



Instant Technologies

One Step Multi-Drug Screen Test Card with the Integrated iCup®

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

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.

For in vitro diagnostic use only.

INTENDED USE

The One Step Multi-Drug Screen Test Card with the integrated iCup® 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
Cocaine (COC)	Benzoylcgonine	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
Methylenedioxyamphetamine (MDMA)	d,l-Methylenedioxyamphetamine	500 ng/mL
Morphine (MOP 300)	Morphine	300 ng/mL
Opiates (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® can consist of 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® 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 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® 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).¹

AMPHETAMINE (AMP 300)

The One Step Multi-Drug Screen Test Card with the integrated iCup® yields a positive result when Amphetamines in urine exceed 300 ng/mL. The suggested Amphetamine screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA) is 1,000 ng/mL.¹ See Amphetamine (AMP 1,000) for a summary.

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 ²

The One Step Multi-Drug Screen Test Card with the integrated iCup® 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 One Step Multi-Drug Screen Test Card with the integrated iCup® 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 Benzoylcgonine.^{3,4} Benzoylcgonine, 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.⁴

The One Step Multi-Drug Screen Test Card with the integrated iCup® 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).¹

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 One Step Multi-Drug Screen Test Card with the integrated iCup® 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 Test Card with the integrated iCup® 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 One Step Multi-Drug Screen Test Card with the integrated iCup® yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxyamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.⁵ 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 Oberlander, 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® yields a positive result when the Methylenedioxyamphetamine in urine exceeds 500 ng/mL.

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 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.²

The One Step Multi-Drug Screen Test Card with the integrated iCup® yields a positive result when the morphine in urine exceeds the 300 ng/mL cut-off level.

OPIATE (OPI 2,000)

The One Step Multi-Drug Screen Test Card with the integrated iCup® 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).¹ See Opiate (MOP 300) for a 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, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).⁶ 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® yields a positive result when the oxycodone level in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for oxycodone positive specimen.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950s. 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.⁷ Phencyclidine 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® 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).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.⁹

The One Step Multi-Drug Screen Test Card with the integrated *iCup*® 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 cutoff 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 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 One Step Multi-Drug Screen Test Card with the integrated *iCup*® yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The One Step Multi-Drug Screen Test Card with the integrated *iCup*® 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, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- 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 panel 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 panel 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

- iCup*® with integrated One Step Multi-Drug Screen Test Card
- Security seal label
- Package insert
- Procedure Card

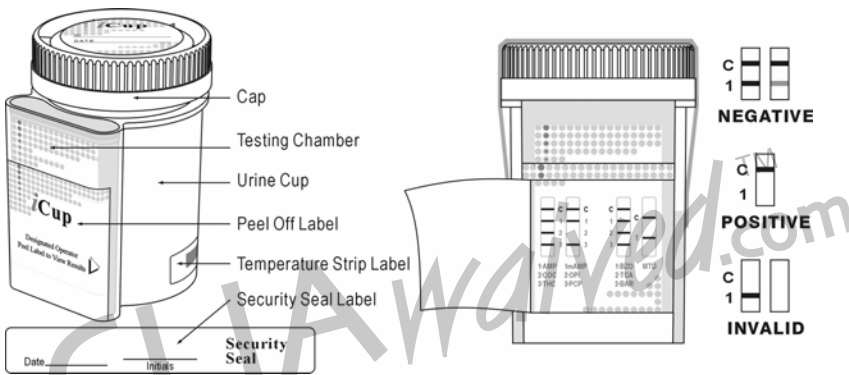
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
- Donor provides specimen.
- Technician replaces and secures cap while the cup is on a flat surface.
- Technician dates and initials the security seal and attaches the security seal over the cup cap.
- Technician peels off the label on the multi-drug test card to view results.
- Start the timer and wait for the colored lines to appear. The results should be read 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.



INTERPRETATION OF RESULTS

(Please refer to the illustration)

NEGATIVE: * **Two lines appear.** One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint line.

POSITIVE: **One colored line appears in the control region (C). No line appears in the test region (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.

QUALITY CONTROL

A procedural control is included in the test. A colored 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

- The One Step Multi-Drug Screen Test Card with the *iCup*® 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}
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A Positive result does not indicate level of intoxication, administration route or concentration in urine.
- 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.

