Package insert for the AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2 test for oral fluids. A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Synthetic Cannabinoid, and their metabolites in human oral fluid.

# For Forensic Use Only

## INTENDED USE

First Sign® Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2 is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Synthetic Cannabinoid, and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off				
Amphetamine (AMP)	D-Amphetamine	50 ng/mL				
Methamphetamine (mAMP)	D-Methamphetamine	50 ng/mL				
Cocaine (COC)	Benzoylecgonine	20 ng/mL				
Opiate (OPI)	Morphine	40 ng/mL				
Marijuana (THC)	11-nor-Δ <sup>9</sup> -THC-9-COOH	12 ng/mL				
Manjuana (THC)	Δ <sup>9</sup> -THC	75 ng/mL				
Phencyclidine (PCP)	Phencyclidine	10 ng/mL				
Benzodiazepines (BZO)	Oxazepam	50 ng/mL				
Oxycodone (OXY)	Oxycodone	50 ng/mL				
Methadone (MTD)	Methadone	75 ng/mL				
Barbiturates (BAR)	Secobarbital	300 ng/mL				
Buprenorphine (BUP)	Buprenorphine	10 ng/mL				
Cotinine (COT)	Cotinine	30 ng/mL				
Synthetic Cannabinoid (K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	20 ng/mL				

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 gas chromatography/tandem mass spectrometry (GC/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. For Forensic Use Only" does not apply to any workplace testing or other non-law enforcement testing, regardless of whether or not that testing is conducted under other federal agency (e.g., Department of Transportation) authority.

## SUMMARY AND EXPLANATION OF THE TEST

Fluid Drug AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2 and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

### AMPHETAMINE (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, Amphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use1

The Amphetamine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

#### METHAMPHETAMINE (mAMP)

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. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after

The Methamphetamine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Methamphetamine concentration in oral fluid exceeds 50 ng/mL.

#### COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use<sup>1</sup>. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use1

The Cocaine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Benzoylecgonine concentration in oral fluid exceeds 20 ng/mL.

#### OPIATE (OPI)

The drug class opiates refers 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. Opiate act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. 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. Using an immunoassay cut-off level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose<sup>2</sup>. 6monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiate assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Morphine concentration in oral fluid exceeds 40 ng/mL.

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in saliva 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) and the subsequent sequestering of the drug in the buccal cavity<sup>3</sup>. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use<sup>3</sup>

The Marijuana assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the 11-nor- $\Delta^9$ -THC-9-COOH concentration in oral fluid exceeds 12 ng/mL.

The Marijuana assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Δ9-THC concentration in oral fluid exceeds 50 ng/mL

The Marijuana assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Δ9-THC concentration in oral fluid exceeds 75 ng/mL

#### PHENCYCLIDINE (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL<sup>4</sup>

The Phencyclidine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Phencyclidine concentration in oral fluids exceeds 10 ng/mL.

# BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

The Benzodiazepines assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Oxazepam concentration in oral fluids exceeds 50 ng/mL.

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

The Oxycodone assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Oxycodone concentration in oral fluid exceeds 50 ng/mL.

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists<sup>5</sup>.

The Methadone assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Methadone concentration in oral fluids exceeds 75 ng/mL.

## BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days5

The Barbiturates assay contained within the First Sign® Oral Fluid Drug Screen Device vields a positive result when the Secobarbital concentration in oral fluid exceeds 300 ng/mL.

### **BUPRENORPHINE (BUP)**

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCI. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The Buprenorphine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Buprenorphine concentration in oral fluid exceeds 10 ng/mL.

