

## Multiple Drug Screen Cup

Package Insert for testing any combination of the following drugs:

AMP/BAR/BZO/COC/THC/MTD/MET/MDMA/OPI300/OPI/OXY/PCP/PPX/TCA

Including Specimen Validity Tests (S.V.T.) for:

Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine

*One step, rapid screening tests for the qualitative detection of drugs and drug metabolites in human urine.*

*For forensic use only.*

*For in vitro diagnostic use only.*

### INTENDED USE:

**Multiple Drug Screen Cup** is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
<b>AMP/Amphetamine</b>	<b>D-Amphetamine</b>	1000 ng/mL
<b>BAR/Barbiturates</b>	<b>Secobarbital</b>	300 ng/mL
<b>BZO/Benzodiazepines</b>	<b>Oxazepam</b>	300 ng/mL
<b>COC/Cocaine</b>	<b>Benzoylcegonine</b>	300 ng/mL
<b>THC/Marijuana</b>	<b>Delta-9-THC-COOH</b>	50 ng/mL
<b>MTD/Methadone</b>	<b>Methadone</b>	300 ng/mL
<b>MET/Methamphetamines</b>	<b>D-Methamphetamine</b>	1000 ng/mL
<b>MDMA/Methylenedioxyamphetamine</b>	<b>MDMA</b>	500 ng/mL
<b>OPI300/Opiates 300</b>	<b>Morphine</b>	300 ng/mL
<b>OPI/Opiates 2000</b>	<b>Morphine</b>	2000 ng/mL
<b>OXY/Oxycodone</b>	<b>Oxycodone</b>	100 ng/mL
<b>PCP/Phencyclidine</b>	<b>Phencyclidine</b>	25 ng/mL
<b>PPX/Propoxyphene</b>	<b>Propoxyphene</b>	300 ng/mL
<b>TCA/Tricyclic Antidepressants</b>	<b>Nortriptyline</b>	1000 ng/mL

**Multiple Drug Screen Cup** provides only a preliminary analytical test result. The test is not intended to be used in monitoring the drug levels. A more specific alternate method must be used in order to confirm the test result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are obtained.

### SUMMARY AND EXPLANATION OF THE TEST

**Multiple Drug Screen Cup** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine. **Multiple Drug Screen Cup** optionally includes an adulteration strip for testing pH, Specific Gravity and Oxidants/PCC.

### AMPHETAMINE / AMP

Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and overall feeling of well-being. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in higher tolerance levels and physiological dependency leading to substance abuse. The effect of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. **Multiple Drug Screen Cup** yields a positive result when Amphetamines in urine exceed 1000 ng/mL, which is the suggested screening cut-off for positive specimens by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

### BARBITURATES / BAR

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are

extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse. **Multiple Drug Screen Cup** yields a positive result when secobarbital in urine exceed 300ng/mL.

### BENZODIAZEPINES / BZO

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse. **Multiple Drug Screen Cup** yields a positive result when oxazepam in urine exceed 300ng/mL.

### COCAINE/ COC

Cocaine is an alkaloid present in Coca leaves (Erythroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, Cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the urine primarily as Benzoylcegonine, which can generally be detected for 24 – 48 hours after cocaine exposure. **Multiple Drug Screen Cup** yields a positive result when the Cocaine metabolite in urine exceeds 300ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration(SAMHSA, USA).

### MARIJUANA / THC

THC ( $\Delta^9$  – tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the urine is 11-nor- $\Delta^9$  – tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$  –THC-COOH), which is found in the urine within hours of exposure and remain detectable for 3-10 days after smoking. **Multiple Drug Screen Cup** yields a positive result when the concentration of THC-COOH in urine exceeds 50ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA,USA).

### METHADONE / MTD

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, Morphine). 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-1,5-dimethyl-3,3-diphenylpyrrolidine), and EMDP (2- ethyl-5-methyl-3,3-diphenylpyrrolidine). **Multiple Drug Screen Cup** yields a positive result when the concentration of Methadone in urine exceeds 300ng/mL.

