

Data Sheet - UA:10Csvt

Panels: 12 panel
Alcohol: No
SVT Strip: Yes

Drug names: Direct Read
Opiates: Dual levels
Product Use: Employment Only
Package Insert B22624-03

SECTION 01

Product Overview

The UA:10C rapid drug screen by Labb is a urine point-of-care drug screen that is designed to meets Official DOT look-alike requirements. This screen includes the same 14 drugs mandated by DOT SAMHSA certified laboratorys panels along with 2 optional add-on assays. The UA:10C detects substances like Marijuana, Cocaine, Amphetamine, Methamphetamine, MDMA/MDA, Morphine, Codeine, Hydrocodone, Hydromorphone, Oxycodone, Oxymorphone, 6-MAM, and PCP.

The UA:10C meets or surpasses each of the SAMHSA required screening levels for DOT testing on all 14 drugs & analytes, ensuring accurate detection. The UA:10C should be used in conjunction with certified laboratory confirmation programs to ensure reliable results. The UA:10C provides outcomes substantially equivalent to standard laboratory testing.

This Data Sheet is not a package insert. It is important to note that only the package insert can be used to determine precise product performance. The package insert is located in the box along with the 25 UA:10C urine drug screen cups. The information contained in this Data Sheet may be outdated.

IMPORTANT: Always refer to the product's official package insert located in box along with 25 rapid drug test cups.

SECTION 02

Rapid DOT Look-Alike

The UA:10C is an 12 panel rapid drug screen that includes 10 assays designed to mimic the DOT drugs & cut-off levels. The UA:10C, when used in conjunction with the Labb Station app can be customized to generate a DOT-look-alike drug screen result.

The UA:10C is one of two Labb brand drug tests that is able to detect the same analytes as a DOT screen at or below the corresponding cut-off levels for all drugs. It is for this reason that the UA:10C scored 28 out of a possible 28 on Labb's DOT look-alike scoring system.

The UA:10C also includes additional drugs not associated with DOT-look-alike panel such as a low cut-off level opiate & synthetic opiate assays such as Morphine 300 & Hydrocodone 10.

Drug Analyte	DOT Requirement	UA:10C assay used	Drug & Level Match?
Phencyclidine	25 ng/mL	PCP 25	Yes - Yes
Marijuana (THCA)	50 ng/mL	THC 50	Yes - Yes
Benzoylecgonine	150 ng/mL	COC 150	Yes - Yes
Morphine Codeine	2000 ng/mL 2000 ng/mL	OP2K 2000 OP2K 2000	Yes - Yes Yes - Yes
Hydrocodone Hydromorphone	300 ng/mL 300 ng/mL	HMO 300 HMO 300	Yes - Yes Yes - Yes
Oxycodone Oxymorphone	100 ng/mL 100 ng/mL	OXY 100 HMO 300	Yes - Yes Yes - Yes
6-Acetylmorphine	10 ng/mL	6AM 10	Yes - Yes
Amphetamine	500 ng/mL	AMP 500	Yes - Yes
Methamphetamine	500 ng/mL	MET 500	Yes - Yes
MDMA MDA	500 ng/mL 500 ng/mL	MDMA 500 AMP 500	Yes - Yes Yes - Yes

UA:10C DOT Look-alike alignment chart - (https://www.labb.com/dot-look-alike-scale

<u>IMPORTANT</u>: This UA:10C drug test must be used in conjunction with a Labb Station reader to be considered a DOT-look-alike rapid drug test solution.

NOTE: This UA:10C is not an offical DOT drug test nor can it be used on conjunction with or as part of any Federally regulated testing programs including, but not limited to DOT (Department of Transportation) or any other regulatory agency.

SECTION 03

Drugs & Detection Levels

UA:10C drug test is designed to detect the following drugs and/or metabolites at the following concentration levels.

6-MONOACETYLMORPHINE (6-MAM) - Drug 1

6-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.

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

AMPHETAMINE (AMP) - Drug 2

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.

Amphetamine 500	
D-Amphetamine	500
D,L-Amphetamine	500
Methylenedioxy-amphetamine (MDA)	200
L-Amphetamine	25,000
4-Hydroxyamphetamine HCL	300
Diethylstihestrol	2,500
Phentermine	4,000

COCAINE (COC) - Drug 3

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.

Cocaine 150	
Benzoylecgonine	150
Cocaethylene	150
CocaineHCL	150

HYDROMORPHONE (HMO) - Drug 4

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.

