UScreen+ Oral Cube
Instructions For Use

For Forensic Use Only

Instructions For Use: Instructions for testing oral fluid for any combination of the following drugs:
Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Codeine, Cotinine, Ecstasy, EDDP, Fentanyl, Heroin (6-MAM), Ketamine, Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone (MDPV), Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Synthetic Cannabinoid (K2), Tramadol, Tricyclic Antidepressants and Alcohol.

This device has various combinations. Please refer to product labeling for exact drug panels and cutoffs.

INTENDED USE

The UScreen+ Oral Cube is intended for screening for the presence of drugs and alcohol and their metabolites in oral fluid.

The UScreen+ Oral Cube is a lateral flow chromatographic immunoassay for the qualitative and simultaneous detection of drugs and drug metabolites in human oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	25/50
Barbiturate (BAR)	Secobarbital	20/50/300
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine (BUP)	Buprenorphine	5/10
Cocaine (COC)	Benzoylecgonine	10/20/50
Codeine (COD)	Codeine	10
Cotinine (COT)	Cotinine	30/50
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	30/50
Fentanyl (FEN)	Fentanyl	5
Fentanyl (NFYL)	Norfentanyl	5/10
Heroin (6-MAM)	6-Monoacetylmorphine	10/15
Ketamine (KET)	Ketamine	50/100
Lysergic acid diethylamide (LSD)	d-Lysergic acid diethylamide	25
Marijuana Metabolite (THC)	11-nor-Δ^9-THC-9 COOH	3/8/12
Marijuana (THC)	Δ^9-THC	25/40/50
Methadone Metabolite (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Methadone (MTD)	Methadone	30/75
Methamphetamine (MET)	D-Methamphetamine	25/50
Methaqualone (MQL)	Methaqualone	100/150
Methylenedioxypyrovalerone (MDPV)	Methylenedioxypyrovalerone	50/100
Morphine (MOP)	Morphine	15
Opiates (OPI)	Morphine	10/40
Oxycodone (OXY)	Oxycodone	10/20/50
Phencyclidine (PCP)	Phencyclidine	5/10
Propoxyphene (PPX)	Propoxyphene	50
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	5/25
Tramadol (TRA)	Tramadol	35/50
Tricyclic Antidepressants (TCA)	Nortriptyline	100
Alcohol (ALC)	Alcohol	> 0.02 % B.A.C

This test will detect other related compounds and metabolites, please refer to the Analytical Specificity table in these Instructions For Use.

SUMMARY

AMP: Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion.[1]

BAR: Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets.

BZO: Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. Benzodiazepines are taken orally or by intramuscular or intravenous injection and are extensively oxidized in the liver to metabolites. Benzodiazepines can be detected in oral fluid after use.

BUP: Buprenorphine is a semisynthetic opioid analgesic derived from thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (*Erythroxylum coca*).[1]

COD: Codeine is an opiate used to treat pain, as a cough medicine, and for diarrhea. It is typically used to treat mild to moderate degrees of pain. Greater benefit may occur when combined with paracetamol (acetaminophen) or a nonsteroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen. Evidence does not support its use for acute cough suppression in children or adults. In Europe it is not recommended as a cough medicine in those under twelve years of age. It is generally taken by mouth. It typically starts working after half an hour with maximum effect at two hours. The total duration of its effects last for about four to six hours.

COT: Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

MDMA: MDMA is an abbreviation for the chemical methylenedioxymethamphetamine. It has street many name including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, etc. It is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. It is detectible in the saliva for up to 3 days after use.

FEN: Fentanyl, belongs to powerful narcotics analgesics, and is a special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations “Single Convention of narcotic drug in 1961”. Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain.[1] After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc.[2,3]

KET: Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug.

LSD: D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram.

THC: Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations).[2]

EDDP: EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is formed by N-demethylation and cyclization of methadone in the liver. The detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient’s metabolism are avoided.

MTD: Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. In addition to use as a narcotic agonist, methadone is being used more frequently as a pain management agent. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Based on the saliva/plasma ratio calculated over salivary pH ranges of 6.4-7.6 for therapeutic or recreational doses of methadone.

MET: Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion.[1]

MQL: Methaqualone is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form and is also available in Europe on countries in combination with diphenhydramine (Mandrax).

MDPV: “Bath salts”, a form of designer drugs, also promoted as ‘plant food’ or ‘research chemicals’ and is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a ‘legal’ high. The technical term for ‘bath salts’ is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. The white crystals resemble legal bathing salts, thus the name of ‘bath salts’.

