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Instant Technologies

One Step Multi-Drug Screen Test Card with the Integrated i Cup[®]/iCup_®^{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®AD. 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,I-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene	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®AD. 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 are excreted in the uniter in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The One Step Multi-Drug Screen Test Card with the Integrated [Cup®/ICup_e^{AD}, 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).

AMPHETAMINE (AMP 300)

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®^{AD}. yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAM NE (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 action (a.g. Secoharbital)

100 mg PO (oral)

4.5 days Long acting (e.g. Phenobarbital) 400 mg PO (oral)

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/fiCup@AD. 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

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 percention.

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® vields a positive res

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

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, Burrenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Burrenorphine 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.

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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, intransaal and inhalation routes.
The One Step Multi-Drug Screen Test Card with the Integrated iCup*/fiCup_sAD 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

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. 45 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

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®AD 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).

COCAINE (COC 150)

The One Step Multi-Drug Screen Test Card with the Integrated iCup[®]/iCup_®^{AD}. yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCA NE (COC 300) for the summary.

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-Λ⁹-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The One Step Multi-Drug Screen Test Card with the Integrated iCup ICup AD. vields 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).

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.

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

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

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® AD 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®^{AD.} 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. 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 laws.

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The One Step Multi-Orug Screen Test Card with the Integrated iCup®/iCup_®^{AD}, yields a positive result when the concentration of Methylenedioxymethamphetamine in one exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHsA) must be 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

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.

The One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® AD. 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_®^{AD} 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

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 Indegrated ICup®iCup, An 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

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 PCF

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

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[®] by yields a positive result when the concentration of Propoxyphene or Nopropoxyphene 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 metabolizes are excreted in urine mostly in the form of metabolities for up to ten days.

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_® *AD* 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

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 creating 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
 qlutaraldehyde 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®AD. 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

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

MATERIALS

Materials Provided

- One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®AD. [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
- Security seal label
- Package insert
- Procedure card

Materials Required But Not Provided

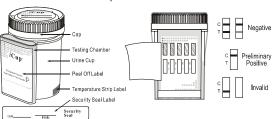
- . A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External controls

DIRECTIONS FOR USE

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

- 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.
- 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.
- Technician peels off the label on the multi-drug test card to view results.
- The adulteration strip(s), if applicable, should be read between 2-5 minutes. Compare the colors on the
 adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.
- 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.

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural

control. t confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

QUALITY CONTROL

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 Integrated iCup®/iCup®AD. 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. 1,4,3
- There is a possibility that technical or procedural errors, as well as 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.
- 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

- 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.
- 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.
- 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.
- 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.
- 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® 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, α-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-∆9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d I-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

Predicate Test Pecults % Agreement with

	Method		Predicate	rest Results	% Agreement with		
	Welliou		Positive	Negative	Predicate Test		
-	AMP 1,000	Positive	129	0	>99%		
	AIVIP 1,000	Negative	0	172	>99%		
	AMP 300	Positive	127	0	>99%		
	AIVIF 300	Negative	0	173	>99%		
One Step	BAR	Positive	126	1	>99%		
Multi-Drug	DAR	Negative	0	166	>99%		
Screen Test	BUP	Positive	*	*	*		
Card with the Integrated		Negative	*	*	*		
iCup [®] /iCup _® ^{A.D.}	BZO	Positive	131	0	>99%		
icup /icup®	BZU	Negative	1	162	>99%		
	COC 300	Positive	112	1	>99%		
	COC 300	Negative	0	186	99%		
	COC 150	Positive	141	0	>99%		
	COC 150	Negative	0	159	>99%		
	mAMP 1.000	Positive	121	0	99%		
	MAINIP 1,000	Negative	1	174	>99%		
	mAMP 500	Positive	108	39**	>99%		
	MAIVIP 500	Negative	0	153	80%		

MDMA	Positive	86	0	>95%
IVIDIVIA	Negative	4	152	>99%
MOP	Positive	125	0	95%
WIOF	Negative	7	150	>99%
MTD	Positive	120	0	89%
IVITO	Negative	18	168	>99%
OPI	Positive	131	0	98%
OFI	Negative	2	164	>99%
OXY	Positive	142	0	97%
OXI	Negative	4	154	>99%
PCP	Positive	71	0	99%
FOF	Negative	1	160	>99%
PPX	Positive	157	0	>99%
FFA	Negative	0	157	>99%
TCA	Positive	45	0	92%
TCA	Negative	4	177	>99%
THC	Positive	124	1	>99%
Inc	Negative	0	175	99%

