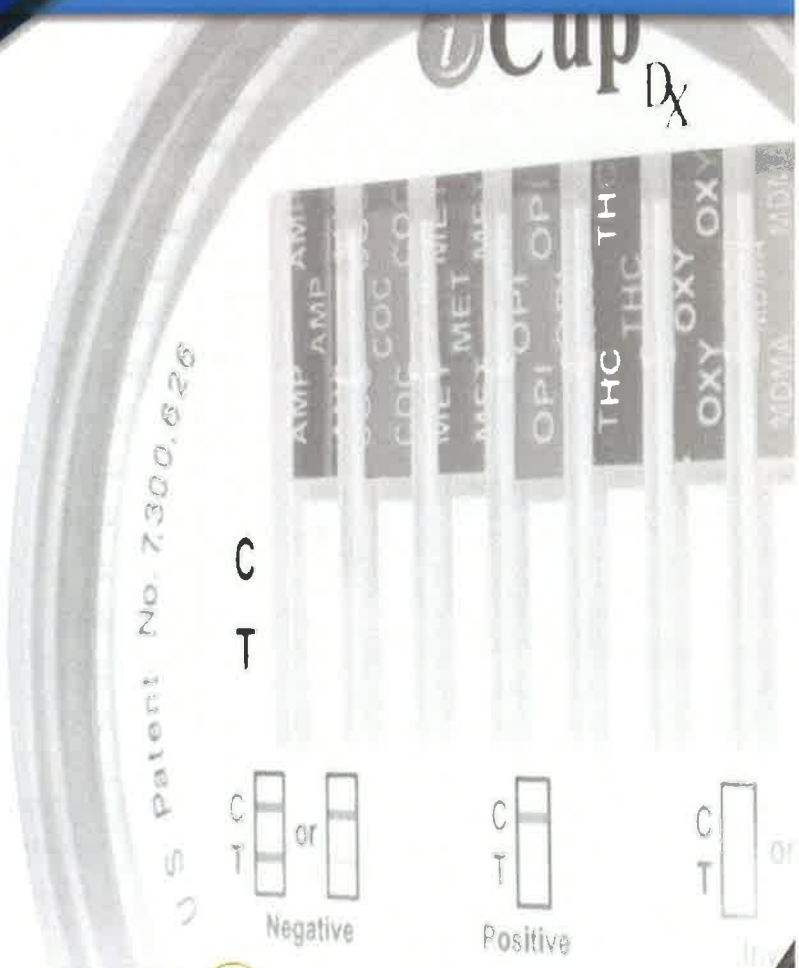
iCup® Dx

CLIA Waived



iCup® Dx Drug Screen

Rapid Drug Screening Made Simple.

CLIA Waived

- CLIA Waived
- Up to 12 drugs
- Simple Process - tilt, read at 5 minutes
- All Inclusive - no urine exposure
- Leak-proof, secure collection cup
- Tester activates the test when ready
- Integrated Temperature Strip
- Tamper Resistant

Innovative Drug Screening Solutions

Quality • Choices • Support

Instant Technologies, Inc.™

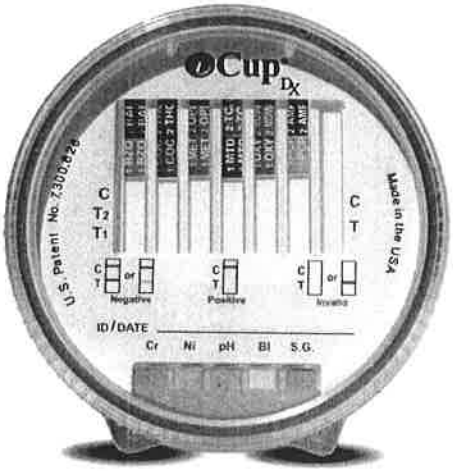
an inverness medical company

iCup® Dx Drug Screen

Rapid Drug Screening Made Simple.

Detect the presence of drugs and adulterants in minutes.
It's drug screening efficiency you can count on.