6-MAM: 6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excrete. Since 6-MAM is a unique metabolite to heroin, its presence in the saliva confirms that heroin was the opioid used. This is significant because on a saliva 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 sulfate, and heroin.

OPI: The drug class opiates refer to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates control pain by depressing the CNS and demonstrate addictive properties when used for sustained periods of time. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation.[3]

*The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Morphine is detectable for several days after a dose.

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. The approximate half- life in serum is averaged about 14 hours.

PCP: Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.[5]

PPX: Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours).

K2: Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice. As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid

receptors. JWH-073 has been identified in numerous herbal products, such as “Spice”, “K2”, K3” and others. These products may be smoked for their psychoactive effects.

TRA: Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine but has a low binding affinity to themuopioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2]

TCA: TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver.

ALC: Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (20 mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

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) and Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

(1) The UScreen+ Oral Cube is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a portion of the oral fluid specimen migrates along the test strip by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. A procedural control, will appear as colored line 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 the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3\overset{H}{\underset{|}{C}}=O + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_2O$$

Blue

REAGENTS

(1)The UScreen+ Oral Cube contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol oxidase, Peroxidase, Buffer and Stabilizing Proteins.

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not reuse the test
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.
- Safety data sheets are available upon request

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected by the collection swab provided within the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this test. Oral fluid collected at any time of the day may be used. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8°C or -20°C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8°C). Perform testing immediately after collection.

MATERIALS

Materials Provided

- Test cubes
- Saliva collectors
- Color chart card for alcohol (when applicable)
- Security seal labels
- Instructions For Use
- Procedure card

Materials Required but Not Provided

- Timer
- Gloves

DIRECTIONS FOR USE

Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

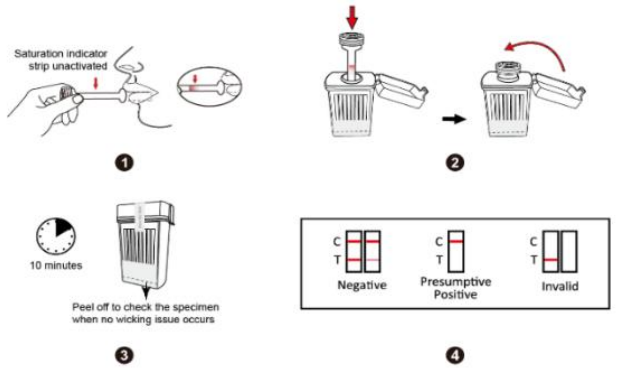
   Remove the collection swab from packaging. Start Timer. Relax the mouth and insert the collection swab into the mouth. The collection swab must be horizontal throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum until a red color on the saturation indicator strip appears in the indicator window of collection swab.

   Important: Do not bite, suck or chew on the collection swab. It is critical that the collection swab is held horizontally during collection otherwise there will be insufficient saliva collected although the indicator turns red. During collection of the oral fluid, relax the mouth while swabbing the tongue and cheek as this will aid in the collection of the oral fluid.

   Note: Refer to Notes and Troubleshooting if the saturation indicator strip does not activate after 4 minutes. If after 7 minutes, color has not appeared, proceed with the test below. (See illustration 1)
2. Remove test device from sealed pouch and place upright on a clean, flat surface. **Gently and slowly** insert the collection swab into the test device, sponge first, until it reaches the bottom of the test device. Push the cap until it locks in place and is secure. (See illustration 2)

   Important: Keep test device upright while inserting collection swab. Once the collection swab is locked in place, the test device is airtight, tamper evident and ready to be shipped to a lab for confirmation if required. Alternatively, the test device can be disposed of.
3. Keep test device upright on a flat surface until the test is complete. Start timer. **Important:** If any test strips do not develop (invalid), peel away bottom of device label to inspect specimen volume. Refer to Notes and Troubleshooting.
4. Interpret results at 10 minutes.

   If positive results are observed, apply the security seal label from cap down to sides of the device, then send the device to a laboratory for confirmation. The laboratory can access the reservoir through the Sample Port.