### METHAMPHETAMINES / MET

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of methamphetamine are greater. Methamphetamine can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10 to 20 % of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. **Multiple Drug Screen Cup** yields a positive result when the concentration of Methamphetamine in urine exceeds 1000ng/mL.

### METHYLENEDIOXYMETHAMPHETAMINE /MDMA

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathsogen as it releases mood-altering chemicals, such as cartoning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2 – 3 hours. **Multiple Drug Screen Cup** yields a positive result when the concentration of

MDMA in urine exceeds 500ng/mL.

### OPIATES 300 / OPI300

Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake. **Multiple Drug Screen Cup** yields a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

### OPIATES 2000 / OPI

Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake. **Multiple Drug Screen Cup** yields a positive result when the concentration of Opiates in urine exceeds 2000ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

### OXYCODONE / OXY

Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy. **Multiple Drug Screen Cup** yields a positive result when the concentration of Oxycodone in urine exceeds 100ng/mL.

### PHENCYCLIDINE / PCP

Phencyclidine, commonly known as PCP or “angel dust” is used primarily as recreational drug due to its hallucinogenic effects. It is generally self administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of Phencyclidines (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heat rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%). **Multiple Drug Screen Cup** yields a positive result when the concentration of Phencyclidine in urine exceeds 25ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA,USA).

### PROPOXYPHENE /PPX

Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. **Multiple Drug Screen Cup** yields a positive result when the concentration of propoxyphene level in urine exceeds 300ng/mL.

### TRICYCLIC ANTIDEPRESSANTS/TCA

Tricyclic Antidepressants /TCA are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include

agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs. **Multiple Drug Screen Cup** yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

### S.V.T. SUMMARY

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 (bleach under the brand name UrineLuck) is a commonly used adulterant.<sup>6</sup> 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<sup>9</sup> 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 UrinAid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.<sup>7</sup> 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.<sup>8</sup> 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 (<5 mg/dl) is indicative of a specimen not consistent with human urine.

### PRINCIPLE OF TEST

**Multiple Drug Screen Cup** is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test device, the urine specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

### REAGENTS

**Multiple Drug Screen Cup** contain membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Marijuana, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

### S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.04%	99.96%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.75%
Oxidants / PCC	0.36%	99.64%

### MATERIALS PROVIDED

1. Drug Test Cup
2. Product insert
3. Security Seal
4. Procedure Card
5. Adulteration color card (Optional)

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. External controls

### PRECAUTIONS

1. For *forensic* use only.
2. For *in vitro diagnostic use* only.
3. Do not use after the expiration date.
4. The test cup should remain in the sealed pouch until use.
5. All specimens should be considered potentially hazardous and handle in the same way as an infectious material.
6. All used cup should be discarded according to federal, state and local regulation.

### STORAGE AND STABILITY

Store **Multiple Drug Screen Cup** in the sealed pouch at 2° to 30°C. The cup is stable through the expiration date printed on the sealed pouch. The cup must remain in the sealed pouch until use. If store at 2° to 8°C, allow the cup to reach room temperature (15° to 30°C) before performing the test. Do not freeze, do not use beyond the expiration date.

### SPECIMEN COLLECTION AND STORAGE

Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

For best results, test a fresh specimen immediately following collection. Storage of specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to using.

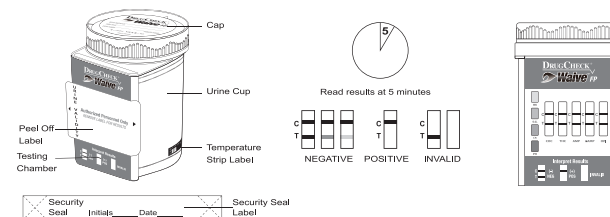
### TEST PROCEDURE

Allow the cup, urine specimen, and/or controls to reach room temperature (15-30°C) before testing.

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. Read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90-100°F.
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.
7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration,

we recommend not to interpret the drug test results and either retest the urine or collect another specimen.

8. **Read the test results at 5 minutes.** See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



### INTERPRETATION OF RESULTS

**Positive: One colored line appears in the Control zone (C). No line appears in the Test Zone (T).** The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug or its metabolite level is above the detectable level.