CLIA Waived



iCup Dx 12-Panel with SVT

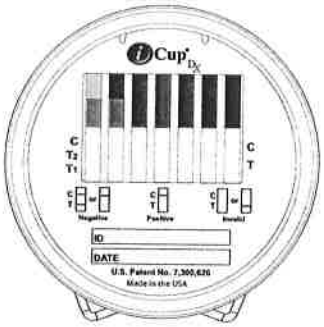
Drug Class:	Abbreviation:	Cutoff Levels:
Amphetamine	AMP	1000ng/ml
Barbiturates	BAR	300ng/ml
Benzodiazepines	BZO	300ng/ml
Cocaine	COC	300ng/ml
Ecstasy	MDMA	500ng/ml
Marijuana	THC	50ng/ml
Methadone	MTD	300ng/ml
Methamphetamine	mAMP	1000ng/ml
Opiates	OPI	2000ng/ml
Oxycodone	OXY	100ng/ml
Phencyclidine	PCP	25ng/ml
Tricyclic Antidepressants	TCA	1000ng/ml

Instructions

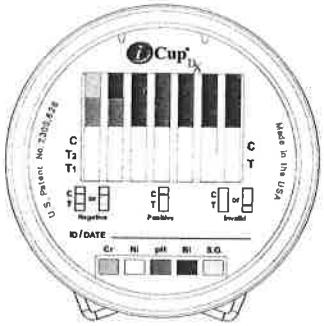
1. **Collect specimen and secure test lid**
2. **Tilt cup on its side to activate test**
3. **Read the results**

Read results at five (5) minutes.

NEGATIVE **NON-NEGATIVE** **INVALID**



iCup Dx without SVT.



iCup Dx with SVT.

ADULTERATION COLOR COMPARISON CHART

	ABNORMAL (LOW)		NORMAL				ABNORMAL (HIGH)
Creatinine (CR) 45 seconds	<10	10	20	50	100	200 mg/dl	
Nitrite (NI) 45 seconds			0	0.1-0.2	0.5-5.0		≥15 mg/dl
pH Immediate	2	3	4	5	7	9	≥10
Bleach (Bl) 45 seconds			Negative				Positive
Specific Gravity (S.G.) 60 seconds	1.000		1.005	1.015	1.025		≥1.030

SAMPLE ONLY - Color chart NOT Exact

Catalog #	Drugs/Panel	*Optional Specimen Validity Tests (SVT)*
I-DXA-187-016 *	8	COC, THC, OPI, AMP, mAMP, BZO, OXY, MTD (Cr, Ni, pH, Bl, S.G.)
I-DXA-1107-015 *	10	COC, THC, OPI, AMP, MDMA, PCP, BAR, BZO, MTD, TCA (Cr, Ni, pH, Bl, S.G.)
I-DXA-1107-142 *	10	COC, THC, OPI, AMP, mAMP, MDMA, BZO, BAR, OXY, MTD (Cr, Ni, pH, Bl, S.G.)
I-DXA-1127-023	12	COC, THC, OPI, AMP, mAMP, PCP, BZO, BAR, OXY, MTD, TCA, MDMA (Cr, Ni, pH, Bl, S.G.)

*** Coming Soon**

iCup® DX

A rapid, all-inclusive drug screen with optional Specimen Validity Tests.

(BZ0/BAR)+(COC/THC)+(MET1000/OPI2000)
+(MTD/TCA)+(OXY/MDMA)+(PCP/AMP)