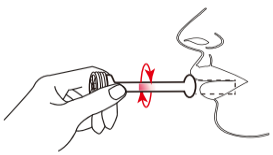
NOTES AND TROUBLESHOOTING

1. Invalid results may occur, if the strips do not wick, peel off the label at the bottom of the device as marked to check if either there is enough specimen, or the oral fluid is too thick or viscous to run.

a.) If strips do not appear to flow when there is enough oral fluid, or the oral fluid is too thick to run move the device back and forth several times across a flat, clean surface. Ensure the device remains upright. Do not tilt the device when the test is running before reading results.

b.) Oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running. Gently tap the device on the table or counter surface popping the air bubble allowing capillary action to begin, thus initiating the test.

2. The indicator strip has not turned red after 4 minutes. Some donors may have a dry mouth. Nerves may contribute to this. Rotate the swab in a circular motion while swabbing each area of the oral cavity until the saturation indicator activates. (See illustration 3)



NTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) indicates a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

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

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line (C) 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 device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream colored); it should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color, but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be

interpreted as being negative (no alcohol present).

Alcohol Presumptive Positive Result: The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02% B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

QUALITY CONTROL

The colored line appearing in the control region (C) is considered the internal procedural control. It confirms sufficient specimen volume and adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The UScreen+ Oral Cube 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) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
3. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
4. A negative result may not necessarily indicate a drug-free specimen. Drug(s) may be present in the specimen below the cut-off level of the test.
5. The test does not distinguish between drugs of abuse and certain medications.
6. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and tested with the UScreen+ Oral Cube. The results are summarized below.

Drug Conc. (Cut-off range)	AMP25		AMP50		BAR20		BAR50		BAR300		BZO10		BZO50	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	BUP 5		BUP 10		COC10		COC20		COC50		COD10		COT30	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	COT 50		MDMA30		MDMA50		FEN5		NFYL 5		NFYL10		KET50	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	1	29	0	30	0	30

Drug Conc. (Cut-off range)	KET100		LSD25		THC3		THC8		THC 12		THC 25		THC 40	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	1	29	0	30

Drug Conc. (Cut-off range)	THC 50		EDDP20		MTD30		MTD75		MET25		MET50		MQL100	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	MQL150		MDPV50		MDPV100		6-MAM 10		6-MAM 15		MOP15		OP110	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	OPI40		OXY10		OXY 20		OXY 50		PCP5		PCP10		PPX50	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	K2 5		K2 25		TRA35		TRA50		TCA100	
	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the UScreen+ Oral Cube identified positive results at 10 minutes.

Drug Compound	Concentration (ng/mL)
AMPHETAMINE (AMP25)	
d-Amphetamine	25
Phentermine	60,000
R (-)-Amphetamine	5,000
(±)-Amphetamine	25
Serotonin	100,000
Octopamine	20,000
(±)-Phenylpropanolamine hydrochloride	50,000
Tryptamine	1,500
AMPHETAMINE (AMP50)	
d-Amphetamine	50
Phentermine	120,000
R (-)-Amphetamine	10,000
(±)-Amphetamine	50
Serotonin	500,000
Octopamine	60,000
(±)-Phenylpropanolamine hydrochloride	100,000
Tryptamine	1,500
BARBITURATE (BAR20)	
Secobarbital	20
Amobarbital	50
Alphenal	50
Aprobarbital	15
Butabarbital	10
Butalbital	200
Butethal	15
Cyclopentobarbital	25
Pentobarbital	40
Phenobarbital	20
BARBITURATE (BAR50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30

Drug Compound	Concentration (ng/mL)
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	30
BARBITURATE (BAR300)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO10)	
Oxazepam	10
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
α-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
BENZODIAZEPINES (BZO50)	
Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	125
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1,000
(±)-Lorazepam	1,000

Drug Compound	Concentration (ng/mL)
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1,000
Nordiazepam	125
Temazepam	30
Triazolam	125
BUPRENORPHINE (BUP5)	
Buprenorphine	5
Norbuprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Buprenorphine Glucuronide	20
BUPRENORPHINE (BUP10)	
Buprenorphine	10
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	20
Buprenorphine Glucuronide	10
COCAINE (COC10)	
Benzoylecgonine	10
Cocaine	15
Cocaethylene	15
Ecgonine	1,200
Ecgonine methyl ester	10,000
N-Acetylprocainamide	10,000
Norcocaine	2,000
COCAINE (COC20)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methyl ester	12,500
N-Acetylprocainamide	12,500
Norcocaine	500
COCAINE (COC50)	
Benzoylecgonine	50
Cocaine	50
Cocaethylene	60
Ecgonine	2,500
Ecgonine methyl ester	25,000
N-Acetylprocainamide	25,000
Norcocaine	1,250
CODEINE (COD10)	
Codeine	10
Ranitidine	6,250
Heroin	30
Dihydrocodeine HCL	15
Ethyl Morphine	10
Hydrocodone	62.5
Hydromorphone	31.25
Levorphanol	250