^{*} Commercial kit unavailable for BUP

					0.00			
	ethod		1		C/MS			
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup® A.D.			Neg.	Near cutoff neg.	Near cutoff pos.	Pos.	%	
		Neg.	(< -25%	(-25% cutoff to	(cutoff to +25%	(> +25%	agreement	
			cutoff)	cutoff)	cutoff)	cutoff)	with GC/MS	
	Positive	0	1	8	18	114	97%	
1,000	Negative	149	1	5	4	0	95%	
minigrated AMP 1,000 BAR BUP BZO COC 300 THC MTD mAMP 1,000 MDMA MOP	Positive	0	0	4	5	117	92%	
5, (Negative	150	1	5	1	9	98%	
One Ster Screen Test Integrated in AMP 1,000 BAR BUP BZO COC 300 THC MTD MTD MAMP 1,000 MDMA MOP	Positive	0	0	0	5	50	98%	
ВОІ	Negative*	150	15	5	1	0	>99%	
P70	Positive	0	7	1	5	26	97%	
BZO	Negative	149	7	1	3	1	95%	
COC	Positive	0	2	15	16	103	96%	
300	Negative	150	5	7	1	1	90%	
300 THC	Positive	0	13	9	12	109	96%	
	Negative	150	6	0	0	1	97%	
	Positive	0	0	10	10	112	99%	
	Negative	150	17	0	0	1	94%	
mAMP	Positive	0	0	10	9	126	99%	
1,000	Negative	150	0	4	1	0	94%	
MDMA	Positive	0	0	3	6	82	98%	
MDMA	Negative	147	0	2	0	0	>99%	
1400	Positive	0	2	7	10	131	>99%	
WOP	Negative	150	0	0	0	0	94%	
	Positive	0	0	16	18	116	>99%	
	Negative	150	0	0	0	0	90%	
OPI -	Positive	0	0	6	10	40	>99%	
	Negative	150	6	0	0	0	97%	
	Positive	0	12	8	15	20	>99%	
*TCA	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:

M	ethod		GC/MS							
One Step Multi-Drug Screen Test Card with the Integrated iCup®/iCup®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%			
BUP	Negative	150	15	5	1	0	>99%			
PPX	Positive	0	0	2	7	158	94%			
FFA	Negative	152	5	18	10	0	99%			
AMP	Positive	0	1	1	2	123	99%			
300	Negative	150	18	5	0	0	99%			

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

M	ethod		GC/MS						
Screen Tes	p Multi-Drug at Card with the iCup [®] /iCup _® ^{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	Positive	0	0	10	131	>99%			
150	Negative	150	7	0	2	98%			
OXY	Positive	0	5	2	135	98%			
OAT	Negative	147	8	2	1	97%			

M	lethod		GC/N	IS
	p Multi-Drug			
with	reen Test Card in the Integrated Cup [®] /iCup _® ^{A.D.}	Neg.	Pos.	% agreement with GC/MS
mAMP	mAMP Positive		140	>99%
500	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[®]/iCup_® ^{AD.} 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.

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 \pm 50% and \pm 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n	n Site A		Sit	e B	Site C	
Diag Colic.	per site	-	+	-	+	-	+
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 \pm 50% and \pm 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n	Sit	e A	Sit	e B	Site	e C
Drug Conc.	per site	-	+	•	+	•	+
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 \pm 50% and \pm 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Ī	Amphetamine	n per	Site	Site A		Site B		Site C	
	conc. (ng/mL)	site	-	+	-	+	-	+	
Ī	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	
Ī	450	15	0	15	0	15	0	15	

BUPRENORPHINE (BUP)

Buprenorphine	n per	Sit	e A	Site	e B	Site	e C
conc. (ng/mL)	site	-	+	-	+	-	+
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	15	0	1	14	0	15
15	15	15	0	0	15	0	15

COCAINE (COC 150)

•	Benzoylecgonine	n per	n per Site A		Site	Site B		e C
	conc. (ng/mL)	site	-	+	-	+	-	+
	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	n per	Site A		Site B		Site C	
conc. (ng/mL)	site	-	+	-	+	-	+
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	n per	Site A		Site B		Site C	
conc. (ng/mL)	site	-	+	-	+	-	+
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)

n per	Site	e A	Site	9 B	Site	a C
site	-	+	-	+	-	+
15	15	0	15	0	15	0
15	15	0	15	0	14	1
15	10	5	8	7	7	8
15	0	15	0	15	1	14
15	0	15	0	15	0	15
	site 15 15 15 15	site - 15 15 15 15 15 10 15 0	site - + 15 15 0 15 15 0 15 10 5 15 0 15	site - + - 15 15 0 15 15 15 0 15 15 10 5 8 15 0 15 0	site - + - + 15 15 0 15 0 15 15 0 15 0 15 10 5 8 7 15 0 15 0 15	site - + - + - 15 15 0 15 0 15 15 15 0 15 0 14 15 10 5 8 7 7 15 0 15 0 15 1

