CLARITY

PROCEDURE MANUAL

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.

PROCEDURE MANUAL

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.

Lab Name:

Multi-Drug Screen Urine Panel Test with Adulteration Assay

INTENDED USE

The Clarity *Multi-Drug of Abuse Urine Test* is a rapid qualitative immunoassay for screening potential abuse of one or more drugs. The device detects any combination of one up to twelve drugs or drug metabolites at or above the specified cut-off levels. It is for health care professional use only.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
AMP300*	Amphetamine	300 ng/ml
BAR**	Barbiturates	200 ng/ml
BUP/NBUP	Buprenorphine/Norbuprenorphine	10 ng/ml**
BZD**	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
COC150*	Cocaine	150 ng/ml
MET	Methamphetamine	1000 ng/ml
MET500*	Methamphetamine	500 ng/ml
MET300*	Methamphetamine	300 ng/ml
MOR	Morphine	2000 ng/ml
MOR300*	Morphine	300 ng/ml
MTD	Methadone	300 ng/ml
OXY*	Oxycodone	100 ng/ml

PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA****	Tricyclics	1000 ng/ml
THC	Marijuana/Hashish	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

**Not SAMHSA levels. **Combined concentrations of Buprenorphine (BUP) and Norbuprenorphine (NBUP). ***SAMHSA has not recommended the screening cutoff levels for positive specimens. ****The BAR, BZD, TCA test will yield preliminary positive*
Lab Name:

Results when BAR, BZD and TCA is ingested at or above therapeutic doses. There are No uniformly recognized drug levels for barbiturate, benzodiazepine, and Tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level.

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

SUMMARY AND EXPLANATION

Amphetamine (AMP and AMP300)

The detection of amphetamines in human urine has been widely used to assess the abuse of amphetamines. Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and overall feeling of well being. Overdose and extended usage of amphetamines may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours after administration (any type), and be present for about 24-48 hours after the last dose.

Barbiturates (BAR)

Barbiturates are central nervous system depressants and used as hypnotic sedatives. Overdose and extended usage of barbiturates may lead to severe and/or permanent damage to the human nervous system. Barbiturates are classified as (1) ultra-short, (2) short-intermediate, and (3) long-acting. The duration range of the ultra short-acting compounds, secobarbital, pentobarbital etc. is from fifteen (15) minutes to six (6) hours. The duration range of the intermediate acting compounds, amobarbital, etc. is from three (3) to twenty-four (24) hours. The duration range of the long-acting compounds, phenobarbital etc. is from fifteen (15) to forty-eight (48) hours.

The most commonly abused barbiturates are short- and intermediate-acting agents. The long-acting agents are rarely subject to abuse. Barbiturate derivatives are excreted into urine in varying amounts of unchanged drug and metabolites. Long-acting barbiturates are excreted with a higher percentage of unchanged drugs in the urine, while shorteracting barbiturates, secobarbital and amobarbital, are extensively metabolized and excreted in the urine with a smaller percentage of unchanged drugs

Lab Name:

Buprenorphine/Norbuprenorphine (BUP/NBUP)

Buprenorphine is an analgesic drug. It is also used in heroin substitution and detoxification treatment. With this increased medical use, it also occurs on the black market as an illicit drug; and fatalities have occurred when used in combination with other drugs.

Buprenorphine is administered clinically by intravenous, intramuscular or sublingual routes. Buprenorphine is metabolized by N-dealkylation to form the pharmacologically active Norbuprenorphine. Both buprenorphine and norbuprenorphine are also glucuronidated to the clinically inactive conjugates buprenorphine-3-beta-D-glucuronide &norbuprenorphine-3-beta-D-glucuronide.Buprenorphine and its metabolite norbuprenorphine (along with the glucuronide forms) are both excreted in urine during the course of several days. Buprenorphine and its metabolites are eliminated mainly in the feces (68%), with a small proportion excreted in urine (27%). It was reported that urine samples taken from patients who had received treatment for 2 weeks with 4 mg of buprenorphine daily (sublingually) showed buprenorphine concentrations ranging from 54 to 260 ng/ml 24 hours after the dose. It was found in another study that the concentrations of the unconjugated buprenorphine and unconjugated norbuprenorphine in the urine samples collected 10 hours after a single dose intramuscular injection of 0.3 mg buprenorphine were 500 pg/ml and 2 ng/ml, respectively.