Drug Compound	Concentration (ng/mL)
6-acetylmorphine	25
Nalorphine	1,562.5
Normorphine	6,250
Norcodeine	2,000
COTININE (COT30)	
(-) Cotinine	30
S(-)-Nicotine	3,000
Flephedrone(4-fluoromethcathinone)	50,000
N-Benzylisopropylamine	5,000
COTININE (COT50)	
(-) Cotinine	50
S(-)-Nicotine	5,000
Flephedrone(4-fluoromethcathinone)	80,000
N-Benzylisopropylamine	8,000
ECSTASY (MDMA30)	
3,4-Methylenedioxymethamphetamine	30
Butylone HCl	2,000
Ephedrine HCL	10,000
Ethylone	1,000
Phentermine	5,000
l-Methamphetamine	800
Methylone HCL	20,000
3,4-Methylenedioxyamphetamine (MDA)	400
3,4-Methylenedioxyethylampheta mine (MDEA)	50
(1R,2S)- (-)-Ephedrine	2,000
ECSTASY (MDMA50)	
3,4-Methylenedioxymethamphetamine	50
Butylone HCl	6,250
Ephedrine HCL	12,500
Ethylone	12,500
Phentermine	12,500
l-Methamphetamine	1,562.5
Methylone HCL	50,000
3,4-Methylenedioxyamphetamine (MDA)	781.25
3,4-Methylenedioxyethylampheta mine (MDEA)	97.7
(1R,2S)- (-)-Ephedrine	3,125
FENTANYL (FEN 5)	
Fentanyl	5
Carfentanil	2,000
Sufentanil Citrate	250
Cyclopropyl fentanyl	250
Furanyl Fentanyl	250
p-Fluorobutyryl fentanyl (PFBF)	2,500
4-Fluoro-isobutyryl fentanyl	60
o-Fluorofentanyl	50
2'-Fluoro ortho-Fluorofenyanyl	80
Valeryl Fentanyl	80
Remifentanil HCl	2,500
(±)-β-Hydroxythiofentanyl	1,000
Tetrahydrofuranyl fentanyl	60

Drug Compound	Concentration (ng/mL)
2-Thiofuranyl fentanyl	5,000
Methoxyacetyl fentanyl	80
Acetyl norfentanyl oxalate	250
Norcarfentanil oxalate	50
4-methoxybutyryl fentanyl(para)	1,250
Acetyl-α-methyl fentanyl	1,250
4'-methyl acetyl fentanyl	250
Benzyl fentanyl	10
meta-methoxy Furanyl fentanyl	2,500
α-methyl fentanyl	1,250
para-Fluorofentanyl	80
Ocfentanil	80
Isobutyryl fentanyl HCl	80
Butyryl fentanyl	500
Acetyl fentanyl	500
Acryl fentanyl HCl	80
Sufentanil-D5	2,500
Norbuprenorphine	30,000
FENTANYL (NFYL 5)	
Norfentanyl	5
Fentanyl	10
Buspirone	2,500
FENTANYL (NFYL 10)	
Norfentanyl	10
Fentanyl	20
Buspirone	12,500
HEROIN (6-MAM10)	
6-Monoacetylmorphine (6-MAM)	10
Codeine	>600,000
Morphine	>550,000
Heroin	250
Diethylstilbestrol	70,000
Trimethoprim	50,000
HEROIN (6-MAM15)	
6-Monoacetylmorphine (6-MAM)	15
Codeine	>600,000
Morphine	>600,000
Heroin	250
Diethylstilbestrol	75,000
Trimethoprim	52,000
KETAMINE (KET50)	
Ketamine	50
Norketamine	500
Dextrolphorphan	25
Dextrolphantartratrate	25
D-Norpropxyphene	1,560
KETAMINE (KET100)	
Ketamine	100
Norketamine	1,000
Dextrolphorphan	70