HYDROMORPHONE (HMO)	
Hydromorphone	300
Ranitidine	50,000
Gatifloxacin	6,250
Procaine	25,000
Morphine	12,500
Coteine Phosphate	12,500
Heroin	3,125
Naltrexone hydrochloride	781
Dihydrocodeine HCL	1,526
Hydrocodone	195
Oxymorphone-D3	97.65
Codeine	6,250

Heroin Hydromorphone	6,250
Oxymorphone	24.4
6-acetylmorphine	50,000

HYDROCODONE - Low Level (HCD) - Drug 5

Hydrocodone is used to treat moderate to severe pain, although it is often prescribed to treat mild pain as well. In liquid formulations, it is used as an antitussive to treat cough. In one study comparing the potency of hydrocodone to that of oxycodone, it was found that it took 50% more hydrocodone to achieve the same degree of miosis (pupillary contraction). The investigators interpreted this to mean that oxycodone is about 50% more potent than hydrocodone.

However, in a study of emergency department patients with fractures, it was found that an equal amount of either drug provided about the same degree of pain relief, indicating that there is little practical difference between them when used for that purpose. Some references state that the analgesic action of hydrocodone begins in 20-30 minutes and lasts about 4-8 hours. The manufacturer's information says onset of action is about 10-30 minutes and duration is about 4-6 hours. Recommended dosing interval is 4-6 hours.

HYDROCODONE (HCD)	
Hydrocodone	10
Dihydrocodeine HCL	312.5
EthylMorphine	10,000
Hydromorphone	2,500
Levorphanol	10,000
Oxymorphone-D3	10,000
Codeine	2,500

MARIJUANA (THC) - Drug 6

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 I

-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 II -nor-A9-tetrahydrocannabinol-9-carboxylic acid (A9-TRC-COOR).

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

METHAMPHETAMINE (MET) - Drug 7

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 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 delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

Methamphetamine 500

d-Methamphetamine	500
Methamphetamine	500
3,4-methylenedioxymethamphetamine(MDMA)	1,250
3,4-Methylenedioxymethamphetamine(MDEA)	10,000
Fenfluramine	25,000
p-Hydroxymethamphetamine	5,000

ECSTASY (MDMA) - Drug 8

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.

Ecstasy 500	
3,4-Methylenedioxy-methamphetami ne (MDMA)	500
D-Amphetamine	>100,000
3,4-methylenedioxy-amphetamine (MDA)	3,000
3,4-Methylenedioxy-ethylamphetamine (MDEA)	300
I-Methamphetamine	100,000

MORPHINE - High Level (OP2K) - Drug 9

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.

Morphine 2000	
Morphine	2,000
Codeine	1,000
Ethylmorphine	250
Hydrocodone	50,000
Hydromorphone	2,500
Heroin	5,000
6-Acetylmorphine	2,500
Oxycodone	75,000

MORPHINE - Low Level (OP300) - Drug 10

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

MORPHINE (I	MOP 300)
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Morphine	300
O6-Acetylmorphine	400
Codeine	300
Dihydrocodeine HCI	1,000
EthylMorphine	100
Heroin	600
Hydromorphone	10,000
Hydrocodone	10,000
Levorphanol tartrate	10,000
Morphine-3-β-D-glucuronide	1,000
Nalorphine HCI	50,000
Thebaine	6,240

OXYCODONE (OXY) - Drug 11

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).

Oxycodone 100	
Oxycodone	100
Hydrocodone	5,000

Hydromorphone	5,000
Oxymorphone	200

PHENCYCLIDINE (PCP) - Drug 11

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%).

Phencyclidine 25	
Phencyclidine	25
4-Hydroxy Phencyclidine	90

SECTION 04

Adulteration SVT

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.

SECTION 05

Collecting a Specimen

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.

SECTION 06

Download Labb Station

The Labb Station platform is a proprietary software technology developed by Labb to make rapid drug testing simple, accurate, & more reliable than traditional point of care tests. To open an account for Labb Station you must be a professional drug testing facility, clinic, occupational health facility, and/or manage an in-house workplace drug testing program with a minimum of 25 tests a month.

If you are already a Labb Station client, you may download and use the Labb Station mobile app found on the Apple iOS app store and the Android Google Play store.

To download on the Applie iOS app store:



Visit https://apps.apple.com/us/app/id1542054233



Visit

https://play.google.com/store/apps/details?id=systems.smartscreens.smartReader.v3.production&hl=en_US&gl=US

SECTION 07

Labb.com

Labb offers a variety of drug testing products and services. The UA Series rapid drug screen is just on of many drug testing options available by Labb.



The Labb Station mobile app, tablet readers, and UA Series rapid drug screens are manufactured for Labb. Labb is a Virginia corporation located at:



Labb

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