*Note: The samples with positive results should be confirmed with more specific method.*

**Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone.** The negative result indicates the drug or its metabolite level is below the detectable level.

**Invalid: No line appears in the Control zone.** If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new cup. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new cup. If the problem persists, discontinue using the current lot and contact your suppliers.

### ADULTERANT INTERPRATION

(Please refer to the color chart, if applicable)  
Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

### QUALITY CONTROL

1. Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new device.
2. External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
3. Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

### S.V.T. ADULTERATIONS LIMITATIONS.

1. The adulteration tests included with the product 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.
2. 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 the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. 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.
5. 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.
6. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

**LIMITATIONS**

1. **Multiple Drug Screen Cup** provides only a qualitative, preliminary testing result. A more specific testing method must be used in order to obtain a confirmed testing 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 erroneous results.
3. Adulterants such as bleach or other oxidizing agents may produce erroneous results. If suspected, the test should be repeated with a fresh specimen and a new cup.
4. The urine specimens with bacterial contamination should not be used for testing, as these contaminations may interfere with the test and cause false results.
5. A positive result does not indicate the level of intoxication, the route of the drug administration or the concentration of the drug in the urine.
6. 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 test.
7. Test does not distinguish between drugs of abuse and certain medications.

**PERFORMANCE CHARACTERISTICS**

**Accuracy:**

The comparison studies were conducted using **Multiple Drug Screen Cup** and commercially available rapid drugs of abuse tests. The studies were performed on approximately 128 clinical specimens per drug type previous collected from the clinical settings. Presumptive positive results were confirmed by GC/MS. The following results are summarized from these comparison studies:

**% Agreement with Commercial Kit**

	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	OPI300	OPI	OXY	PCP	PPX	TCA
Positive Agreement	100%	98%	97%	100%	100%	98%	100%	97%	100%	100%	98%	100%	98%	100%
Negative Agreement	98%	98%	97%	100%	98%	97%	98%	97%	100%	100%	98%	98%	98%	98%
Total Agreement	99%	98%	97%	100%	99%	97.5%	99%	97%	100%	100%	98%	99%	98%	99%

**% Agreement with GC/MS**

	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	OPI300	OPI	OXY	PCP	PPX	TCA*
Positive Agreement	100%	98%	97%	100%	100%	98%	100%	97%	100%	100%	98%	100%	98%	100%
Negative Agreement	98%	98%	97%	100%	98%	97%	98%	97%	100%	100%	98%	98%	98%	98%
Total Agreement	99%	98%	97%	100%	99%	97.5%	99%	97%	100%	100%	98%	99%	98%	98%

TCA\* : TCA was based on HPLC data.

**Sensitivity:**

Sensitivity of **Multiple Drug Screen Cup** was characterized by validating the test performance around the claimed cut-off concentration of each test. The results were summarized as the following:

**Amphetamine Sensitivity Study:**

Amphetamine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	1/19	95%
1500	20	0/20	100%

**Barbiturates Sensitivity Study:**

Barbiturates Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

**Benzodiazepines Sensitivity Study:**

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

**Cocaine Sensitivity Study:**

Cocaine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	7/13	65%
450	20	0/20	100%

**Methamphetamines Sensitivity Study:**

Methamphetamines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	0/20	100%
1500	20	0/20	100%

**MDMA Sensitivity Study:**

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
250	20	20/0	0%
375	20	20/0	0%
625	20	0/20	100%
750	20	0/20	100%

**Opiates 300 Sensitivity Study:**

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

**Opiates 2000 Sensitivity Study:**

Opiates 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
1000	20	20/0	0%
1500	20	13/7	35%
2500	20	0/20	100%
3000	20	0/20	100%

**Methadone Sensitivity Study:**

Methadone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	1/19	95%
450	20	0/20	100%

**Oxycodone Sensitivity Study:**

Oxycodone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
50	20	20/0	0%
75	20	20/0	0%
125	20	3/17	85%
150	20	0/20	100%