Drug Compound	Concentration (ng/mL)
Dextrolphantartratrate	70
D-Norpropxyphene	3,000
LYSERGIC ACID DIETHYLAMIDE (LSD25)	
D-lysergic acid diethylamide	25
Fentanyl	40
Norfentanyl	150
Risperidone	4,000
Prilocaine	8,000
MARIJUANA (THC3)	
11-nor-Δ^9-THC-9 COOH	3
Cannabinol	7,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	5,000
Δ^9-THC	4,500
MARIJUANA (THC8)	
11-nor-Δ^9-THC-9 COOH	8
Cannabinol	10,000
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	5,000
Δ^9-THC	10,000
MARIJUANA (THC12)	
11-nor-Δ^9-THC-9 COOH	12
Cannabinol	31,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	20,000
MARIJUANA (THC25)	
Δ^9-Tetrahydrocannabinol	25
Δ^8-Tetrahydrocannabinol	50
11-nor-Δ^9-THC-9 COOH	3
11-hydroxy-Δ^9-THC	28
Cannabinol	125
Cannabidiol (CBD)	1,400
11-Nor-Δ^9-THC-carboxy-glucuronide	40
(+)-11-nor-9-carboxy-Δ^9-THC	30
11-nor-Δ^8-THC-9-COOH	12
8-beta-11-dihydroxy-Δ^9-THC	125
8-beta-hydroxy-Δ^9-THC	125
Exo-THC	50
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	10
Δ^8-THC Carboxylic Acid	12
Δ^9-THC Carboxylic Acid	2
MARIJUANA (THC40)	
Δ^9-Tetrahydrocannabinol	40
Δ^8-Tetrahydrocannabinol	80
11-nor-Δ^9-THC-9 COOH	4
11-hydroxy-Δ^9-THC	45
Cannabinol	200
Cannabidiol (CBD)	2,200
11-Nor-Δ^9-THC-carboxy-glucuronide	60
(+)-11-nor-9-carboxy-Δ^9-THC	50

Drug Compound	Concentration (ng/mL)
11-nor-Δ^8-THC-9-COOH	20
8-beta-11-dihydroxy-Δ^9-THC	200
8-beta-hydroxy-Δ^9-THC	200
Exo-THC	75
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	15
Δ^8-THC Carboxylic Acid	20
Δ^9-THC Carboxylic Acid	4
MARIJUANA (THC50)	
Δ^9-Tetrahydrocannabinol	50
Δ^8-Tetrahydrocannabinol	100
11-nor-Δ^9-THC-9 COOH	5
11-hydroxy-Δ^9-THC	55
Cannabinol	250
Cannabidiol (CBD)	2,800
11-Nor-Δ^9-THC-carboxy-glucuronide	75
(+)-11-nor-9-carboxy-Δ^9-THC	60
11-nor-Δ^8-THC-9-COOH	25
8-beta-11-dihydroxy-Δ^9-THC	250
8-beta-hydroxy-Δ^9-THC	250
Exo-THC	100
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	20
Δ^8-THC Carboxylic Acid	25
Δ^9-THC Carboxylic Acid	4
EDDP (EDDP20)	
EDDP	20
Meperidine	20,000
Methadone	20,000
Norfentanyl	20,000
Phencyclidine	20,000
Promazine	10,000
Promethazine	5,000
Prothipendyl	10,000
Prozine	2,500
METHADONE (MTD30)	
Methadone	30
Promethazine	30,000
PCP(Phencyclidine)	5,000
Levorphanol	10,000
Disopyramide	1,000
METHADONE (MTD75)	
Methadone	75
Promethazine	39,000
PCP(Phencyclidine)	6,500
Levorphanol	13,000
Disopyramide	1,300
METHAMPHETAMINE (MET25)	
d-Methamphetamine	25
Fenfluramine	30,000
p-Hydroxymethamphetamine	100

