Lab Name: **Procedure #:**

Procedure: CLIA Complexity: WAIVED

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Clarity Diagnostics provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

CLIA Complexity: WAIVED

INTENDED USE:
Clarity Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Nortriptyline and Methadone in human urine at the cutoff concentrations of:

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	1000 ng/mL
BAR	Secobarbital	300 ng/mL
BUP	Buprenorphine	10 ng/mL
BZO	Oxazepam	300 ng/mL
COC	Benzoylecgonine	300 ng/mL
MDMA	3,4-Methylenedioxy-methamphetamine	500 ng/mL
MET	D-Methamphetamine	1000 ng/mL
MTD	Methadone	300 ng/mL
OPI	Morphine	300 ng/mL
MOP	Morphine	2000 ng/ml
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-Δ^9-THC-9-carboxylic acid	50 ng/mL

Configuration of the Clarity Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method may be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

SUMMARY:

The test is intended for use as the first step to provide health care professionals and consumers with information concerning the presence or absence of the above stated drugs in a urine sample.

PRECAUTIONS:

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The Test Cup should remain in the sealed pouch until use.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The Test Cup is stable through the expiration date printed on the sealed pouch. The Test Cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION:

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used.

MATERIALS:

Materials Provided

• Test Cup • Package insert • Disposable Gloves • Procedure Card • Adulteration Color Chart

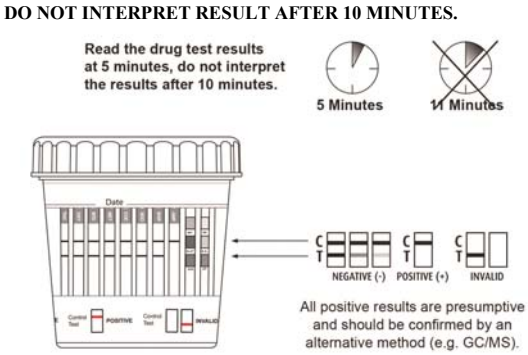
MATERIALS REQUIRED BUT NOT PROVIDED:

•Timer • Positive and Negative Controls

DIRECTIONS FOR USE:

If refrigerated, allow the test cup to come to room temperature 59-86°F (15-30°C)] prior to testing.

1. Remove the cup from the sealed pouch.
2. Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
3. Donor dates and initials the body label. Operator checks the cap for tightness.
4. Remove the peel off label.
5. Check the temperature strip label at 2-4 minutes after specimen collection. A Green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100 °F (32-38 °C).
6. Drug test results are indicated by the presence or absence of colored bands(s) in the result area. The results should be read at 5 minutes. Do not interpret the results after 10 minutes.
7. Positive results may be confirmed by another test method. Send the cup and urine sample intact to a toxicology lab of your choice for confirmation.
8. For checking adulteration , compare with Color Chart and the results should be read at 2 minutes, do not interpret the results after 5 minutes



INTERPRETATION OF RESULTS FOR THE DRUG CUP:

(Please refer to the illustration above)
NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.
POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.
INVALID: Control line fails to appear. Insufficient sample volume or not conducting the test as instructed are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact Clarity Diagnostics Technical Support at 1-877-485-7877.
A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present.

What Is A False Positive Test?

The definition of a false positive test would be an instance where the Clarity Multi-Drug Urine Test is positive even though the target drugs are not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by Clarity Multi-Drug Urine Test. If the sample is diluted or contaminated, a false negative result may occur.

INTERPRETATION OF RESULTS FOR ADULTERATION STRIPS:

The Urine Adulteration test strips are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dl. Under rare conditions, certain kidney diseases show dilute urine.

Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections .Nitrite levels of > 20 mg/dl may produce false positive Glutaraldehyde results.

Glutaraldehyde: Glutaraldehyde is not normally found in urine. However certain metabolic abnormalities such as Ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.

Specific Gravity: Elevated levels of protein in urine may cause abnormally high urine Specific Gravity values.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as Ascorbic acid, may result in false negative results for Oxidants/PCC pad.

ADULTERATION TEST:

The strips contain chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to assess the integrity of the urine sample.

