SPLIT-SPECIMEN CUP™

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/mAMP/MDMA/MOP/OPI/PCP/TCA

Some cup configurations are available with adulteration strips that may include tests for Oxidants/Pyridinium Chlorochromate, pH and Specific Gravity, Nitrite, Glutaraldehyde and Creatinine

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The Split-Specimen Cup™ is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L-Methylenedioxymethamphetamine	500 ng/mL
Morphine (MOP 300)	Morphine	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the Split-Specimen Cup™ come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical 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 result, particularly when preliminary positive results are indicated.

SUMMARY

The Split-Specimen Cup™ is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP)
Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. 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. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects 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.
The Split-Specimen Cup™ yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

BARBITURATES (BAR)
Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.
Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.
Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.
The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[1]

The Split Specimen Cup™ yields a positive result when the Barbiturates in urine exceed 300 ng/mL.

BENZODIAZEPINES (BZO)
Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.
Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.
Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.
The Split-Specimen Cup™ yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

COCAINE (COC)
Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.
Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine [2,3]. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[3]
The Split-Specimen Cup™ yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

MARIJUANA (THC)
THC (Δ^9–tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).
The Split-Specimen Cup™ yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

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). The pharmacology of oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.
Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[1]
The Split-Specimen Cup™ yields a positive result when the Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (mAMP)
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 is made in illegal laboratories and has a high potential for abuse and dependence. The drug 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. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.
The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.
The Split-Specimen Cup™ yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[8] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws. The Split-Specimen Cup™ yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

MORPHINE (MOP 300)
Opiate refers 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. Opioid is more general, referring to any drug that acts on the opioid receptor.
Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose. [1]
The Split-Specimen Cup™ yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (2000)
The Split-Specimen Cup™ yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4] See Morphine (MOP 300) for a summary.

PHENCYCLIDINE (PCP)
Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.
Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.
PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]
The Split-Specimen Cup™ yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

TRICYCLIC ANTIDEPRESSANTS (TCA)
TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.
The Split-Specimen Cup™ yields a positive result when the concentration Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The Split-Specimen Cup™ is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepine, Methadone, Barbiturate or Tricyclic Antidepressants.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for in vitro diagnostic use only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- The Split-Specimen Cup™
- The Split-Specimen™ Cup has a Fahrenheit temperature strip affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable).
- Key
- Adulterant color chart (if applicable)
- Security seal
- Package insert

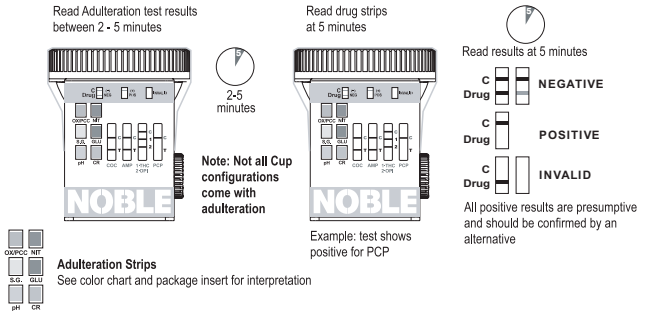
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test card, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Donor provides specimen and secures the cap tightly.
3. Technician dates and initials the security seal and attaches the security seal over the cup cap.
4. Technician places cup on a flat surface, inserts key and pushes in.
5. Technician peels off the label on the multi-drug test card to view results.
6. If the cup contains adulteration test strip(s), read the adulteration strip(s) between 2-5 minutes. Compare the colors on the adulteration strips to the color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen
7. Read the drug strips at 5 minutes. The drug test results remain stable for up to sixty minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card and Color Chart.



INTERPRETATION OF RESULTS

(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 specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

SUMMARY

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 or destroying the drugs present in the urine.

Diluting, flushing or adding adulterants to the sample after collection are ways that users of illicit drugs have attempted to defeat drug tests and invalidate the testing procedures. Diluting samples or adding household chemicals such as detergents, bleach or soaps are some of the creative ploys that abusers use to mask positive samples. One of the best ways to test for adulteration or dilution is to look for certain characteristics such as pH, oxidization, specific gravity, nitrites, glutaraldehyde and creatinine. Color and temperature may also help indicate sample tampering.