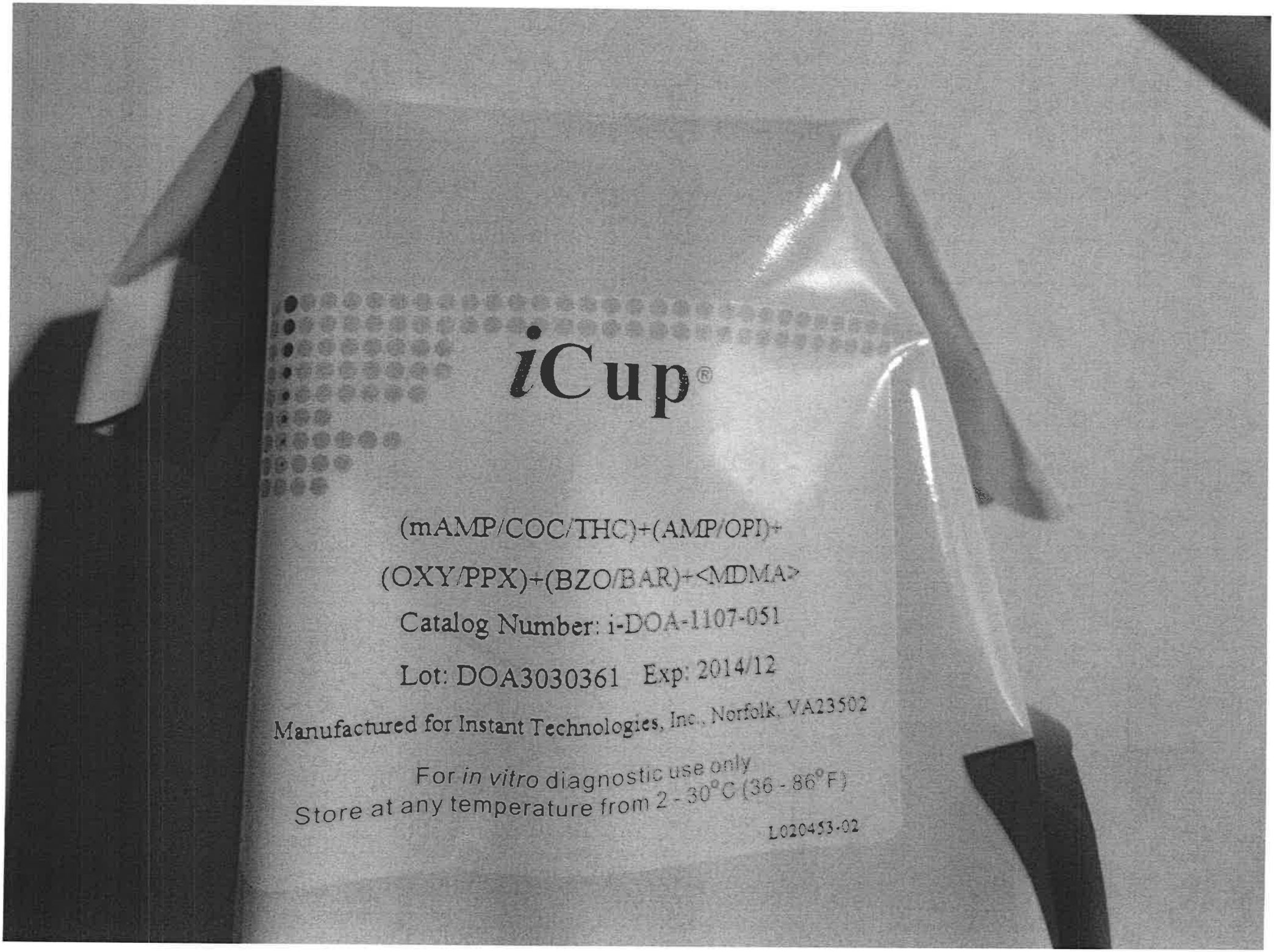
Item# I-DXA-1127-023
Lot: 90856 **Exp:** 12/2010

Contents: Individually packaged devices (25), package insert (1)
Security Seals (25), Color Comparison Chart (1)

For *in vitro* diagnostic use only
Storage temperature: 2 - 30°C (36 - 86°F)

Manufactured for: inverness medical
Orlando, FL 32810 USA

made in the USA


iCup®
(mAMP/COC/THC)+(AMP/OPI)+
(OXY/PPX)+(BZO/BAR)+<MDMA>
Catalog Number: i-DOA-1107-051
Lot: DOA3030361 Exp: 2014/12
Manufactured for Instant Technologies, Inc., Norfolk, VA23502
For in vitro diagnostic use only
Store at any temperature from 2 - 30°C (36 - 86°F)
L020453-02

*i*Cup®

25 CUPS

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

(mAMP/COC/THC)+(AMP/OPI)+
(OXY/PPX)+(BZO/BAR)+<MDMA>
Catalog Number: i-DOA-1107-051

Lot:DOA3030361
Exp:2014/12

For *in vitro* diagnostic use only
Store at any temperature from 2 - 30°C (36 - 86°F)
This assay provides only a preliminary result. A quantitative analytical method is needed to obtain a confirmed result (see package insert).
Manufactured for Instant Technologies, Inc., Norfolk, VA 23502

L040437-01

Instant Technologies

One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup® A.D.

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

Available with Specimen Validity Tests (S.V.T.) for Oxidants/PCC, Specific Gravity, pH, 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** 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 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D. 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** 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 1,000)

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 (CNS) 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of amphetamines in urine exceeds 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).[1]

AMPHETAMINE (AMP 300)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS 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[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

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 benzodiazepines in urine is 3-7 days.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.[3] The plasma half life of Buprenorphine is 2-4 hours.[3] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system 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.[4,5] 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.[5]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzoylecgonine 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).[1]

COCAINE (COC 150)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.

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 (THC-COOH).

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** 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).[1]

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.[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS 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 CNS 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

OPIATE (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 CNS. 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.[2]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of 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).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

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.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP 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 PCP.

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.[7] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[8]

The **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.** yields a positive result when the concentration of phencyclidine 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).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®$^{A.D.}$ yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS 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 One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®$^{A.D.}$ yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

S.V.T. SUMMARY

(Information regarding Specimen Validity Tests does not require FDA review.)