The concentration of the metabolite norbuprenorphine is usually higher than buprenorphine. The median ratio of buprenorphine to norbuprenorphine is dependent on the time between sampling and dose intake. It was reported that in suspected abusers, the ranges were 2.3 to 796 ng/ml for unconjugated buprenorphine and 5 to 2580 ng/mL for unconjugated norbuprenorphine. It was also found that the concentration of free buprenorphine and norbuprenorphine in urine may be relatively small (<1 ng/mL) if taken in clinically administered doses, but can reach up to 20 ng/mL if abused.

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Benzodiazepines (BZD)

Benzodiazepines, including Alprazolam, Diazepam, Lorazepam, Triazolam, Chlordiazepoxide, Flurazepam and Temazepam are sedative, hypnotic and anti-anxiety drugs commonly used as tranquilizers. Most benzodiazepines are extensively metabolized in the liver and excreted in the urine as metabolites. The benzodiazepines have a low potential for physical or psychological dependence. However, the same as other central nervous system stimulating drugs, they may induce drowsiness and muscle relaxation. Chronic abuse of benzodiazepines may result in intoxication, similar to drunken behavior. Overdose and extended usage of benzodiazepines may lead to coma and possibly death. Benzodiazepines may remain effective for 4-8 hours. The members **Lab Name:**

Of the benzodiazepine family are absorbed at different rates and their effects may vary with the absorption rate. They are excreted in the urine primarily as their parent Compounds or an inactive metabolite (Oxazepam glucuronide) that is only detectable for one (1) to two (2) days. Oxazepam, a common metabolite of many benzodiazepines that is also a marketed drug (Serax), may remain detectable if in urine for up to one week. That makes Oxazepam a useful marker of benzodiazepines abuse.

Cocaine (COC and COC150)

Cocaine is a nervous system stimulant that can be addictive. Cocaine may appear in urine for only few hours after use, whereas the Benzoylecgonine, a hydrolytic degradation product of cocaine, may be detectable in urine over 2 days after taking cocaine. Therefore the detection of Benzoylecgonine in human urine is widely used to evaluate cocaine usage.

Methamphetamine (MET, MET500 and MET300)

Methamphetamine in over dosage causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions, and coma. Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis. D-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine. It is utilized in the treatment of obesity. Methamphetamine is administered by oral, nasal insufflation, or intravenous injection with duration of 2-4 hours. Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. During normal conditions, up to 43% of a dose is eliminated with about 4-7% as amphetamine. In acidic urine, up to 76% is found as unchanged drug and 7% as amphetamine in 24 hours, whereas in alkaline urine the corresponding values are 2% and less than 0.1%. Methamphetamine urine concentrations of 0.5-4.0 mg/L are commonly observed during the first 24 hours after ingestion of 10 mg. Methamphetamine

concentrations of 24-333 mg/L (average, 142) were observed in the urine of methamphetamine abusers.

Morphine (MOR and MOR300)

Morphine is a popular marketed drug (Serax) for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered either by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include pupillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma, and pulmonary edema. Death may occur following an over dosage.

The duration of effect of morphine is 3-6 hours. Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine. Heroin is rapidly

Metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized; 10-15% of the dose is demethylated to form morphine and Norcodeine. It has been reported that the unchanged morphine may remain detectable in urine for up to one week, which make morphine a marker of opiates abuse.

Methadone (MTD)

Methadone, also called Dolophine, Methadose and Amidone, possesses many of the pharmacologic properties of morphine and is approximately equipotent as an analgesic when administered parenterally. Unlike morphine, however, methadone produces marked sedative effects with repeated administration as a result of drug accumulation. Methadone has been used as a major substitute for opiates, such as heroin, morphine, and codeine in drug maintenance treatment clinics. It is administered either orally or by intravenous or intra-muscular injection. The duration of effect of methadone is 12-24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5dimethyl-3, 3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3, 3-diphenylpyrrolidine). The percentage of methadone excreted unchanged in urine is 5-50%, much higher than EDDP and EMDP, of the dose in 24 hours. Large individual variations in the percentage of unchanged methadone excreted in urine have been observed due to urine pH, urine volume, dose and rate of metabolism, etc. Methadone has been found remaining in urine at levels higher than 1,000 ng/ml 24 hours after overdose. Therefore the concentration of methadone in human urine has been used as a marker of methadone abuse.