- **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 "spiked" or altered.
- **Oxidants** tests for the presence of oxidizing reagents such as bleach and Hydrogen Peroxide. Normal urine should contain no trace of oxidants.
- **PCC (Pyridinium Chlorochromate) -** Normal urine should contain no PCC. One of the commonly used adulterants on the market, Urine Luck, contains PCC and can alter the test results.
- **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.
- **Creatinine** is a waste product of creatine, an amino-acid contained in muscle tissue and found in urine. Creatinine tests for "internal" or *in vivo* dilution. 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 ways to mask drug use. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (<5mg/dl) is indicative of a specimen not consistent with human urine.
- **Nitrites** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite detected by GC/MS. By the time a positive sample arrives to the lab for confirmation, the detectable THC carboxylic acid metabolite has been destroyed. Normal urine should contain no trace of nitrites. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of aldehyde. Adulterants such as UrinAid and Clear Choice contain Glutaraldehyde and can cause false negative screening results by disrupting the test. Glutaraldehyde is not normally in urine and detection is generally an indicator of an adulterant.
- **Color** – A clear color may indicate that the sample has been diluted. Unadulterated, normal urine should be pale to dark yellow or amber in color. However, a sample should not be considered positive by color alone, but should be suspect for closer examination.
- **Temperature** - The temperature of a urine specimen should be between 91 and 98 degrees when checked within 4 minutes of collection. Urine that is submitted at body temperature will exceed 90.5 degrees Fahrenheit. A specimen that falls below that range is suspect.

ADULTERANT INTERPRETATION

(Please refer to the color chart for color comparison)

The test strips aid in the detection of urine adulteration for drugs of abuse test screens. The test is based on the chemical reaction to the reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with a corresponding color chart.

Oxidants/PCC (Pyridinium chlorochromate): Tests for presence of oxidizing reagents and PCC. Normal urine contains no trace of oxidants or PCC. A dark blue or green color may indicate their presence.

Specific gravity: Tests for sample dilution. Green to dark yellow indicates normal range. Blue and bright yellow indicate abnormal ranges. Normal range is between 1.003 and 1.030.

pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH will range from 4.0 to 9.0 and have an orange color. Colors outside the normal range will vary from pink (low pH) to dark brown (high pH).

Nitrites: Tests for the presence of nitrites which can cause discrepancies between the initial screening result and the GC/MS confirmation testing. Nitrites are not a normal component of urine. Abnormal nitrite levels (above 50mg/dl) will have red to dark red color.

Glutaraldehyde: Tests for the presence of glutaraldehyde which can alter the test result and produce a false negative result. Normal urine should contain no Glutaraldehyde. A purple color indicates the presence of glutaraldehyde.

Creatinine: Normal urine samples contain Creatinine between 20 and 350 mg/dl (milligrams per deciliter). A specimen with a creatinine level below 20 is considered dilute.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen 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.

ADULTERATION LIMITATIONS

1. The adulteration tests included with this 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. Normal urine should contain no oxidants. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidant pad.
3. Elevated levels of protein in urine may cause specific gravity values to be higher.
4. Normal creatinine levels are between 20 and 350 mg/dl. Under rare conditions, certain kidney diseases show dilute urine.
5. Normal urine should contain no trace of nitrite. However, nitrite found in urine may indicate urinary tract infections or bacterial infections.
6. Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (starvation) may interfere with the test result.

LIMITATIONS

1. The Split-Specimen Cup™ provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [3,4,7]
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 and/or alum, in urine specimens may produce erroneous 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. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Split-Specimen Cup™ and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, a-OH-Alprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L Methylenedioxyamphetamine
OPI	Morphine, Codeine
PCP	Phencyclidine
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	90%	95%	98%	99%
Negative Agreement	100%	>99%	97%	>99%	100%	>99%
Total Results	98%	99%	94%	98%	99%	>99%

	mAMP	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	98%	100%	100%	>99%	98%	95%
Negative Agreement	100%	99%	100%	>99%	100%	>99%
Total Results	99%	99%	100%	>99%	99%	99%

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	96%	96%	97%	99%
Negative Agreement	95%	>99%	96%	>90%	88%	>94%
Total Results	96%	99%	96%	93%	91%	>96%

	mAMP	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	99%	96%	100%	>99%	100%	>99%
Negative Agreement	94%	98%	94%	>90%	97%	89%
Total Results	96%	97%	97%	>95%	98%	91%

Forty (40) clinical samples for each drug were run using each of the Split-Specimen Cup™ by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.
*Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	5	0
750	5	5	0	1	4	1	4
1,250	5	0	5	0	5	0	5
1,500	5	0	5	0	5	0	5

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	4	1	5	0	5	0
225	5	1	4	4	1	5	0
375	5	0	5	0	5	2	3
450	5	0	5	0	5	1	4

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	4	1	3	2	4	1
225	5	2	3	4	1	2	3
375	5	0	5	0	5	3	2
450	5	0	5	0	5	1	4

COCAINE (COC)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	5	0	4	1	5	0
225	5	5	0	1	4	5	0
375	5	1	4	0	5	2	3
450	5	0	5	0	5	1	4

MARIJUANA (THC)