The strip contains chemically treated reagent pads. 3-5 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 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 and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[6] Normal human urine should not contain oxidants or 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 or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Preliminary 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 screening results by disrupting the enzyme used in some immunoassay tests.[8] 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.[2] 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

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®$^{A.D.}$ 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 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 region.

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

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

REAGENTS

Each test contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

S.V.T. REAGENTS

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

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 cup 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 cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). 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. When tests include S.V.T., storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, test specimens immediately following collection.

MATERIALS

Materials Provided

- Cups with multi-drug panels [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Adulteration color chart (if applicable)
- Security seal label
- Package insert
- Procedure card

Materials Required But Not Provided

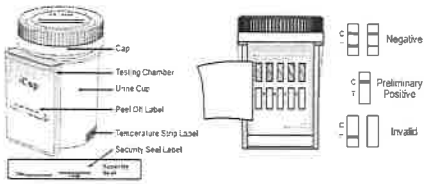
- A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External controls

DIRECTIONS FOR USE

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) 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.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Donor dates and initials the security seal and attaches the security seal over the cup cap.
5. Technician peels off label to reveal adulteration strip(s), if applicable.
6. Technician peels off the label on the multi-drug test card to view results.
7. The adulteration strip(s), if applicable, should be read between 3-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.
8. If results do not indicate adulteration, read the drug test result 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.
9. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

Cup without SVT



Cup with SVT

INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A 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.

LIMITATIONS

1. **The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®$^{A.D.}$** 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.[1,4,5]
2. There is a possibility that technical or procedural errors, as well as 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. If adulteration is suspected, the test should be repeated with another urine specimen.
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. This 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.

S.V.T. 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. 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 preliminary 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®$^{A.D.}$** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present 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 Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BUP	Buprenorphine
BZO	Oxazepam, Nordiazepam, o-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.	AMP 1,000	Positive	129	0	>99%
		Negative	0	172	>99%
	AMP 300	Positive	127	0	>99%
		Negative	0	173	>99%
	BAR	Positive	126	1	>99%
		Negative	0	166	>99%
	BUP	Positive	*	*	*
		Negative	*	*	*
	BZO	Positive	131	0	>99%
		Negative	1	162	>99%
	COC 300	Positive	112	1	>99%
		Negative	0	186	99%
	COC 150	Positive	141	0	>99%
		Negative	0	159	>99%
	mAMP 1,000	Positive	121	0	99%
		Negative	1	174	>99%
	mAMP 500	Positive	108	39**	>99%
		Negative	0	153	80%
	MDMA	Positive	86	0	>95%
		Negative	4	152	>99%
	MOP	Positive	125	0	95%
		Negative	7	150	>99%
	MTD	Positive	120	0	89%
		Negative	18	168	>99%
	OPI	Positive	131	0	98%
		Negative	2	164	>99%
	OXY	Positive	142	0	97%
		Negative	4	154	>99%
	PCP	Positive	71	0	99%
		Negative	1	160	>99%
	PPX	Positive	157	0	>99%
		Negative	0	157	>99%
	TCA	Positive	45	0	92%
		Negative	4	177	>99%
	THC	Positive	124	1	>99%
		Negative	0	175	99%

* Commercial kit unavailable for BUP

** 32 specimens showed >500 ng/mL concentration by GC/MS

Method		GC/MS					
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP 1,000	Positive	0	1	8	18	114	97%
	Negative	149	1	5	4	0	95%
BAR	Positive	0	0	4	5	117	92%
	Negative	150	1	5	1	9	98%
BUP	Positive	0	0	0	5	50	98%
	Negative*	150	15	5	1	0	>99%
BZO	Positive	0	7	1	5	26	97%
	Negative	149	7	1	3	1	95%
COC 300	Positive	0	2	15	16	103	96%
	Negative	150	5	7	1	1	90%
THC	Positive	0	13	9	12	109	95%
	Negative	150	6	0	0	1	97%
MTD	Positive	0	0	10	10	112	98%
	Negative	150	17	0	0	1	94%
mAMP 1,000	Positive	0	0	10	9	126	99%
	Negative	150	0	4	1	0	94%
MDMA	Positive	0	0	3	6	82	96%
	Negative	147	0	2	0	0	>99%
MOP	Positive	0	2	7	10	131	>99%
	Negative	150	0	0	0	0	94%
OPI	Positive	0	0	16	18	116	>99%
	Negative	150	0	0	0	0	90%
PCP	Positive	0	0	6	10	40	>99%
	Negative	150	8	0	0	0	97%
*TCA	Positive	0	12	8	15	20	>99%
	Negative	150	17	0	0	0	89%

* When compared with HP/LC at a cut-off of 1,000ng/ml, the following results were tabulated:

Method		GC/MS					
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
*BUP	Positive	0	0	0	5	50	98%
	Negative	150	15	5	1	0	>99%
PPX	Positive	0	0	2	7	156	94%
	Negative	152	5	18	10	0	99%
AMP 300	Positive	0	1	1	2	123	99%
	Negative	150	18	5	0	0	99%

* Negative samples were confirmed negative using LC/MS by pooling these samples into groups of 15.