Oxycodone (OXY)

Oxycodone is a semi-synthetic Opioids with a structure similar to codeine. It is prescribed for the relief of moderate to severe pain. Like all opiate agonists, Oxycodone provides pain relief by acting on Opioids receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respirator depression, hypotension, and stripiac arrest.

Oxycodone is metabolized by demethylation into Oxymorphone and noroxycodone.
After a single 5 mg oral dose, 13-19% of the Oxycodone is excreted as unchanged in a 24-hour urine collection. The time window for detection of Oxycodone in urine is expected to be similar to that of other Opioids such as morphine.

Phencyclidine (PCP)

Phencyclidine (PCP), also called Angel Dust, Hog, and Killer Weed, is a popular drug of abuse, as well as being a legitimate veterinary tranquilizer. It is self-administered either by smoking, nasal insufflation, intravenous injection or by oral ingestion. Its duration of Effect is 2-4 hours, and psychosis may last for weeks. PCP has three major metabolites; however, the percentage of an intravenous dose excreted unchanged in urine is 30-50% In 72 hours. Only 2% of a dose in excreted in feces. An average of 77% of an intravenous dose is excreted in urine and feces in 10 days. Therefore, the PCP in human urine has been used as a marker of PCP abuse. Concentrations of unchanged drug in the urine of ambulatory users of PCP are most frequently between 0.04 and 3.4mg/L.

Propoxyphene (PPX)

Propoxyphene is a prescription drug for the relief of pain. Propoxyphene hydrochloride (Darvon, Dolene, and others) is available in 32mg and 65mg capsules; Propoxyphene napsylate (Darvon-N) is available in 100mg tablets or as a suspension. It is structurally related to methadone. Overdose of the drug can affect the brain region and cause euphoria as many Opioids do. The progressive symptomatology of Propoxyphene includes analgesia, stupor, respiratory depression, and coma, etc. The half-life of Propoxyphene is 8-24 hours. Following oral administration, Propoxyphene reaches its peak in 1 to 2 hours. There is great variability between subjects in the rate of clearance. The percentage of excreted unchanged Propoxyphene in urine is less than 1%. The major metabolite of Propoxyphene is norpropoxyphene. Therefore, the detection of norpropoxyphene is widely used for the testing of Propoxyphene abuse. The half-life of norpropoxyphene is about 30 hours, and its accumulation with repeated doses may be responsible for some of the toxicity observed.

Tricyclics (TCA)

Tricyclic Antidepressants (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure. TCA can be taken orally or intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hyper tonicity, seizures, and EKG changes. The half-life of TCA varies from few hours to few days. The commonly used Tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting TCA or metabolites of TCA in human urine has been used for screening the abuse of TCA. This test is able to detect amitriptyline, desipramine, imipramine and nortriptyline at a cut off level of 1,000 ng/ml.

Lab Name:

Marijuana (THC)

Tetrahydrocannabinols (THC, Δ-9-THC, Δ-1-THC) are the most active of the principle constituents, as well as the major metabolites, of Cannabinoid such as marijuana and hashish. Cannabinoid have been used as central nervous system depressants. Overdose and extended usage of Cannabinoid may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. The detection of THC in human urine is widely used to evaluate the abuse of Cannabinoid.

MDMA (Ecstasy, XTC)

MDMA is an abbreviation of the chemical methylenedioxymethamphetamine. It also has street names such as Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. It is described as an empathogen since it releases mood-altering chemicals, such as cartooning and Ldopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke.

MDMA belongs to a “family” of man-made drugs; its “relatives” are MDA (methylenedioxyamphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also know as EVE, the sister of MDMA. They all have the amphetamine-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg; the threshold toxic dose is 500mg. The effects of the MDMA begin 30 minutes after taking. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine and it is detectible in the urine for up to 3 days after use.

PRINCIPLE OF THE PROCEDURE

The Clarity Multi-Drug of Abuse Urine Test device consists of any combination between one (1) to ten (10) individual test strip(s) for the drug(s) being tested. The assay is a one-step lateral flow chromatographic immunoassay based on the principle of competition for

limited antibody binding sites between the drug or drug metabolite(s) in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During test, the urine sample migrates to the testing area of the membrane by capillary action, mobilizing the colored antibody conjugates. Then the antibody conjugates move along the membrane to the testing area. In the absence of the drug or if the drug concentration is below the cutoff limit in the sample, the colored conjugates attach to the drug antigen immobilized in the test line region, forming a burgundy-colored band (T line). When the drug is present in the sample, the drug or drug metabolite(s) compete for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the colored conjugates to the antigen in the test line area of the membrane. Therefore the colored line will not form.