WHAT IS ADULTERATION:

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results. One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

- **Oxidants/PCC (Pyridinium chlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name Urine Luck) is a commonly used adulterant. Normal human urine should not contain oxidants of PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.9 Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as Urin Aid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine. A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (less than 5 mg/dl) is indicative of a specimen not consistent with human urine.

LIMITATIONS:

1. The Clarity Multi-Drug Urine Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method may be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause incorrect results.

3. Substances, such as bleach and/or alum, in urine samples may produce incorrect results regardless of the analytical method used.

4. A positive result does not indicate level or intoxication, administration route or concentration in urine.

5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

6. The test does not distinguish between drugs of abuse and certain medications.

7. A positive result might be obtained from certain foods or food supplements.

QUALITY CONTROL:

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, 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.Please contact our Technical Support at 1-877-485-7877 for controls that are compatible with the Clarity Multi-Drug Urine Test Cup.

PERFORMANCE CHARACTERISTICS:

Accuracy

960 (eighty of each drug) clinical urine specimens were analyzed by GC/MS and by the **Clarity Multi-Drug Urine Test Cup**. Each test was performed by three operators. Samples were divided by concentration into five categories:

drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Methamphetamine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

% agreement among positives is 96.7%
% agreement among negatives is 100%

Cocaine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Operator B	Positive	0	0	0	16	24
	Negative	10	17	13	0	0
Operator C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Opiates 300

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	25
	Negative	10	15	15	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	15	15	0	0
Operator C	Positive	0	0	0	15	25
	Negative	10	15	15	0	0

% agreement among positives is 97.5%
% agreement among negatives is 100%

Morphine 2000

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Operator C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Oxazepam

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	16	15	2	0
Operator B	Positive	0	0	1	14	24
	Negative	10	16	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	16	15	2	0

% agreement among positives is 95%
% agreement among negatives is 100%

Marijuana

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

% agreement among positives is 94.2%
% agreement among negatives is 100%

Amphetamine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator C	Positive	0	0	0	15	23
	Negative	10	16	14	2	0

% agreement among positives is 93%
% agreement among negatives is 100%

Oxycodone

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93%
% agreement among negatives is 100%

Secobarbital

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 93.3%
% agreement among negatives is 100%

Phencyclidine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Ecstasy

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 91.7%
% agreement among negatives is 100%

Buprenorphine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 94.2%
% agreement among negatives is 100%

Methadone

Clarity Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 94.2%
% agreement among negatives is 100%

Nortriptyline (TCA)

Clarity Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93.3%
% agreement among negatives is 100%

ANALYTICAL SPECIFICITY:

The following table lists compounds that are positively detected in urine by the **Clarity Multi-Drug Urine Test Cup**.

Drug	Concentration (ng/ml)	% Cross-Reactivity
METHAMPHETAMINE		
D-Methamphetamine	1,000	100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000	5%
Procaine (Novocaine)	60,000	2%
Trimethobenzamide	20,000	5%
Methamphetamine	1000	100%
Ranitidine (Zantac)	50,000	2%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2500	40%
Chloroquine	50,000	2%
Ephedrine	100,000	1%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%
COCAINE		
Benzoylecogonine	300	100%
Cocaethylene	300	100%
CocaineHCl	300	100%
MARIJUANA		
11-nor-Δ9-THC-9-COOH	50	100%
Delta-9-Tetrahydrocannabinol	50,000	0.1%
11-nor-delta-9-THC-carboxyglucuronide	75	67%
(-)-11-nor-9-carboxy-delta9-THC	75	67%
11-Nor-Δ9-Tetrahydrocannabinol	50	100%
11-Hydroxy-Δ9-Tetrahydrocannabinol	5,000	1%
11-Nor-Δ8-Tetrahydrocannabinol	50	100%
Δ8-THC-COOH	50,000	0.1%
Morphine		
Morphine	300	100%
O6-Acetylmorphine	400	75%
Codeine	300	100%
EthylMorphine	6240	5%
Heroin	600	50%
Hydromorphone	3120	10%
Hydrocodone	50000	0.6%
Levorphanol	1500	20%
Oxycodone	30000	1%
Procaine	15000	2%
Thebaine	6240	5%
Oxazepam		
Alprazolam	200	150%
Bromazepam	1,560	19%
Chlordiazepoxide HCL	1,560	19%
Clobazam	100	300%
Clonazepam	780	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,560	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
a-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,560	19%
RS-Lorazepam glucuronide	160	188%
Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
Temazepam	100	300%
Triazolam	2,500	12%
AMPHETANINE		
D-Amphetamine	1,000	100%
D,L - Amphetamine (Amphetamine Sulfate)	1,000	100%
Phentermine	1,250	80%
(+/-)-4-Hydroxyamphetamine HCL	600	167%
L-Amphetamine	20,000	5%
(+/-)-Methylenedioxyamphetamine(MDA)	1,500	67%
d-Methamphetamine	>100000	<1%
1-Methamphetamine	>100000	<1%
ephedrine	>100000	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	>100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	>100000	<1%
OXYCODONE		
Oxycodone	100	100%