**Phencyclidine Sensitivity Study:**

Phencyclidine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
12.5	20	20/0	0%
18.75	20	20/0	0%
31.25	20	5/15	75%
37.5	20	0/20	100%

**Marijuana Sensitivity Study:**

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
25	20	20/0	0%
37.5	20	20/0	0%
62.5	20	2/18	90%
75	20	0/20	100%

**Propoxyphene Sensitivity Study:**

Propoxyphene Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

**Tricyclic Antidepressants Sensitivity Study:**

Tricyclic Antidepressants Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	4/16	80%
1500	20	0/20	100%

**Precision / Reproducibility:**

Reproducibility was determined by replicating tests on five different concentrations of each drug in urine specimens: negative, 50% below cut-off, 25% below cut-off, 25% above cut-off and 50% above cut-off. Each drug test was tested four times daily for five consecutive days with a total 20 assays at each concentration. The data are summarized below:

**Amphetamine Precision/Reproducibility Study:**

Amphetamine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	1/19	95%
1500	20	0/20	100%

### Barbiturates Precision/Reproducibility Study:

Barbiturates Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

### Benzodiazepines Precision/Reproducibility Study:

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

### Cocaine Precision/Reproducibility Study:

Cocaine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	7/13	65%
450	20	0/20	100%

### Methamphetamines Precision/Reproducibility Study:

Methamphetamines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	0/20	100%
1500	20	0/20	100%

### MDMA Precision/Reproducibility Study:

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	0/20	100%
750	20	0/20	100%

### Opiates 300 Precision/Reproducibility Study:

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

### Opiates 2000 Precision/Reproducibility Study:

Opiates 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
1000	20	20/0	100%
1500	20	13/7	65%
2500	20	0/20	100%
3000	20	0/20	100%

### Methadone Precision/Reproducibility Study:

Methadone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	1/19	95%
450	20	0/20	100%

### Oxycodone Precision/Reproducibility Study:

Oxycodone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	20/0	100%
125	20	3/17	85%
150	20	0/20	100%

### Phencyclidine Precision/Reproducibility Study:

Phencyclidine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
12.5	20	20/0	100%
18.75	20	20/0	100%
31.25	20	5/15	75%
37.5	20	0/20	100%

### Marijuana Precision/Reproducibility Study:

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
25	20	20/0	100%
37.5	20	20/0	100%
62.5	20	2/18	90%
75	20	0/20	100%

### Propoxyphene Precision /Reproducibility Study:

Propoxyphene Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	4/16	80%
450	20	0/20	100%

### Tricyclic Antidepressants Precision/Reproducibility Study:

Tricyclic Antidepressants Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	4/16	80%
1500	20	0/20	100%

### Analytical Specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. Analyzing various concentration of each compound by using **Multiple Drug Screen Cup**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

### Amphetamine:

Drug Compound	Response equivalent to cutoff in ng/mL
D-Amphetamine	1000
D,L-Amphetamine	2500
L-Amphetamine	50,000
(±) 3,4-Methylenedioxyamphetamine (MDA)	2,000
Ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000

### Barbiturates

Drug Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Phenobarbital	2500
Butalbital	500
Pentobarbital	1500
Amobarbital	2500
Cyclopentobarbital	500
Butethal	800
Barbital	300
Butabarbital	1500

### Benzodiazepines

Drug Compound	Response equivalent to cutoff in ng/mL
Oxazepam	300
Alprazolam	200
α -hydroxyalprazolam	1000
Bromazepam	250
Chlordiazepoxide	2500
Clobazam	100
Clonazepam	850
Clorazepate	250
Delorazepam	1600
Diazepam	200
Estazolam	200
Flunitrazepam	300
Lorazepam	1000
Midazolam	1500
Nitrazepam	100
Nordiazepam	400
Temazepam	150
Triazolam	500

### Cocaine

Drug Compound	Response equivalent to cutoff in ng/mL
Cocaine	>100,000
Benzoyllecgonine	300
Ecgonine HCl	35,000