- Test does not distinguish between drugs of abuse and certain medications.
- 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 One Step Single Drug Test Strip 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 Contributing to the GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, α-OH-Alprazolam, Desalkylflurazepam
COC	Benzoylcegonine
THC	11-nor-Δ ⁹ -tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI / MOP	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

%Agreement with Commercial Kit

	AMP	AMP 300	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	>99%	90%	95%	98%	99%
Negative Agreement	>99%	>99%	>99%	97%	>99%	>99%	>99%
Total Results	98%	>99%	99%	94%	98%	99%	>99%

	mAMP	MDMA	MOP	OPI	OXY	PCP	PPX	TCA*
Positive Agreement	98%	>99%	>99%	>99%	97%	98%	>99%	95%
Negative Agreement	>99%	99%	>99%	>99%	97%	>99%	>99%	>99%
Total Results	99%	99%	>99%	>99%	97%	99%	>99%	99%

%Agreement with GC/MS

	AMP	AMP 300	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	>99%	96%	96%	97%	99%
Negative Agreement	95%	99%	>99%	96%	>90%	88%	>94%
Total Results	96%	99%	99%	96%	93%	91%	>96%

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

Forty (40) clinical samples for each drug were run using each of The One Step Single Drug Test Strip 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 1,000)

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

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

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)

Benzoyllecgonine 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- Δ^9 -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)

Methylenedioxy-methamphetamine 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 2,000)

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

OPIATES (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

OXYCODONE (OXY)

Oxycodone 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	15	0	14	1	5	10
375	15	15	0	3	12	2	13
450	15	0	15	0	15	0	15

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

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

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline 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 the concentrations listed. The results are summarized below.

Drug concentration	n	AMP		AMP 300		BAR		BZO	
Cut-off Range		-	+	-	+	-	+	-	+
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	25	5	27	3	26	4
Cut-off	30	18	12	16	14	22	8	12	18
+25% Cut-off	30	1	29	4	26	7	23	3	27
+50% Cut-off	30	0	30	0	30	2	28	0	30

Drug concentration	n	COC		THC		MTD		mAMP		MDMA	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	29	1	30	0	30	0
-25% Cut-off	30	30	0	12	18	24	6	30	0	26	4
Cut-off	30	4	26	1	29	21	9	18	12	17	13
+25% Cut-off	30	0	30	1	29	2	28	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration	n	MOP		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+
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	23	7	19	11
Cut-off	30	17	13	13	17	13	17	16	14
+25% Cut-off	30	1	29	4	26	8	22	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug concentration	n	PPX		TCA	
		-	+	-	+
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
-25% Cut-off	30	24	6	22	8
Cut-off	30	17	13	12	18
+25% Cut-off	30	7	23	7	23
+50% Cut-off	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 Multi-Drug Screen Test Card at 5 minutes.

Compound	Concentration ng/mL
AMPHETAMINE (AMP 1,000)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE (AMP 300)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000

Compound	Concentration ng/mL
Tyramine	100,000
p-Hydroxynorephedrine	100,000
p-Hydroxyamphetamine	1,560
d/l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
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
Oxazepam	300
Temazepam	98
Triazolam	2,500
COCAINE (COC)	
Benzoyllecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
MARIJUANA (THC)	
11-nor-Δ ⁹ -THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ ⁹ -THC-9 COOH	30
Δ ⁸ -THC	15,000
Δ ⁹ -THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE (MET)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
(±)-3,4-Methylenedioxyamphetamine (MDA)	2,000
Mephentermine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
d,l-3,4-Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300

Compound	Concentration ng/mL
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1500
6-Monoacetylmorphine	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
OPIATES 2000 (OPI)	
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
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,562
Hydromorphone	12,500
Oxymorphone	1,562
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (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->1.035) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Multi-Drug Screen Test Card was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does 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 One Step Multi-Drug Screen Test Card. The results demonstrate that varying ranges of pH does 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, Methylenedioxyamphetamine, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with One Step Multi-Drug Screen Test Card at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine*
Bilirubin	d,l-Brompheniramine
Caffeine	Cannabidol
Chloralhydrate	Chloramphenicol
Chlorothiazide	d,l-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	l-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diflunisal	Digoxin
Diphenhydramine	Ecgonine methyl ester
l-Ephedrine	β-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine	l-Epinephrine
Erythromycin	Fenoprofen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone
o-Hydroxyhippuric acid	
p-Hydroxytyramine	Ibuprofen
lproniazid	d,l-Isoproterenol
Isosuprine	Ketamine
Ketoprofen	Labetalol
Loperamide	Meperidine
Meprobamate	Methoxyphenamine
Methylphenidate	Nalidixic acid
Naloxone	Naltrexone
Naproxen	Niacinamide
Nifedipine	Norethindrone
Noscapine	
d,l-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G
Pentazocine	Perphenazine
Phenelzine	Trans-2-phenylcyclopropylamine
l-Phenylephrine	Prednisolone
Prednisone	d,l-Propranolol
	d-Pseudoephedrine
Quinacrine	Quinine
Quindine	Ranitidine
Salicylic acid	Serotonin
Sulfamethazine	Sulindac
Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (β-D-glucuronide)	Tetrahydrozoline
Thiamine	Thioridazine
d,l-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine
Trimethoprim	Tryptamine
d,l-Tryptophan	Uric acid
Verapamil	
Zomepirac	