The control line (C line) serves as an internal quality control of the system. It should always appear as a burgundy-colored band regardless of the presence of the drug. The adulteration control strip in the sample well of the device has 3 pads each of which includes an indicator reagent that reacts with components in the urine sample effecting color changes. Results are obtained by comparing the color of each pad with that of the corresponding pad in the color chart provided. The pads assess:

pH: Tests for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Specific Gravity: Tests for sample dilution. This test is based on the apparent pKa change of certain pretreated poly electrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

Oxidants: Tests for presence of oxidizing reagents. In this reaction, a color indicator reacts with oxidants such as bleach, hydrogen peroxide or Pyridinium chlorochromate to form a blue or brown color complex. Other colors may indicate the presence of other oxidants.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a foil pouch with a desiccant and a dropper pipette
- 1 package insert (Instructions for Use)
- 1 Adulteration Color Comparison Chart

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MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- External positive and negative controls

WARNINGS AND PRECAUTIONS

1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially bio-hazardous.
5. Do not use the test if you are colored-blind.

KIT STORAGE AND STABILITY

• Store the product at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch. ***Do not freeze and/or expose the kit to temperatures over 30°C (86°F).***

SPECIMEN COLLECTION AND STORAGE

- Each urine specimen must be collected in a clean container. Do not combine specimens.
- Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

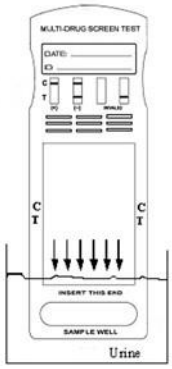
TEST PROCEDURE

IMPORTANT: REFRIGERATED SPECIMENS AND OTHER TEST MATERIALS, INCLUDING DEVICES, MUST BE EQUILIBRATED TO ROOM TEMPERATURE BEFORE TESTING.

1. Bring the pouch to room temperature before opening.
2. Remove the test device from the sealed pouch and label it with specimen identification.
3. Remove the cap from the device, add urine sample to the device using either “Dip Method (I)” or “Dropper Method (II)” as follows:

Lab Name:

I. DIP METHOD



Note: Immerse the sample well completely in the urine sample. Make sure the tip of the arrows in the device's window is above the urine sample surface.

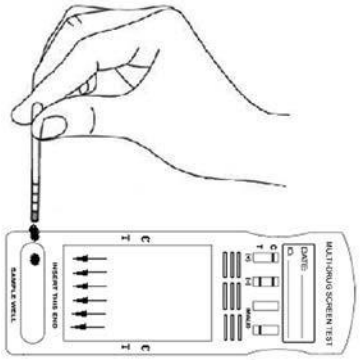
Dip the sample well end of the device into the specimen.

a. Start the timer.
b. Remove the device from the specimen after 10 seconds.
c. Replace the cap back onto the device. Set the device on a clean and level surface.
d. Read results between 4-7 minutes.

II. DROPPER METHOD (Recommended for small sample volumes.)

a) Set the device on a clean and level surface.
b) Use the provided dropper to pick up the urine sample, fill the sample to the mark.

c) Transfer all of the urine sample in the dropper to the sample well of the device. Avoid trapping air bubbles in the sample well.
d) For a 2-sided panel (7-12 tests), turn the device over to the other side and add a full dropper of urine sample (up to the mark on the dropper) to the sample well on side 2.
e) Start the timer.
f) Read results between 4-7 minutes.



INTERPRETATION OF RESULTS

Each test strip is labeled with abbreviations for a test. For example, “COC” is for cocaine test. A complete list for each test can be found in the intended use section on Page 1.

IMPORTANT:

- **Read each test independently.**
- **Do not compare color intensity of one test to anther.**
- **Do not compare color intensity of the T line to the C line.**
- **Do not read adulteration results after 2 minutes or drug test after seven (7) minutes**

ADULTERATION ASSAY

Between 1-2 minutes after sample addition, compare the color of each pad with that of the corresponding pad in the color chart attached to the back of this insert. Changes in color

after 2 minutes are of no value to interpretation. The 3 pads, as read from left to right in the sample well, assess the following parameters: pH SG OX

pH Tests: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

SG (Specific Gravity): Random urine samples may vary in specific gravity from 1.0031.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016-1.022. Elevated urine specific gravity may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

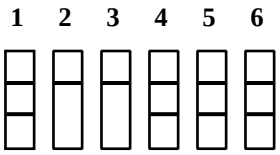
OX (Oxidants): The presence of oxidizing reagents in the urine is indicative of adulteration since oxidizing reagent are not normal constituents of urine. Oxidizing reagents include bleach, Hydrogen Peroxide, Pyridinium Chlorochromate, etc.