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

Drug concentration Cut-	n	AMP	1,000	AMP	300	BA	AR .	BZ	ZO
off Range	l "	-	+	-	+	-	+	-	+
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	n	COC 300		COC 150		THC		MTD	
Cut-off Range	-	٠	+	٠	+	٠	+	٠	+
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-	n	mAMP	1,000	mAM	P 500	MD	MA	M	OP
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	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	_	0	PI	0)	(Y	PC	CP	PI	PX	TC	A
Cut-off Range	n	-	+	-	+	-	+	-	+	-	+
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	n	BUP			
Cut-off Range	l "	-	+		
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®/iCup_® A.D. at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,I-Amphetamine	3,000
I-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
	-
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
I-Amphetamine	50,000
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
Alphenol	150

Compound	ng/mL
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
1 Honobarottal	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
	1,562
Bromazepam	
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
THAZOIAITI	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
Norbuprenorphine 3-b-gluculonide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
	150
Benzoylecgonine	150 400
Cocaine	6,250
Cocaethylene	
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
	E0
11-nor-Δ ⁹ -THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ ⁸ -THC-9 COOH	30
∆8−THC	15,000
Δ ⁹ -THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
I-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
	•
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
а / иприскапине	50,000

Compound	ng/mL
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
I-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
	6,250
Ethylmorphine	
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 12,500
Hydrocodone	
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
BUENOVOLIDINE (BOD)	
PHENCYCLIDINE (PCP)	
Phencyclidine	
4-Hydroxyphencyclidine	25
	12,500
PROPOXYPHENE (PPX)	12,500
d-Propoxyphene	12,500
	12,500
d-Propoxyphene	12,500
d-Propoxyphene	12,500
d-Propoxyphene d-Norpropoxyphene	12,500
d-Propoxyphene d-Norpropoxyphene TRICYCLIC ANTIDEPRESSANTS (TCA)	12,500 300 300
d-Propoxyphene d-Norpropoxyphene TRICYCLIC ANTIDEPRESSANTS (TCA) Nortriptyline Nordoxepin	12,500 300 300 1,000 1,000
d-Propoxyphene d-Norpropoxyphene TRICYCLIC ANTIDEPRESSANTS (TCA) Nortriptyline Nordoxepin Trimipramine	12,500 300 300 1,000 1,000 3,000
d-Propoxyphene d-Norpropoxyphene TRICYCLIC ANTIDEPRESSANTS (TCA) Nortriptyline Nordoxepin	12,500 300 300 1,000 1,000

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® AD. 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®AD. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

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_®^{AD.} at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Creatinine d-Pseudoephedrine Acetaminophen Ketoprofen Acetophenetidin Deoxycorticosterone Labetalol Quinacrine Dextromethorphan N-Acetylprocainamide Loperamide Quinine Acetylsalicylic acid Diclofenac Meperidine Quindine Aminopyrine Diflunisal Menrohamate Rantidine* Amoxicillin Digoxin Methoxyphenamine Salicylic acid Ampicillin Diphenhydramine Methylphenidate Serotonin I-Ascorbic acid I -Ψ-Ephedrine Sulfamethazine Nalidixic acid Apomorphine Sulindac B-Estradiol Naproxen Aspartame Estrone-3-sulfate Niacinamide Tetracycline Nifedipine Tetrahydrocortisone Atropine Ethyl-p-aminobenzoate Benzilic acid I (-)-Epinephrine Norethindrone 3-acetate Benzoic acid Erythromycin Noscapine Tetrahydrocortisone d,I-Octopamine Benzphetamine³ Fenoprofen 3-(β-D-glucuronide) Bilirubin Furosemide Oxalic acid Tetrahydrozoline d.I-Brompheniramine Oxolinic acid Gentisic acid Thiamine Caffeine Thioridazine Hemoglobin Oxymetazoline Cannabidol Hydralazine Papaverine d,I-Tyrosine Chloralhydrate Hydrochlorothiazide Penicillin-G Tolbutamide Chloramphenicol Hydrocortisone Pentazocine Triamterene Chlorothiazide o-Hydroxyhippuric acid Perphenazine Trifluoperazine d,I-Chloropheniramine p-Hydroxytyramine Trimethoprim Phenelzine Chlorpromazine Ibuprofen Trans-2-phenylcyclo Tryptamine Cholesterol Iproniazid propylamine d,I-Tryptophan d,I-Isoproterenol Prednisolone Cortisone Isoxsuprine Prednisone Verapamil d,I-Propranolol Zomepirac I-Cotinine *Parent compound only

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Printed in China

Manufactured for: Instant Technologies, Inc. Norfolk, VA 23502

> DN: 1155942301 Eff. Date: 2007-08-21



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