UA:10C SVT PLUS by Labb (10-panel drug test cup)

Urine Drug Screen Spec Sheet

With optional lower opiate & hydrocodone cut-offs

This informational document is for the Labb UA:10C SVT drug test kit designed to mimic the cut-off levels as those established by the US Department of Transportation and SAMHSA[8,9]. This "Employment Use Only" EUO drug test cup is designed to screen for the following drugs: 6-Monoacetylmorphine, Methamphetamine, Cocaine, Marijuana, Morphine, Ecstasy, Oxycodone, Phencyclidine, Amphetamine, and HydroCodone / Hydromorphone..

The UA:10C SVT is a rapid, one step screening test for the simultaneous, qualitative detection of Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, Oxycodone, Phencyclidine, Hydrocodone, 6-Monoacetylmorphine, Marijuana and the metabolites in human urine.
For workplace use only.

This One Step Multi-Drug Screen Test Cup (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites at the following cut-off concentrations in urine:

Test	Calibrator	Cut-off
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Methamphetamine (MET)	D-Methamphetamine	500
Cocaine (COC)	Benzoylecgonine	150
Marijuana (THC)	ll-nor-A9-TRC-9 COOR	50
Morphine (OPI)	Morphine	2000
Ecstasy (MDMA)	D,L-3,4-Methylenedioxymethamphetamine	500
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Amphetamine (AMP)	D-Amphetamine	500
Rydromorphone (HMO)	Hydromorphone	300

The following details can be found on the US Government website listed below:
https://www.transportation.gov/odapc/part40/40-87
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DOT Rule 49 CFR Part 40 Section 40.87; subpart F outlines the cut-off requirements for initial screenings and allowable adjustments.

For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

R1 - Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be **80 percent or greater**; if not, separate immunoassays must be used for the analytes within the group.

R2 - Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

R3 - (2)An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

R4 - (3)Alternate technology (THCA and Benzoylecgonine): When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100 ng/mL for Benzoylecgonine).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.
(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, August 16, 2010; 77 FR 26473, May 4, 2012; 82 FR 52244, November 13, 2017]

Last updated: Wednesday, April 15, 2020

Drug Analyte	DOT Requirement	Corresponding Assay	Initial Screen Requirement
Phencyclidine	25 ng/mL	PCP25	R1
Marijuana (THCA)	50 ng/mL	THC50	R 1&3
Benzoylecgonine	150 ng/mL	COC150	R1
Morphine/Codeine[8] Target = 200% cross-reactivity	2000 ng/mL	OPI 2000	R1
Hydrocodone/Hydromorphone	300 ng/mL	HMO 300	R1
Oxycodone/Oxymorphone[9] Target = 92% cross-reactivity	100 ng/mL	HMO 300	R1
6-Acetylmorphine	10 ng/mL	6AM 10	R1
Amphetamine	500 ng/mL	AMP 500	R1
Methamphetamine	500 ng/mL	MET 500	R1
MDMA/MDA	500 ng/mL	MDMA 500	R 1,5.4, 5.5

Labb UAD:10C SVT cut-offs as completed to DOT requirements

[8] Specimens containing Codeine in concentrations between 1000 ng/mL to 1999 ng/mL may have a slightly higher rate of negative confirmation than other assays.

[9] Specimens that contain Oxymorphone in concentrations between 25 to 99 or Oxymorphone-d in concentrations between 98 ng/mL - 99 ng/mL may have a slightly higher rate of negative confirmation than other assays.

This test will detect other related compounds, please refer to the Analytical Specificity table in this informational document. 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 used.

6-MONOACETYLMORPHINE (6-MAM)

-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

METHAMPHETAMINE (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects ofMethamphetamine 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 ofMethamphetamine 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 delaminated derivatives. However, 10-20% ofMethamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine. 1.2 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. 2

MARIJUANA (THC)

THC (8.9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes l -nor-A9-tetrahydrocannabinol-9-carboxylic acid (A9-TRC-COOR). of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana 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 ll -nor-A9-tetrahydrocannabinol-9-carboxylic acid (A9-TRC-COOR).

MORPHINE (MOP)

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 dependence 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.4

MDMA (ECSTASY)

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 ofMDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

OXYCODONE (OXY)

Oxycodone,
[4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR® , OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin® , has a longer duration of action (8-12 hours).

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 19501s. 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, user1s age, weight, activity, and diet. 5 Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

HYDROMORPHONE (HMO)

Hydromorphone, also known as dihydromorphinone, is a centrally acting pain medication of the opioid class. It is made from. morphine. It works by changing the way the brain and nervous system respond to pain. Hydromorphone extended-release tablets are used to relieve severe pain in people who are expected to need pain medication around the clock for a long time and who cannot be treated with other medications. Hydromorphone extended-release tablets should only be used to treat people who are tolerant (used to the effects of the medication) to opioid medications because they have taken this type of medication for at least one week and should not be used to treat mild or moderate pain, short-term pain. pain after an operation or medical or dental procedure, or pain that can be controlled by medication that is taken as needed.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.

Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
Specific Gravity (S.G): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
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 below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

PRINCIPLE

(1) The One Step Multi-Drug Screen Test Cup (Urine) 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.
(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:
CffiCHiOH + 02 Al ' 0h o l °"="™=' ---> CffiCHO + HiO,
Hi02+ DH, Peroxidase —- D+2Hi0

REAGENTS

Each test line in the test cup contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

Reactive indicator pad	Calibrator	Non-reactive ingredients
Oxydants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
pHencyclidine (PCP)	0.06%	99.94%

PRECAUTIONS

- For workplace and insurance 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 local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30° C). The Test Cup is stable through the expiration date printed on the sealed pouch. The Test Cup must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

WHEN TO COLLECT URINE FOR THE TEST?
The minimum detection time is 2-7 hours, so you may collect urine samples 2-7 hours after suspected drug use.

HOW TO COLLECT URINE?

SPECIMEN COLLECTION AND PREPARATION

1. Urinate directly into the provided urine cup.
2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.
3. The residual urine sample in the urine cup is for your self-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.

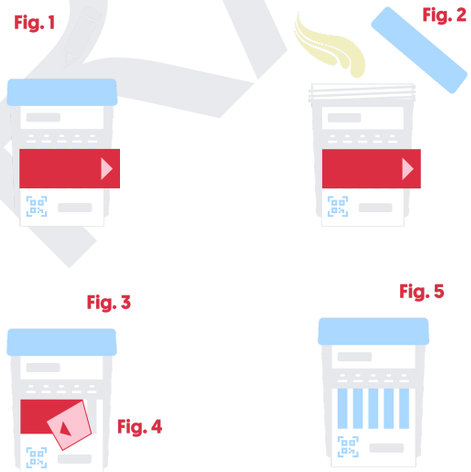
MATERIALS

- Test Cup
- Disposable gloves
- Color Chart Card for Alcohol
- Package Insert
- Procedure card
- Desiccant

- Timer (Not provided)
- Labb Station app (Not provided)

DIRECTIONS FOR USE

Allow the test cup to come to room temperature [15-30° C (59-86° F)] prior to test.
1) Tear the foil bag open, remove the test cup and disposable gloves provided for the donor. Label the device with donor information. (Fig. 1)



2) Open the test cup lid. Urinate directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30ml to maximum 110ml. (Fig. 2)
3) Close the lid securely and place the cup on a flat surface. Start the timer. (Fig. 3)
4) Put on the glove provided. Peel off label to reveal test result.(Fig. 4)
5) Read the adulteration strip at 2 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret or scan the drug test results. Either retest the urine or collect another specimen from the donor.
6) Read the drug strip results after 5 minutes. DO NOT INTERPRET RESULT OR SCAN AFTER 10 MINUTES. (Fig. 5)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level
*NOTE: The shade of red in the test line region (Drug(f) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drugtr). 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.
Note: There is no meaning attributed to line color intensity or width.
A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others. IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?
The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Urine Test. The most common causes of a false positive test are cross reactants.

Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?
The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Urine Test. If the sample is diluted, or the sample is adulterated that may cause false negative results.

ADULTERANT INTERPRETATION

(Please refer to the color chart)

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

I. The One Step Multi-Drug Screen Test Cup (Urine) 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.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when a drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

80 clinical urine specimens were analyzed by GC-MS and by the One Step Multi-Drug Screen Test Cup (Urine). Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the One Step Multi-Drug Screen Test Cup (Urine) at 5 minutes.

6-Monoacetylmorphine	
6-Monoacetylmorphine	**10**
Oxymorphone	>100,000
Oxycodone	>100,000
Codeine	>600,000
Norcodine	>100,000
Naltrexone	>100,000
Morphine	>500,000
Heroin HCL	250
Hydrocodone	>100,000
Hydromorphone	>100,000

Methamphetamine 500	
d-Methamphetamine	**500**
L-Methamphetamine	4,000
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)(-)-Ephedrine	50,000
3,4-methylenedioxymethamphetamine(MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine(MDEA)	20,000
Procaine (Novocaine	50,000
Trimethobenzamide	20,000

Cocaine 150	
Benzoylecgonine	**150**
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000

Morphine / Opiates 2000	
Morphine	**2,000**
Codeine	1,000
Ethylmorphine	250
Hydrocodone	5,000
Hydromorphone	2,500

Heroin	5,000
6-Acetylmorphine	2,500
Oxycodone	75,000

Marijuana 50	
11-nor-Δ9-THC-9-COOH	**50**
11-nor-Δ8-THC-9-COOH	**50**
Δ8- Tetrahydrocannabinol	15,000
Δ9- Tetrahydrocannabinol	50,000
Δ8- THC-COOH	50,000