If test pads indicate an invalid sample for the assays, note the information on the sample record.

Positive:

If the C line appears and there is no T line, the test is positive for that drug. More than one test may be Positive.

Note: Positive results should be confirmed with a more specific method. LC/MS or HPLC is a preferred confirmatory method.

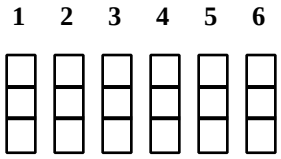


Positive for test 2 and test 3 **C C**

T T

Negative:

If both C line and T line appear on a test, the test is negative for that drug. If both C line and T line appear for all tests, the urine specimen is negative for all the drugs tested.



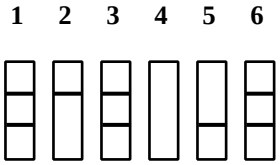
CC **Negative for all 6 drugs tested**

T T

Note: Even a very faint T line is negative.

Invalid:

If no C line develops within 4 minutes on any test strip, the test is invalid. In this case, don't report test results. Repeat the assay with a new test device. If the result is still invalid, stop using the test device. Contact the Clarity Diagnostics at 1-877-485-7877



C C **Invalid for test 4 and**

QUALITY CONTROL

Built-in Control Features:

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the testing with a new device.

External Quality Control:

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS

1) This kit is for *professional in vitro* diagnostic use only.
2) Results obtained by this device provide only a preliminary qualitative analytical test result. A more specific alternate method must be used in order to obtain a confirmed analytical result.
3) This product is designed for testing human urine only.
4) Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When suspected, collect a fresh specimen and repeat the test with a new device.

5) Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results

EXPECTED VALUES

This test is capable of detecting each drug and/or drug metabolite specified in human urine at or above its specific cutoff concentration indicated in the intended use section on page 2.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study was performed at two Physician's Office Laboratories (POL) and a Reference Laboratory. Samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site, with the multi-drug of abuse urine test device, and compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (Negative), above 125% cutoff (Positive), Between 75% cutoff and cutoff, between cutoff and 125% cutoff according to the analytes concentrations from GC/MS for all analytes except BUP/NBUP and TCA, which was tested with HPLC/MS? Overall, this device agrees with the results from the selected analytical method more than 90% for each analytes. The test results are tabulated below.

Method			GC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
AMP	1000	Positive	0	0	37	15	148	
		Negative	176	76	23	1	0	
		Total	176	76	60	16	148	476
		Agreement	100%	100%	38.3%	93.8%	100%	92%
AMP300	300	Positive	0	0	0	39	75	
		Negative	30	45	45	6	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	86.7%	100%	97.5%
BAR	200	Positive	0	0	0	27	140	
		Negative	200	12	20	1	0	
		Total	200	12	20	28	140	400

		Agreement	100%	100%	100%	96.4%	100%	99.8%
BZD	300	Positive	0	0	7	32	144	
		Negative	168	24	25	0	0	
		Total	168	24	32	32	144	400
		Agreement	100%	100%	78%	100%	100%	98.3%
COC	300	Positive	0	0	9	24	164	
		Negative	188	4	11	0	0	
		Total	188	4	20	24	164	400
		Agreement	100%	100%	55%	100%	100%	97.8%
COC150	150	Positive	0	0	2	42	75	
		Negative	30	45	43	3	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	95.6%	93.3%	100%	97.9%
MET	1000	Positive	0	0	12	24	136	
		Negative	200	16	12	0	0	
		Total	200	16	24	24	136	400
		Agreement	100%	100%	50%	100%	100%	97%
MET500	500	Positive	0	0	6	24	152	
		Negative	220	36	22	16	0	
		Total	220	36	28	40	152	476
		Agreement	100%	100%	78.6%	60%	100%	95.4%