Drug Compound	Concentration (ng/mL)
Methoxyphenamine	15,000
3,4-Methylenedioxymethamphetamine (MDMA)	25
l-Phenylephrine	2,000
Procaine	1,500
(1R,2S)- (-) Ephedrine	200
1-Ephedrine	200
Mephentermine	400
(-) Deoxyephedrine	2,000
Ephedrine	200
4-Methylethcathinone hydrochloride	12,000
Ethylone hydrochloride	12,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	50
(+/-)-Methylenedioxyamphetamine(MDA)	12,000
D,L-Methamphetamine	1,000
(±)-Amphetamine	5,000
Acetylsalicylic	2,000
Chlorothiazide	12,000
R(-)-Methamphetamine	400
METHAMPHETAMINE (MET50)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)- (-) Ephedrine	400
1-Ephedrine	400
Mephentermine	800
(-) Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
4-Methylethcathinone hydrochloride	25,000
Ethylone hydrochloride	25,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	100
(+/-)-Methylenedioxyamphetamine(MDA)	25,000
D,L-Methamphetamine	4,000
(±)-Amphetamine	10,000
Acetylsalicylic	4,000
Chlorothiazide	25,000
R(-)-Methamphetamine	400
METHAQUALONE (MQL100)	
Methaqualone	100
METHAQUALONE (MQL150)	
Methaqualone	150
METHYLENEDIOXYPYROVALERONE (MDPV50)	
Methylenedioxypyrovalerone	50
Butylone	4,000
Ethylone	50
Methylone	11,000
Brompheniramine	800
Methedrone	5,000
Naphyrone	>100,000

Drug Compound	Concentration (ng/mL)
Flephedrone	>100,000
METHYLENEDIOXYPYROVALERONE (MDPV100)	
Methylenedioxypyrovalerone	100
Butylone	5,000
Ethylone	50
Methylone	10,000
Brompheniramine	1,000
Methedrone	5,000
Naphyrone	>100,000
Flephedrone	>100,000
MORPHINE (MOP15)	
Morphine	15
Codeine	15
Ethyl morphine	15
Hydromorphone	50
Hydrocodone	50
Morphine 3-β-d-glucuronide	30
Nalorphine	300
Oxymorphone	25,000
Thebaine	5,000
Diacetylmorphine (Heroin)	15
6-Monoacetylmorphine (6-MAM)	15
Oxycodone	12,500
OPIATE (OPI10)	
Morphine	10
Codeine	10
Ethyl morphine	10
Hydromorphone	40
Hydrocodone	40
Morphine 3-β-d-glucuronide	20
Nalorphine	156
Oxymorphone	1,000
Thebaine	2,000
Diacetylmorphine (Heroin)	10
6-Monoacetylmorphine (6-MAM)	10
Oxycodone	6,250
OPIATE (OPI40)	
Morphine	40
Codeine	10
Ethyl morphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-d-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500

Drug Compound	Concentration (ng/mL)
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
OXYCODONE (OXY10)	
Oxycodone	10
Dihydrocodeine HCL	1,500
Gatifloxacin	12,500
Hydrocodone	800
Hydromorphone	400
Heroin	6,000
Oxymorphone-D3	25
Oxymorphone	1,500
OXYCODONE (OXY20)	
Oxycodone	20
Dihydrocodeine HCL	3,125
Gatifloxacin	25,000
Hydrocodone	1,562.5
Hydromorphone	781.25
Heroin	12,500
Oxymorphone-D3	390.6
Oxymorphone	48.8
Naltrexone hydrochloride	3,125
OXYCODONE (OXY50)	
Oxycodone	50
Dihydrocodeine HCL	6,250
Gatifloxacin	60,000
Hydrocodone	6,250
Hydromorphone	1,562
Heroin	25,000
Oxymorphone-D3	781
Oxymorphone	100
Naltrexone hydrochloride	6,250
PHENCYCLIDINE (PCP5)	
Phencyclidine	5
Tetrahydrozoline	25,000
PHENCYCLIDINE (PCP10)	
Phencyclidine	10
Tetrahydrozoline	50,000
PROPOXYPHENE (PPX50)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
SYNTHETIC CANNABINOID (K2 (5))	
JWH-018 5-Pentanoic acid metabolite	5
JWH-073 4-butanoic acid metabolite	5
JWH-250 4-Hydroxypentyl metabolite	25,000
JWH-210 5-Hydroxypentyl metabolite	50,000
JWH-073 4-Hydroxybutyl metabolite	250
JWH-019 5-hydroxyhexyl metabolite	5,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	500
JWH-019 6-Hydroxyhexyl	700