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

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iCup ACCURACY DATA

AMPHETAMINE (AMP) DRUG SCREEN

Accuracy: The performance of the the **iCup** amphetamine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 1,000 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 500 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iCup Test Device	Results	Positive	Negative	
	Positive	142	0	142
	Negative	9	149	158
Total Results		151	149	300

Relative Sensitivity: 94% Relative Specificity: >99% Accuracy: 97%

Note: The FDA requires on-site test devices to be accurate within +25% of the drug screen's cut-off level. The **iCup** detected 100% of the GC/MS positive specimens within 25% of the screen's 1000ng cut-off.

The only GC/MS positive specimens not identified as positive by the **iCup** were close to or below the **iCup**'s 1000 ng/ml cut-off. Specimens whose results differed between GC/MS and the **iCup** contained the following concentration levels in ng/ml: (781,862, 878, 898, 898, 1000, 1032, 1137, and 1204).

METHAMPHETAMINE (mAMP) DRUG SCREEN

Accuracy: The performance of the the **iCup** methamphetamine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 1,000 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 500 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iCup Test Device	Results	Positive	Negative	
	Positive	145	0	145
	Negative	1	154	155
Total Results		146	154	300

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

Note: The **iCup** detected 100% of the GC/MS positive specimens at or above the screen's 1000ng cut-off.

The only GC/MS positive specimen not identified as positive by the **iCup** was below the **iCup**'s 1000 ng/ml cut-off. The discrepant specimen contained d-methamphetamine at a concentration of 954 ng/ml.

MARIJUANA (THC) DRUG SCREEN

Accuracy: The performance of the the **iCup** amphetamine drug screen was compared to the laboratory initial screen and a leading commercially available marijuana rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 50 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 15 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iCup Test Device	Results	Positive	Negative	
	Positive	143	0	143
	Negative	7	150	157
Total Results		150	150	300

Relative Sensitivity: 95% Relative Specificity: >99% Accuracy: 98%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The **iCup** detected all but two of the GC/MS positive specimens within +25% of the screen's 50ng cut-off.

The only GC/MS positive specimens not identified as positive by the **iCup** were close to or below the **iCup**'s 50 ng/ml cut-off. Specimens whose results differed between the GC/MS and the **iCup** contained the following concentration levels in ng/ml: (15, 15, 16, 32, 51, 73, and 79)

iCup ACCURACY DATA

COCAINE DRUG SCREEN

Accuracy: The performance of the the *iCup* cocaine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 300 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 150 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>iCup</i> Test Device	Positive	136	0	136
	Negative	13	151	164
	Total Results	149	151	300

Relative Sensitivity: 91% Relative Specificity: >99% Accuracy: 96%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *iCup* detected all but one of the GC/MS positive specimens within 25% of the screen's 300ng cut-off.

The only GC/MS positive specimens not identified as positive by the *iCup* were close to or below the *iCup*'s 300 ng/ml cut-off. Specimens whose results differed between GC/MS and the *iCup* contained the following concentration levels in ng/ml: (153, 158, 188, 202, 228, 233, 243, 254, 265, 270, 298, 358 and 381)

OPIATES-2000 (OPI) DRUG SCREEN

Accuracy: The performance of the the *iCup* opiates drug screen was compared to the laboratory initial screen and a leading commercially available opiates rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 2,000 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 2000 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>iCup</i> Test Device	Positive	134	16	150
	Negative	0	150	150
	Total Results	134	166	300

Relative Sensitivity: >99% Relative Specificity: 90% Accuracy: 95%

Note: The *iCup* correctly identified 100% of the specimens determined to be positive by GC/MS.

The specimens identified as positive by the *iCup* but below 2000 ng/ml by GC/MS were all at or above 1500 ng/ml. Therefore the *iCup* performed at >99% accuracy within +/-25% of the screens 2000 ng/ml cut-off.

PCP DRUG SCREEN

Accuracy: The performance of the the *iCup* PCP drug screen was compared to the laboratory initial screen and a leading commercially available PCP rapid test. Testing was performed on 212 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 25 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 25 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>iCup</i> Test Device	Positive	50	5	55
	Negative	0	157	157
	Total Results	50	162	212

Relative Sensitivity: >99% Relative Specificity: 97% Accuracy: 98%

Note: The *iCup* correctly identified 100% of the specimens determined to be positive by GC/MS.

The specimens identified as positive by the *iCup* but below 25 ng/ml by GC/MS were all at or above 15 ng/ml. Therefore; the *iCup* detected 5 positive specimens that were below the 25 ng/ml GC/MS cut-off, but there were no false-positive results.