### Methamphetamines

Drug Compound	Response equivalent to cutoff in ng/mL
+/-Methamphetamine	2,000
+Methamphetamine	1,000
3,4-Methylenedioxyethylamphetamine(MDEA)	35,000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Ranitidine (Zantac)	>100,000
3,4-Methylenedioxyamphetamine (MDA)	>100,000
D-Amphetamine	>100,000
L-Amphetamine	>100,000
Ephedrine	>100,000

### Methylenedioxyamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	500
D-Amphetamine	>100,000
D-Methamphetamine	100,000
3,4-Methylenedioxyethylamphetamine(MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000

### Methadone

Drug Compound	Response equivalent to cutoff in ng/mL
Methadone	300
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50,000
Doxylamine	50,000

### Opiates 300

Drug Compound	Response equivalent to cutoff in ng/mL
Morphine	300
Codeine	300
Hydrocodone	2,000
Hydromorphone	3,500
Morphine 3-β-D-glucuronide	300
6-Monoacetylmorphine	600
Normorphone	100,000
Oxycodone	10,000
Oxymorphone	50,000
Thebaine	7,000

### Opiates 2000

Drug Compound	Response equivalent to cutoff in ng/mL
Morphine	2,000
Codeine	2,000
Hydrocodone	10,000
Hydromorphone	7,000
Morphine 3-β-D-glucuronide	2,000
6-Monoacetylmorphine	5,000
Normorphone	100,000
Oxycodone	20,000
Oxymorphone	100,000
Thebaine	70,000

### Oxycodone

Drug Compound	Response equivalent to cutoff in ng/mL
Oxycodone	100
Morphine	50,000
Codeine	25,000
Morphine 3-β-D-glucuronide	50,000
Hydrocodone	1600
Hydromorphone	15,000
Normorphone	100,000
Oxymorphone	1500

### Phencyclidine

Drug Compound	Response equivalent to cutoff in ng/mL
Phencyclidine	25
4-Hydroxyphencyclidine	15,000

### Marijuana

Drug Compound	Response equivalent to cutoff in ng/mL
11-Nor-Δ <sup>8</sup> -THC-9-COOH	50
11-Nor-Δ <sup>9</sup> -THC-9-COOH	50
Δ <sup>8</sup> -Tetrahydrocannabinol	8,000
Δ <sup>9</sup> -Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

### Propoxyphene

Drug Compound	Response equivalent to cutoff in ng/mL
Propoxyphene	300
Norpropoxyphene	7,500
Methadone	>100,000

### Tricyclic Antidepressants

Drug Compound	Response equivalent to cutoff in ng/mL
Notriptiline	1,000
Trimipramine	4,500
Amitriptyline	1,000
Promazine	3,000
Desipramine	1,000
Imipramine	1,000
Clomipramine	7,500
Doxepin	3,000
Maprotiline	50,000

### Interfering Compounds:

The following compounds in both drug-free urine and drug positive urines with Amphetamine, Cocaine, Barbiturate, Benzodiazepine, Methamphetamine, Methylenedioxyamphetamine, Marijuana, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants show no cross-reactivity when tested with **Multiple Drug Screen Cup** at a concentration of 100µg/mL.

### Common Substances:

Acetaminophen	Ibuprofen
Acetone	(+/-)-Isoproterenol
Albumin	Ketamine
Ampicillin	Levorphanol
Ascorbic Acid	Lidocaine
Aspartame	(+)-Naproxen
Aspirin	Niacinamide
Atropine	Nicotine
Benzocaine	(+/-)-Norephedrine
Bilirubin	Oxalic Acid
Caffeine	Penicillin-G
Chloroquine	Pheniramine
(+)-Chlorpheniramine	Phenothiazine
(+/-)-Chlorpheniramine	1-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline
Furosemide	Tyramine
Glucose	4-Dimethylaminoantipyrene
Guaiaacol Glyceryl Ether	(1R,2S)-(-)-N-Methyl-Ephedrine
Hemoglobin	

### Biological Materials:

Albumin	Vitamin (L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH 4.5-9.0
Hemoglobin	Urine Specific Gravity 1.002-
Glucose	1.035g/mL

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

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