Drug Compound	Concentration (ng/mL)
JWH-019 5-Hydroxyhexyl	400
MAM2201	40,000
JWH-122 5-Hydroxypentyl metabolite	700
APINACA 5-hydroxypentyl metabolite	50,000
SYNTHETIC CANNABINOID (K2 (25))	
JWH-018 5-Pentanoic acid metabolite	25
JWH-073 4-butanoic acid metabolite	25
JWH-250 4-Hydroxypentyl metabolite	50,000
JWH-210 5-Hydroxypentyl metabolite	9,000
JWH-073 4-Hydroxybutyl metabolite	250
JWH-019 5-hydroxyhexyl metabolite	800
JWH-018 N-(4-hydroxypentyl) metabolite solution	600
JWH-019 6-Hydroxyhexyl	125
JWH-019 5-Hydroxyhexyl	1,000
MAM2201	50,000
JWH-122 5-Hydroxypentyl metabolite	1,000
APINACA 5-hydroxypentyl metabolite	50,000
JWH-122 4-Hydroxypentyl metabolite	3,500
TRAMADOL (TRA35)	
Tramadol	35
N-desmethyltramadol	200
O-desmethyltramadol	10,000
TRAMADOL (TRA50)	
Tramadol	50
N-desmethyltramadol	260
O-desmethyltramadol	12,000
TRICYCLIC ANTIDEPRESSANTS (TCA100)	
Nortriptyline	100
Amitriptyline	250
Clomipramine	5,000
Desipramine	20
Doxepin	30
Imipramine	2,000
Maprotiline	10,000
Nordoxepin	1,500
Promazine	6,000
Promethazine	500
Trimipramine	5,000
Cyclobenzaprine Hydrochloride	500
Norclomipramine	5,000

Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

Interference Compounds

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the UScreen+ Oral Cube when tested at concentrations up to 100 μg/mL.

Non-interfering Compounds Tables

Acetaminophen	Diclofenac	Loperamide	d-Pseudoephedrine
Acetophenetidin	Dicyclomine	Meprobamate	Quinacrine
Acetylsalicylic acid	Diflunisal	Methylphenidate	Quinine
Aminopyrine	Digoxin	Nalidixic acid	Quindine
Amoxicillin	Diphenhydramine	Naproxen	Ranitidine
Ampicillin	β-Estradiol	Niacinamide	Salicylic acid
Amitriptyline	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Ascorbic acid	l-Epinephrine	Nimesulide	Sulindac
Apomorphine	Erythromycin	Norethindrone	Tetracycline
Aspartame	Fenoprofen	Noscapine	Tetrahydrocortisone
Atropine	Furosemide	d,l-Octopamine	3-acetate
Benzilic acid	Gentisic acid	Oxalic acid	Tetrahydrocortisone
Benzoic acid	Hemoglobin	Oxolinic acid	3 (β-d-glucuronide)
Benzphetamine	Hydralazine	Oxymetazoline	Theophylline
Caffeine	Hydrochlorothiazide	Papaverine	Thiamine
Chloral hydrate	Hydrocortisone	Penicillin-G	Thioridazine
Chloramphenicol	o-Hydroxyhippuric acid	Pentazocine	d,l-Tyrosine
Chlorothiazide	βHydroxynorephedrine	Perphenazine	Tolbutamide
d,l-Chlorpheniramine	5-Hydroxytryptamine	Phenelzine	Trazodone
Chlorpromazine	(Serotonin)	Trans-2-phenylcyclo-	Triamterene
Chloroquine	3-Hydroxytyramine	propylamine	Trifluoperazine
Cholesterol	Ibuprofen	Phentermine	Trimethoprim
Clonidine	Iproniazid	Phenylpropanolamine	l-Tryptophan
Cortisone	(-)Isoproterenol	Prednisolone	Tyramine
Creatinine	Isoxsuprine	Phenolbarbital	Uric acid
Deoxycorticosterone	Ketoprofen	Prednisone	Verapamil
Dextromethorphan	Labetalol	d,l-Propranolol	Zomepirac

Alcohol Test

The following substances may interfere with the UScreen+ Oral Cube when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers

(2) Agents which inhibit color development:

Reducing Agents: such as Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanalics and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyldopa, L-dopa, L-methyldopa, and Methampyrone, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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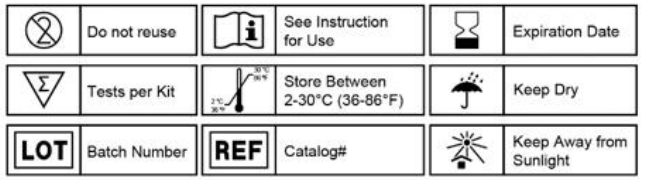
INDEX OF SYMBOLS



ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number 800-644-4145 (9:00 a.m. to 5 p.m. CDT).

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Revised Date：2025-01-02