***i*Cup ACCURACY DATA**

BARBITURATES (BAR) DRUG SCREEN

Accuracy: The performance of the the *i*Cup barbiturates drug screen was compared to the laboratory initial screen and a leading commercially available barbiturates rapid test. Testing was performed on 292 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 300 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 300 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>i</i>Cup Test Device	Positive	122	4	126
	Negative	10	156	166
	Total Results	132	160	292

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *i*Cup's accuracy within 25% of the screen's 300ng cut-off was 97%

The specimens identified as positive by the *i*Cup but below 300 ng/ml by GC/MS were all at or above 218 ng/ml. Therefore; the *i*Cup detected 4 positive specimens that were below the 300 ng/ml GC/MS cut-off, but there were no false-positive results.

Relative Sensitivity: 92% Relative Specificity: 98% Accuracy: 95%

BENZODIAZEPINE (BZO) DRUG SCREEN

Accuracy: The performance of the the *i*Cup benzodiazepines drug screen was compared to the laboratory initial screen and a leading commercially available benzodiazepines rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 300 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 300 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>i</i>Cup Test Device	Positive	129	7	136
	Negative	5	159	164
	Total Results	134	166	300

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *i*Cup detected all but one of the GC/MS positive specimens within +25% of the screen's 300ng cut-off.

The only GC/MS positive specimens not identified as positive by the *i*Cup were close to or below the *i*Cup 's 300 ng/ml cut-off. Specimens whose results differed between the GC/MS and the *i*Cup contained the following concentration levels in ng/ml: (323,326, 334, 335, and 540)

The *i*Cup detected 5 positive specimens that were below the 300 ng/ml GC/MS cut-off, but there were no false-positive results.

Relative Sensitivity: 96% Relative Specificity: 96% Accuracy: 96%

METHADONE (MTD) DRUG SCREEN

Accuracy: The performance of the the *i*Cup methadone drug screen was compared to the laboratory initial screen and a leading commercially available methadone rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 300 ng/ml.** Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 200 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
Results		Positive	Negative	
<i>i</i>Cup Test Device	Positive	132	0	132
	Negative	1	167	168
	Total Results	133	167	300

Note: The *i*Cup detected >99% of the GC/MS positive specimens at +/- 25% of the screens 300 ng/ml cut-off.

The only GC/MS positive specimen not identified as positive by the *i*Cup contained methadone at a concentration of 534 ng/ml.

The *i*Cup did not detect any specimens as positive that did not confirm by GC/MS at 200 ng/ml.

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

***i*Cup ACCURACY DATA**

TRICYCLIC ANTIDEPRESSANT (TCA) DRUG SCREEN

Accuracy: The performance of the the *i*Cup TCA drug screen was compared to the laboratory initial screen and a leading commercially available TCA rapid test. Testing was performed on 200 clinical specimens. **At least ten percent of the specimens evaluated were between -25% or +25% of the cut-off concentration of 1,000 ng/ml.** Presumptive positive results were confirmed by HPLC.

When compared to HPLC at 300 ng/mL, the results are provided in the table below:

Method		HPLC		Total Results
	Results	Positive	Negative	
<i>i</i> Cup Test Device	Positive	60	0	60
	Negative	0	140	140
Total Results		60	140	200

Note: The *i*Cup correctly identified 100% of the specimens determined to be positive by GC/MS, and all specimens identified as positive by the *i*Cup were confirmed positive by HPLC at or above a 300 ng/ml concentration level.

There is no DHHS specified confirmation level for TCA

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

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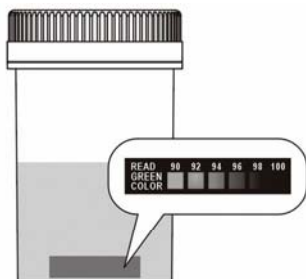
The test is based on the chemical reaction to the reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with a corresponding color chart.

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 that the sample has been “spiked” or altered.

Oxidants: Tests for the presence of many different oxidizing reagents such as bleach and Hydrogen Peroxide.

PCC: Found on the same panel as oxidants, this test panel tests for pyridinium chlorochromate (PCC). Normal urine contains no oxidants or PCC.

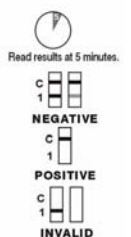
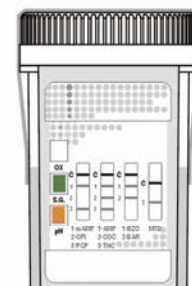
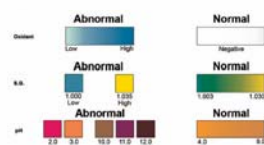
Specific Gravity: Tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range should be considered adulterated.



1. Collect and verify temperature (temp strip on back of iCup)



2. Peel labels to reveal test results



3. Check specimen validity then read test results