Codeine	50,000	0.2%
Ethyl Morphine	75,000	0.1%
Thebaine	50,000	0.2%
Oxymorphone	750	13%
Dihydrocodeine	12500	0.8%
Hydromorphone	>100000	<0.1%
Hydrocodone	>100000	<0.1%
Morphine	>100000	<0.1%
Acetylmorphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
SECOBARBITAL		
Secobarbital	300	100%
Amobarbital	300	100%
Alphenal	750	40%
Aprobarbital	250	120%
Butabarbital	2500	12%
Butethal	2500	12%
Butalbital	2500	12%
Cyclopentobarbital	500	60%
Pentobarbital	2500	12%
BUPRENORPHINE		
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	Negative at 100000	Not detected
Oxymorphone	Negative at 100000	Not detected
Hydromorphone	Negative at 100000	Not detected
METHADONE		
Methadone	300	100%
Doxylamine	5,000	6%
EDDP	Negative at 100,000	Not Detected
EMDP	Negative at 100,000	Not Detected
LAAM HCl	Negative at 100,000	Not Detected
Alpha Methadol	Negative at 100,000	Not Detected
PHENCYCLIDINE		
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	90	28%
MDMA		
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300	167%
d-methamphetamine	2500	20%
d-amphetamine	>100000	Not detected
l-amphetamine	>100000	Not detected
l-methamphetamine	>100000	Not detected

PRECISION:

This study is performed 2 runs/day and lasts 25 days for each drug with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day. A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
Methamphetamine	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	22	28	22	28	22	28
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
Benzoylecogonine	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	18	32	18	32	18	32
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
11-nor-Δ9-THC-9-COOH	0	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	37.5	50	50	0	50	0	50	0
	50	50	14	36	14	36	14	36
	62.5	50	0	50	0	50	0	50
	75	50	0	50	0	50	0	50
	87.5	50	0	50	0	50	0	50
	100	50	0	50	0	50	0	50
Oxazepam	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	20	30	20	30	20	30
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Morphine	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	20	30	20	30	20	30
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Amphetamine	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	1000	50	18	32	18	32	18	32
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Oxycodone	0	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	50	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	100	50	16	34	16	34	16	34
	125	50	0	50	0	50	0	50
	150	50	0	50	0	50	0	50
	175	50	0	50	0	50	0	50
	200	50	0	50	0	50	0	50
Methadone	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	22	28	25	25	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Ecstasy(MDMA)	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	30	20	30	20	30	20
	625	50	0	50	0	50	0	50
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1000	50	0	50	0	50	0	50
Secobarbital	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
	225	50	50	0	50	0	50	0
	300	50	27	23	25	25	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Buprenorphine	0	50	50	0	50	0	50	0
	2.5	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	7.5	50	50	0	50	0	50	0
	10	50	26	24	24	26	25	25
	12.5	50	0	50	0	50	0	50
	15	50	0	50	0	50	0	50
	17.5	50	0	50	0	50	0	50
	20	50	0	50	0	50	0	50
Phencyclidine	0	50	50	0	50	0	50	0
	6	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	19	50	50	0	50	0	50	0
	25	50	16	34	16	34	16	34
	31	50	0	50	0	50	0	50
	37.5	50	0	50	0	50	0	50
	44	50	0	50	0	50	0	50
	50	50	0	50	0	50	0	50
Tricyclic Antidepressants	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	20	30	22	28	18	32
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50