11-nor-Δ9 -THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	**5**	**5**	**0**	**5**	**0**	**5**	**0**
25	**5**	**5**	**0**	**3**	**2**	**5**	**0**
37.5	**5**	**5**	**0**	**2**	**3**	**5**	**0**
62.5	**5**	**1**	**4**	**1**	**4**	**1**	**4**
75	**5**	**0**	**5**	**0**	**5**	**0**	**5**

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	5	0	5	0	5	0
225	5	2	3	5	0	4	1
375	5	1	4	2	3	2	3
450	5	0	5	0	5	0	5

METHAMPHETAMINE (mAMP)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	5	0
750	5	5	0	4	1	1	4
1,250	5	0	5	0	5	3	2
1,500	5	0	5	0	5	0	5

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymeth-amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
250	5	4	1	5	0	5	0
375	5	4	1	3	2	4	1
625	5	0	5	0	5	1	4
750	5	0	5	0	5	0	5

OPIATE (OPI 2000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
1,000	5	5	0	4	1	5	0
1,500	5	5	0	4	1	4	1
2,500	5	0	5	1	4	2	3
3,000	5	0	5	0	5	0	5

MORPHINE (MOP 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
150	5	4	1	5	0	5	0
225	5	2	3	5	0	5	0
375	5	0	5	0	5	3	2
450	5	0	5	0	5	1	4

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
12.5	5	4	1	5	0	5	0
18.75	5	2	3	5	0	3	2
31.25	5	1	4	0	5	1	4
37.5	5	1	4	0	5	0	5

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	5	5	0	5	0	5	0
500	5	5	0	4	1	4	1
750	5	5	0	1	4	3	2
1,250	5	0	5	1	4	0	5
1,500	5	0	5	0	5	0	5

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug Concentration		AMP		BAR		BZO		COC	
Cut-off Range	n	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	27	3	26	4	30	0
Cut-off	30	18	12	22	8	12	18	4	26
+25% Cut-off	30	1	29	7	23	3	27	0	30
+50% Cut-off	30	0	30	2	28	0	30	0	30

Drug Concentration		THC		MTD		mAMP		MDMA	
Cut-off Range	n	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	29	1	30	0	30	0
-25% Cut-off	30	12	18	24	6	30	0	26	4
Cut-off	30	1	29	21	9	18	12	17	13
+25% Cut-off	30	1	29	2	28	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
Drug Concentration		MOP		OPI		PCP		TCA	
Cut-off Range	n	-	+	-	+	-	-	+	-
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	19	11	22	8
Cut-off	30	17	13	13	17	16	14	12	18
+25% Cut-off	30	1	29	4	26	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by One Step Drug Screen Test Card at 5 minutes.

AMPHETAMINE	ng/mL
D-Amphetamine	1,000
D,L-Amphetamine sulfate	3,000
L-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine	2,000
Phentermine	3,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
a-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlordiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±)Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE	
Benzoylecgonine	300
Cocaine HCl	780
Cocaethylene	12,500
Ecgonine HCl	32,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
METHADONE	
Methadone	300

Doxylamine	50,000
METHAMPHETAMINE	
D-Methamphetamine	1,000
ρ-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
(±)3,4-Methylenedioxyamphetamine	2,000
Mephentermine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1500
6-Monoacetylmorphine	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATES (2000)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PCP	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
TCA	
Notriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Split-Specimen Cup™ was tested in duplicate using fifteen 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 the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Split-Specimen 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 drug positive urine containing Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Phencyclidine or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the Split-Specimen Cup™ at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloralhydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
L -Ψ-Ephedrine
Estrone-3-sulfate
[1R,2S] (-) Ephedrine
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
O-Hydroxyhippuric acid
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Methylphenidate
Naloxone
Naproxen
Nifedipine
D-Norpropoxyphene
D/L-Octopamine
Oxolinic acid
Papaverine
Pentazocine hydrochloride
Phenelzine
L-Phenylephrine
Phenylpropanolamine
Prednisone
D-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Tetrahydrocortisone 3 (β-D-glucuronide)
Thiamine
D/L-Tyrosine
Triamterene
Trimethoprim
D/L-Tryptophan
Uric acid
Zomepirac

Acetophenetidin
Acetylsalicylic acid
Amoxicillin
L-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine*
D/L-Brompheniramine
Cannabidol
Chloramphenicol
D/L-Chloropheniramine
Chloroquine
Clonidine
L-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
Ecgonine methyl ester
β-Estradiol
Ethyl-p-aminobenzoate
L(−)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxyamphetamine
Ibuprofen
D/L-Isoproterenol
Ketamine
Labetalol
Meperidine
Methoxyphenamine
Nalidixic acid
Naltrexone
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclo-propylamine hydrochloride
β-Phenylethylamine
Prednisolone
D/L-Propranolol
D-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-acetate
Tetrahydrozoline
Thioridazine
Tolbutamide
Trifluoperazine
Tryptamine
Tyramine
Verapamil

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

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