Method		GC/MS				
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.		Neg.	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
COC 150	Positive	0	0	10	131	>99%
	Negative	150	7	0	2	96%
OXY	Positive	0	5	2	135	96%
	Negative	147	8	2	1	97%

Method		GC/MS		
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.		Neg.	Pos.	% agreement with GC/MS
mAMP 500	Positive	7	140	>99%
	Negative	153	0	96%

Forty (40) clinical samples for each drug were run using each of the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.** 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.

Precision

A study was conducted at three physician offices for Amphetamine (1,000 ng/mL), Cocaine (300 ng/mL), Marijuana, Methamphetamine (1,000 ng/mL), Opiate and Phencyclidine 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 as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	90	0	88	2	89	1
-25% Cut-off	90	80	10	70	20	70	20
+25% Cut-off	90	34	56	13	77	12	78
+50% Cut-off	90	5	85	5	85	3	87

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants 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 as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	83	7	87	3	90	0
-25% Cut-off	90	67	23	75	15	80	10
+25% Cut-off	90	28	62	30	60	22	68
+50% Cut-off	90	1	89	0	90	2	88

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 concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	0	15	1	14	0	15
15	15	0	15	0	15	0	15

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

Analytical Sensitivity

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

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
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	24	6	27	3	25	5	25	5
Cut-off	30	17	13	13	17	13	17	14	16
+25% Cut-off	30	5	25	4	26	7	23	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
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	24	6	27	3	20	10
Cut-off	30	19	11	14	16	14	16	19	11
+25% Cut-off	30	3	27	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		MOP	
		-	+	-	+	-	+	-	+
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	24	6	23	7	20	10	27	3
Cut-off	30	18	12	13	17	18	12	17	13
+25% Cut-off	30	5	25	8	22	10	20	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4	24	6	25	5
Cut-off	30	17	13	18	12	14	16	17	13	18	12
+25% Cut-off	30	4	26	6	24	6	24	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCupe A.D.** at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000

Compound	ng/mL
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	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
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^9–THC	15,000
Δ^8–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000

Compound	ng/mL
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (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	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200

Compound	ng/mL
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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®** A.D. 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 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 **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®** A.D.. 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, Buprenorphine, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®** A.D. at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine
Acetophenetidin	Deoxycorticosterone	Labetalol	Quinacrine
N-Acetylprocainamide	Dextromethorphan	Loperamide	Quinine
Acetylsalicylic acid	Diclofenac	Meperidine	Quinidine
Aminopyrine	Diflunisal	Meprobamate	Ranitidine*
Amoxicillin	Digoxin	Methoxyphenamine	Salicylic acid
Ampicillin	Diphenhydramine	Methylphenidate	Serotonin
l-Ascorbic acid	l -Ψ-Ephedrine	Nalidixic acid	Sulfamethazine
Apomorphine	β-Estradiol	Naproxen	Sulindac
Aspartame	Estrone-3-sulfate	Niacinamide	Tetracycline
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Tetrahydrocortisone
Benzilic acid	l (-)-Epinephrine	Norethindrone	3-acetate
Benzoic acid	Erythromycin	Noscapine	Tetrahydrocortisone
Benzphetamine*	Fenoprofen	d,l-Octopamine	3-(β-D-glucuronide)
Bilirubin	Furosemide	Oxalic acid	Tetrahydrozoline
d,l-Brompheniramine	Gentisic acid	Oxolinic acid	Thiamine
Caffeine	Hemoglobin	Oxymetazoline	Thioridazine
Cannabidol	Hydralazine	Papaverine	d,l-Tyrosine
Chloralhydrate	Hydrochlorothiazide	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrocortisone	Pentazocine	Triamterene
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	Trifluoperazine
d,l-Chlorpheniramine	p-Hydroxytyramine	Phenelzine	Trimethoprim
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo	Tryptamine
Cholesterol	Iproniazid	propylamine	d,l-Tryptophan
Clonidine	d,l-Isoproterenol	Prednisolone	Uric acid
Cortisone	Isoxauprine	Prednisone	Verapamil
l-Cotinine	Ketamine	d,l-Propranolol	Zomepirac

*Parent compound only.

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