MET300	300	Positive	0	0	0	38	75	
		Negative	30	45	45	7	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	84.4%	100%	97.1
MOR300	300	Positive	0	0	13	24	136	
		Negative	180	12	11	0	0	
		Total	180	12	24	24	136	376
		Agreement	100%	100%	45.8%	100%	100%	96.5%
MOR	2000	Positive	0	0	2	28	144	
		Negative	132	64	30	0	0	
		Total	132	64	32	28	144	400
		Agreement	100%	100%	93.8%	100%	100%	99.5%
MTD	300	Positive		0	10	36	144	
		Negative		192	18	0	0	
		Total		192	28	36	144	400
		Agreement		100%	64.3%	100%	100%	97.5%

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OXY	100	Positive	0	0	3	40	75	
		Negative	30	45	42	5	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	93.3%	88.9%	100%	96.7%
PCP	25	Positive		0	8	32	160	
		Negative		184	16	0	0	
		Total		184	24	32	160	400
		Agreement		100%	66.7%	100%	100%	98%
PPX	300	Positive	0	0	0	8	30	
		Negative	40	10	10	2	0	
		Total	40	10	10	10	30	100
		Agreement	100%	100%	100%	80%	100%	98%
THC	50	Positive	0	0	11	17	156	
		Negative	160	36	13	3	0	
		Total	160	36	24	20	156	396
		Agreement	100%	100%	54.2%	85%	100%	96.5%
MDMA	500	Positive	0	0	2	9	10	
		Negative	40	10	9	0	0	
		Total	40	10	11	9	10	80
		Agreement	100%	100%	82%	100%	100%	97.5%

Method			HPLC/MS					
Multi-Drug of Abuse Urine Test			Drugfree	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	Overall
Drug	Cutoff (ng/ml)							
BUP/ NBUP	10	Positive		0	1	18	19	
		Negative		49	5	2	0	
		Total		49	6	20	19	94
		Agreement		100%	83.3%	90%	100%	96.8%
TCA	1000	Positive	0	0	2	8	12	
		Negative	40	10	8	0	0	

		Total	40	10	10	8	12	80
		Agreement	100%	100%	80%	100%	100%	97.5%

Reproducibility

Reproducibility of each test was determined by replicate assays of three different production lots with four levels of samples: drug-free, 75% cutoff, 125% cutoff and 300% cutoff. For AMP, AMP300, BUP/NBUP, COC, COC150, MET500, MET300, MOR300, OXY, THC and MDMA tests, the devices were tested for three consecutive days, six replicates per day, for a total of eighteen tests for each control. For BAR, BZD, MET, MOR, MTD, PCP, PPX and TCA tests, the devices were tested for five consecutive days, five times per day, for a total of 25 assays for each control. The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

Cross Reactivity

The cross reactivity of the test was evaluated by spiking drug free samples with structurally related compounds. Compounds producing positive response are listed below.

Drug	Related Compounds	Concentration (ng/ml)	Related Compounds	Concentration (ng/ml)
AMP	*d-Amphetamine*	*1000*	*d-,l-Amphetamine*	*1000*
	l-Amphetamine	*20,000*	*3,4-methylenedioxyamphetamine (MDA)*	3000
AMP300	*d-Amphetamine*	*300*	*d-,l-Amphetamine*	*300*
	l-Amphetamine	*20,000*	*3,4-methylenedioxyamphetamine (MDA)*	3000
BAR	*Amobarbital*	*250*	*Phenobarbital*	*200*
	Barbital	*250*	*Pentobarbital*	*250*

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	Butabarbital	*300*	*Secobarbital*	*200*
	Butalbital	*200*		
BUP/ NBUP	*Buprenorphine-3-β-Dglucuronide*	*750*	*Norbuprenorphine-3-β-Dglucuronide*	*30,000*
	Nalorphine	*100,000*		
BZD	*Alprazolam*	*300*	*Lormetazepam*	*300*
	Bromazepam	*500*	*Medazepam*	*300*
	Clobazem	*1500*	*Nitrazepam*	*250*
	Chlonazepam	*500*	*Nordiazepam*	*400*
	Diazepam	*200*	*Prazepam*	*250*
	Desmethyldiazepam	*300*	*Triazolam*	*300*
	Flurazapam	*300*	*Oxazepam*	*300*
	Lorazepam	*450*		
COC	*Cocaine*	*300*	*Isoxsuprine*	*1500*
	Benzoylecgonine	*300*		
COC150	*Cocaine*	*150*	*Isoxsuprine*	*1500*
	Benzoylecgonine	*150*		
MET	*d-Amphetamine*	*50,000*	*3,4-methylenedioxyamphetamine (MDA)*	*50,000*
	l-Amphetamine	*10,000*		
MET500	*d-Methamphetamine*	*500*	*l-Amphetamine*	*10,000*
	l-Methamphetamine	*25,000*	*3,4-methylenedioxyamphetamine (MDA)*	*50,000*
	d-Amphetamine	*50,000*		
MET300	*d-Methamphetamine*	*300*	*l-Amphetamine*	*10,000*
	l-Methamphetamine	*25,000*	*3,4-methylenedioxyamphetamine (MDA)*	*50,000*
	d-Amphetamine	*50,000*		

