may affect the drug testing result.

1. Certain over the counter medicines and prescription medicines may cause a preliminary positive result.
2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
4. Failure to use the CLIAwaived,Inc. IDTC II as directed may result in an inaccurate screening result.
5. The following compounds are detected positive in urine by the The CLIAwaived,Inc. Multi-Drug Screen Test Cup. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250(120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		

Compound	Concentration (%)	Compound	Concentration (%)
MTD			
Methadone	300 (100%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor-Δ^9-THC-9-COOH	50 (100%)	(-)-Δ^8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ^9-THC	5,000 (1%)	(-)-Δ^9-THC	20,000 (0.3%)

SHIPPING URINE SAMPLES FOR CONFIRMATION TESTING (OTC ONLY)

About confirmation testing:

Negative samples do not need further testing. You should only send preliminary positive samples to a laboratory for confirmation.

Check the provided shipping package:

The following items are provided (OTC only):

- Mailer: Pre-addressed Mailing Box with Transportation Label
- Zip-lock Plastic Transportation Bag
- Identification Label

Package urine samples for shipping:

- Attach the top portion of the identification label to the urine collection cup.
- Attach the lower portion of the identification label to the instruction sheet where labeled “place identification label here.” For security reasons, you will need this number to retrieve your lab test results.

- Place the urine collection cup in the zip-lock plastic transportation bag, seal and place into the pre-addressed mailing box and close. On the pre-addressed mailing box label, fill in the sample collection date.
- On the mailing box label, check off the drug(s) that gave a preliminary positive result. IT IS IMPORTANT THAT YOU INDICATE WHICH DRUG WAS POSITIVE SO THAT A LAB CONFIRMATION TEST CAN BE PERFORMED FOR THAT DRUG. WITHOUT THIS LABEL, YOUR SAMPLE CANNOT BE TESTED.
- Mail the preliminary positive urine sample as soon as possible. Urine samples cannot be accurately tested if more than 7 days old.
- The mailing box is not pre-paid. To ensure prompt delivery, be sure to pay the appropriate shipping charges.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from CLIAwaived, Inc. or other commercial sources. A minimum of 5mL of positive and/or negative control material is required to activate the CLIAwaived, Inc Multi-Drug Screen Test Cup II. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators. It is recommended that Quality control testing be performed with each new lot, with each new shipment, and every thirty days when storage conditions may have changed or exceeded storage requirements of the product labeling. External controls can be purchased from the following vendor: CLIAwaived, Inc. 1-888-882-7739, www.cliawaived.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the CLIAwaived, Inc. Multi-Drug Screen Test CUP was evaluated in comparison to GC/MS and LC/MS. 40 drug-free urine samples collected from presumed non-user volunteers were tested with the CLIAwaived, Inc. Multi-Drug Screen Test CUP. Of these 40 negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 40 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy and discordant results on Cup formats are shown in the following tables:

Summary of Accuracy Results on the CLIAwaived, Inc Cup

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/ 300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/ 500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/ 1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the CLIAwaived, Inc Cup

Drug Test/ Cutoff (ng/ml)	CLIAwaived,Inc Cup Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine

MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
PPX/300	Positive	242	Norpropoxyphene
	Positive	285	Norpropoxyphene
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor-Δ^9-THC-9-COOH

B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the CLIAwaived, Inc Cup.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the CLIAwaived, Inc Multi-Drug Screen Test Cup. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250 (120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)		
Clobazam	200 (150%)	Nitrazepam	250 (120%)
Clorazepate	750 (40%)	Norchlordiazepoxide	500 (60%)
Desalkylflurazepam	1,200 (25%)	Nordazepam	390 (76.9%)
Diazepam	1,000 (30%)	Nordiazepoxide	400(75%)
Flunitrazepam	250 (120%)	Temazepam	150 (200%)
α-Hydroxyalprazolam	1,900 (15.8%)	Triazolam	2,500 (12%)

Compound	Concentration (%)	Compound	Concentration (%)
COC			
Benzoylecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
MTD			
Methadone	300 (100%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)		
Heroin	8,000 (37.5%)	Norcodeine	6,000 (1.9%)
Hydrocodone	1,250 (24%)	Oxycodone	75,000 (0.4%)
Hydromorphone	2,500 (12%)	Thebaine	90,000 (0.3%)
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)		
Heroin	11,000 (18.2%)	Oxycodone	70,000 (2.9%)
Hydrocodone	5,000 (40%)	Thebaine	95,000 (2.1%)
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor-Δ^9-THC-9-COOH	50 (100%)	(-)-Δ^8-THC	20,000 (0.3%)
(+/-)-11-Hydroxy-Δ^9-THC	5,000 (1%)	(-)-Δ^9-THC	20,000 (0.3%)

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the CLIAwaived, Inc. Multi-Drug Screen Test Cup. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the CLIAwaived, Inc. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL when tested with the CLIAwaived, Inc. Multi-Drug Screen Test CupI:

Acetaminophen	Diphenhydramine	Nicotine
Acetone	Dopamine	(+/-)-Norephedrine
Albumin	(+/-)-Isoproterenol	Oxalic acid
Ampicillin	1R,2S(-)-Ephedrine	Penicillin-G
Ascorbic acid	Erythromycin	Pheniramine
Aspartame	Ethanol	Phenothiazine
Aspirin	Furosemide	L-Phenylephrine
Atropine	Glucose	B-Phenylethylamine
Benzocaine	Guaiacol glyceryl ether	Procaine
Bilirubin	Hemoglobin	Quinidine
Caffeine	Ibuprofen	Ranitidine
Chloroquine	(+/-)-Isoproterenol	Riboflavin
(+)-Chlorpheniramine	Ketamine	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	
4-Dimethylaminoantipyrine	Niacinamide	

ADULTERATION TEST

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The CLIAwaived,Inc. adulteration test is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity 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 change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dl. Values outside this range generally indicate a manipulated test.

Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dl is considered adulterated.

Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may cause disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

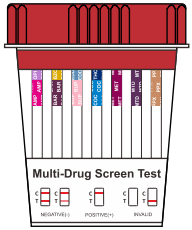
PROCEDURE FOR DRUG TEST WITH ADULTERATION TEST

Preparation:

1. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

Cup:

1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



BIBLIOGRAPHY

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Cocaine metabolism: cocaine and norcocaine hydrolysis by liver and serum esterases. Clin Pharmacol Ther. 1979 Apr;25(4):464-8.
2. Ambre J. The urinary excretion of cocaine and metabolites in humans: a kinetic analysis of published data. J Anal Toxicol. 1985 Nov-Dec;9(6):241-5.
3. Hawks RL, Chiang CN. Examples of specific drug assays. NIDA Res Monogr. 1986;73:84-112.
4. Tietz NW, editor. Textbook of Clinical Chemistry. 1st ed. Philadelphia: WB Saunders Co;1986. p 1735.
5. Food and Drug Administration. Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff. US Department of Health and Human Services Food and Drug Administration; Center for Devices and Radiological Health (CDRH), Dec 2, 2003. Available from: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070612.htm [Accessed Oct 13, 2014].
6. DeCresce RP, Mazura A, Lifshitz M, Tilson J. Drug Testing in the Workplace. 1st ed. Chicago: American Society of Clinical Pathologists (ASCP) Press;1988. 278 p.
7. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis, CA: Biomedical Publ; 1982. p 488.

CLIAwaived Inc.
2721 Loker Ave W
Carlsbad CA 92010