Ecstasy 500	
3,4-Methylenedioxy-methamphetamine (MDMA)	**500**
D-Amphetamine	>100,000
3,4-methylenedioxy-amphetamine (MDA)	3,000
3,4-Methylenedioxy-ethylamphetamine (MDEA)	300
d-Methamphetamine	2,500
6-Methamphetamine	>100,000
l-Amphetamine	>100,000
l-Methamphetamine	>100,000

Oxycodone 100	
Oxycodone	**100**
Hydrocodone	5,000
Hydromorphone	5,000
Oxymorphone	200

Phencyclidine 25	
Phencyclidine	**25**
4-Hydroxy Phencyclidine	90

Amphetamine 500	
D-Amphetamine	**500**
L-Amphetamine	16,000
D,L-Amphetamine	750
Methylenedioxy-amphetamine (MDA)	800
d-Methamphetamine	>100,000
l-Methamphetamine	>100,000
Methylenedioxy-methamphetamine (MDMA)	>100,000
ephedrine	>100,000

Hydromorphone 300	
Hydromorphone	**300**
Hydrocodone	**300**
Gatifloxacin	6,250
Procaine	25,000
Morphine	12,500
Codeine Phosphate	12,500
Heroin	3,125
Oxymorphone-D3	97.65
Dihydrocodeine	25,000
Diacetyl Morphine	10,000
Codeine	6,250
Oxymorphone	24.4
6-acetylmorphine	50,000
Ethylmorphine	25,000

PRECISION

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Drug Conc. (Cut-off range)	AMP 500		COC 150		MET 500		MDMA		MOP 2000	
	-	+	-	+	-	+	-	+	-	+
0% Cut-Off	50	0	50	0	50	0	50	0	50	0
-75% Cut-Off	50	0	50	0	50	0	50	0	50	0
-50% Cut-Off	50	0	50	0	50	0	50	0	50	0
-25% Cut-Off	50	0	50	0	50	0	50	0	50	0
Cut-Off	32	18	31	19	25	25	30	20	20	30
125% Cut-Off	0	50	0	50	0	50	0	50	0	50
150% Cut-Off	0	50	0	50	0	50	0	50	0	50
175% Cut-Off	0	50	0	50	0	50	0	50	0	50
200% Cut-Off	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	HMO 300		6-AM 10		OXY 100		PCP 25		THC 50	
	-	+	-	+	-	+	-	+	-	+
0% Cut-Off	50	0	50	0	50	0	50	0	50	0
-75% Cut-Off	50	0	50	0	50	0	50	0	50	0
-50% Cut-Off	50	0	50	0	50	0	50	0	50	0
-25% Cut-Off	50	0	50	0	50	0	50	0	50	0
Cut-Off	23	27	23	27	16	34	16	34	25	25
125% Cut-Off	5	45	5	45	0	50	0	50	0	50
150% Cut-Off	0	50	0	50	0	50	0	50	0	50

175% Cut-Off	0	50	0	50	0	50	0	50	0	50
200% Cut-Off	0	50	0	50	0	50	0	50	0	50

EFFECTS OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The One Step Multi-drug Screen Test Cup (Urine) was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The One Step Multi-Drug Screen Test Cup (Urine). 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 Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Kratom, Methaqualone, Methadone, Fentanyl, Tramado, Ethyl Glucuronide, Cotinine, Hydrocodone, Hydromorphone, 6-Monoacetylrnorphine, Methylenedioxy-pyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the One Step Multi-Drug Screen Test Cup (Urine) at a concentration of 100 µg/mL.

NON CROSS-REACTING COMPOUNDS

ACETOPHENETIDIN	CORTISONE	MEPROBAMATE
N-ACETYLPROCAINAMIDE	CREATININE	NAPROXEN
ACETYLSALICYLIC ACID	DEXAMETHASONE	NIACINAMIDE
AMILORIDE	DEXTROMETHORPHAN	NOSCAPINE
AMOXICILLIN	DIFLUNISAL	OCTOPAMINE
AMPICILLIN	DIGOXIN	PHENELZINE
L-ASCORBIC ACID	ETHOPROPAZINE	PREDNISONE
APOMORPHINE	FENOPROFEN	PRILOCAINE
ASPARTAME	GENTISIC ACID	QUINIDINE
BENZILIC ACID	HEMOGLOBIN	QUININE
P-AMINOBENZOIC ACID	HYDROCORTISONE	SALICYLIC ACID
BILIRUBIN	ISOXSUPRINE	SEROTONIN
CAFFEINE	PSEUDOEPHEDRINE	TETRAHYDROCORTISONE
CANNABIDIOL	KYNURENIC ACID	THIAMINE
CHOLESTEROL	LABETALOL	URIC ACID
CLONIDINE	LOPERAMIDE	ZOMEPIRAC

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This is not the official package insert for the UA:10B SVT. This is an informational document that includes some information that is not included in the package insert. This document is exclusively for the UA:10Csvt.

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