MOR	*Codeine*	*2000*		
	Ethyl Morphine	*2000*	*Morphine- glucuronide*	*3000*
	Hydro morphine	*2500*	*Meperidine*	*30,000*
MOR300	*Morphine*	*300*		
	Codeine	*300*	*Morphine- glucuronide*	*500*
	Ethyl Morphine	*300*	*Meperidine*	*30000*
	Hydromorphine	*400*	*Oxycodone*	*1000*
MTD	*(-)-a-Methadol*	*800*	*(-)-a-Acetylmethadol (LAAM)*	*1000*
OXY	*Oxycodone*	*100*	*Hydrocodone*	*100,000*
	Morphine	*20,000*	*Ethyl morphine*	*100,000*
PCP	*Methylphenidate*	*25,000*	*Tenocyclidine*	2,000
	Pheniramine	*25,000*		
PPX	*Propoxyphene*	*300*	*2-ethyl-1,5-dimethyl-3,3diphenylpyrroline (EDDP, Methadone Metabolite)*	*200,000*
	Norpropoxyphene	*300*		
	Methadone	*1,350,000*		
TCA	*Nortriptyline*	*1,000*	*Clomipramine*	*5,000*
	Amitriptyline	*1,000*	*Doxepin*	*3,000*
	Imipramine	*800*	*Protriptyline*	*2,000*
	Desipramine	*800*	*Perphenazine*	*75,000*
	Nordoxepine	*1,000*	*Promazine*	*15,000*
	Cycolbenzaprine	*1,500*	*Trimipramine*	*2,000*
THC	*11-nor-D-8-THC-9-COOH*	*50*	*11-hydroxy-D-9-THC*	*100*
	11-nor-D-9-THC-9-COOH	*50*	*9-Tetrahydrocannabinol*	*10,000*
	Cannabonol	*10,000*		
MDMA	*methylenedioxyamphetamine (MDA)*	*2000*	*Methylenedioxyethylamphetamine(MDEA)*	*1000*

Interference

To determine the interference of structurally unrelated analytes, each test analyte was evaluated, using the analytes specific urine test device, in both drug free urine pools and urine pools spiked with the cutoff level of each analytes.

Common substances listed in this table were found not to interfere with the test results at the concentration of 100 µg/ml		
Acetaminophen	*Oxalic Acid*	*Ethanol*
Acetylsalicylic Acid	*Caffeine*	*Lidocaine*
Amikacin	*(+)-Chlorpheniramine*	*Penicillin-G*
Amitriptyline	*Cocaine*	*Phenylpropanalamine*
Ampicillin	*Codeine*	*Ranitidine*
Arterenal	*Cortisone*	*Salicyclic Acid*
Aspirin	*Methadone*	*Thioridazine*
Atropine	*Methanol*	*Trifluoperazine*
Benzoic Acid		

Biological Analytes	**Concentration**	*Biological Analytes*	**Concentration**
Albumin	*200 µg/ml*	*pH*	*5.0 – 9.0*
Bilirubin	*100 µg/ml*	*Specific Gravity*	*1.002 – 1.035 g/ml*
Creatine	*100 µg/ml*	*Uric Acid*	*100 µg/ml*
Glucose	*200 µg/ml*	*Vitamin C (L-Ascorbic Acid)*	*100 µg/ml*
Hemoglobin	*100 µg/ml*		

There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.(e.g., technical or procedural errors)

ASSISTANCE

If you have any questions regarding the use of this product, please call Clarity Diagnostics' Technical Support number, (877) 485-7877, Monday through Friday, between 8:00 a.m. and 6:00 p.m. Eastern Standard Time, U.S.A.

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