EFFECT OF URINARY SPECIFIC GRAVITY:

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **Clarity Multi-Drug Urine Test Cup** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY pH:

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **Clarity Multi-Drug Urine Test Cup**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

CROSS-REACTIVITY:

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Cocaine, Morphine, Amphetamine, Oxycodone, Ecstasy, Buprenorphine, Phencyclidine, Secobarbital, Methadone, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **Clarity Multi-Drug Urine Test Cup** at a concentration of 100 μg/mL.

NON-CROSS REACTING COMPOUNDS:

Acetominophen (4-Acetamidophenol)	Fenoprofen	Oxolinic acid
Acetophenetidin	Furosemide	Oxymetazoline
N-Acetylprocainamide	Gentisic acid	Papaverine
Acetylsalicylic acid	Hydralazine (except BZO test)	Penicillin-G
Aminopyrine	Hydrochlorothiazide (except BZO test)	Pentobarbital (except BAR test)
Amoxicillin	Hydrocodone (except BZO, MOP, OXY tests)	Perphenazine
Ampicillin	Hydrocortisone	Phenelzine
Apomorphine	O-Hydroxyhippuric acid	Phencyclidine(except PCP, OXY tests)
Aspartame	3-Hydroxytyramine	Prednisone
Atropine	Ibuprofen	Procaine (except BZO,tests)
Benzilic acid	D,L-Isoproterenol (except AMP test)	DL-Propranolol
Benzoic acid	Isoxsuprine	D-Propoxyphene
Benzoylecgonine (except COC tests)	Ketamine	D-Pseudoephedrine (except AMP, BAR tests)

Bilirubin	Ketoprofen	Quinine
Cannabidiol (except THC, OXY tests)	Labetalol	Ranitidine
Chloralhydrate	Loperamide	Salicylic acid
Chloramphenicol	Maprotiline	Secobarbital (except BAR tests)
Chlorothiazide	Meperidine (except THC, OXY tests)	Serotonin (5- Hydroxytyramine)
Chlorpromazine	Meprobamate	Sulfamethazine
Chlorquine	Methadone (except MTD tests)	Sulindac
Cholesterol	Methoxyphenamine (except AMP, BAR tests)	Tetrahydrocortisone, 3-acetate (except AMP, BAR tests)
Clonidine	Morphinie-3-β-d-glucuronide (except BZO, MOP, tests)	Tetrahydrocortisone 3-(β-Dglucuronide) (except AMP, BAR tests)
Codeine (except MOP, BZO, OXY tests)	Nalidixic acid	Tetrahydrozoline
Cortisone	Naloxone	Thiamine
(-) Cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	Triamterene
Deoxycorticosterone	Niacinamide	DL-Tyrosine
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	Norcodein (except MOP, BZO, OXY tests)	Trimethoprim
Diflunisal	Norethindrone	D L-Tryptophan (except AMP, BAR tests)
Digoxin	D-Norpropoxyphene	Tyramine (except AMP, BAR tests)
Diphenhydramine	Noscapine	Uric acid
Ecgonine methyl ester	D,L-Octopamine	Verapamil
Erythromycin (except BZO test)	Oxalic acid	Zomepirac
β-Estradiol (except BZO test)	Oxazepam (except BZO, OXY tests)	

LAY USER STUDY:

A lay user study was performed at three intended user sites with 160 lay persons. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The typical results are summarized below.

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
Methamphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Cocaine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Cannabinoids	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Morphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	20	0	100%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Oxazepam	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	3	17	85%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Amphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%

Oxycodone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	17	3	85%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Methadone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
MDMA	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Secobarbital	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Buprenorphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Phencyclidine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Tricyclic Antidepressants	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%

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2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be used by the Consumer, 1997.

ADDITIONAL INFORMATION AND RESOURCES

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

National Clearinghouse for Alcohol and Drug Information, Phone: 1-800-729-6686

Center for Substance Abuse Treatment, Phone: 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 2°C and 30°C


Keep dry


Do not re-use

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