Cotinine ((5S)-1-methyl-5-(3-pyridyl)pyrrolidin-2-one) is a first-stage metabolite of nicotine, an alkaloid that stimulates the autonomic ganglia and central nervous system in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. Aside from tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. Once converted from Nicotine, Cotinine has an in vivo half-life in human body for approximately 20 hours, and is typically detectable for several days and up to one week after the use of tobacco. The level of cotinine in the blood, urine or saliva is proportionate to the amount of exposure to tobacco smoke. Cotinine, therefore, is a valuable indicator of tobacco smoke exposure, including secondary or passive smoke. People who smoke menthol cigarettes may retain cotinine in the blood for a longer period because menthol can compete with enzymatic metabolism of cotinine<sup>7</sup>. Genetic encoding of liver enzymes may also play a role, as people of African descent routinely register higher blood cotinine levels than Caucasians8, Cotinine levels <10 ng/mL are considered to be consistent with no active smoking. Values of 10 ng/mL to 100 ng/mL are associated with light smoking or moderate passive exposure, and levels above 300 ng/mL are seen in heavy smokers who smoke more than 20 cigarettes a day. Values between 11 ng/mL and 30 ng/mL may be associated with light smoking or passive exposure, and levels in active smokers typically reach 500 ng/mL or more. Cotinine assays provide an objective quantitative measure that is more reliable than smoking histories or counting the number of Cotinine also permits the measurement of exposure to second-hand smoke or passive smoking. Various types of drug tests can detect cotinine in the blood, urine, or saliva. Cotinine level in saliva has been found to be the best marker for smoking status compared with saliva nicotine measurements, breath carbon monoxide testing and plasma thiocyanate testing 9.

The Cotinine assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the Cotinine concentration in oral fluid exceeds 30 ng/mL.

## SYNTHETIC CANNABINOID (K2)

Synthetic Cannabinoid is a hallucinogen found as a mixture of herbs and spices that is typically sprayed with a synthetic compound chemically similar to THC, the psychoactive ingredient in marijuana. Since 2004, it has been sold in Switzerland. Austria, Germany and other European countries via internet shops without age restriction. attracting younger people. It is typically sold in small bags of dried leaves, resembling potpourri, and smoked in joints or pipes. Its psychological effects are similar to those of marijuana and include paranoia, panic attacks and giddiness. K2 can also cause an increased heart rate and increase of blood pressure. It appears to be stored in the body for long periods of time and the long-term effects on humans are not fully known.

The Synthetic Cannabinoid assay contained within the First Sign® Oral Fluid Drug Screen Device yields a positive result when the concentration of JWH-018 Pentanoic Acid and JWH-073 Butanoic Acid in oral fluid exceeds 20 ng/mL.

First Sign® Oral Fluid Drug Screen Device AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2 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 upward 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.

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.

#### REAGENT

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, Marijuana, Phencyclidine, Oxazepam, Oxycodone, Methadone, Secobarbital, Buprenorphine, Cotinine and Synthetic Cannabinoid.

### **PRECAUTIONS**

- · For Forensic Use Only.
- · Do not use after the expiration date.
- The oral fluid drug screen device should remain in the sealed pouch until use.
- · Saliva is not classified as biological hazard unless derived from a dental procedure.
- The test device is for single use.
- · The used collector and device should be discarded according to federal, state and local regulations.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices 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 using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

### MATERIALS

· Procedure card

Materials Provided

Test devices
 Package insert

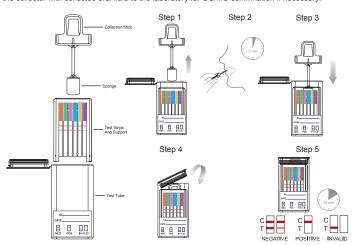
Materials Required But Not Provided

• Timer

# DIRECTIONS FOR USE

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

- 1. Remove the collection stick and test tube from the sealed pouch.
- 2. Tear off the package of the collection stick. (Step 1)
- 3. Insert the sponge end of the collection stick into mouth and soak sponge into saliva for 3 minutes. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.) (Step 2)
- 4. Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
- 5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step
- Read results of alcohol test at 2 minutes and drug tests at 10 minutes. (If there is a label over reading window, peel off the label to read test results.) Do not read alcohol test result after 5 minutes and drug tests results after 1 hour. (Step 5)
- 7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.



#### INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

#### NEGATIVE:

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

### POSITIVE:

One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

### INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

#### QUALITY CONTROL

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

### LIMITATIONS

- The First Sign® Oral Fluid Drug Screen Device 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 gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
- 2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the assay.

## PERFORMANCE CHARACTERISTICS

#### Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of  $\pm$  50% cut-off and  $\pm$  25% cut-off and tested with the *First Sign*® *Oral Fluid Drug Screen Device*. The results are summarized below.

Drug Concentration	n	Al	MP	mA	MP	CO	OC	0	PI	TI	HC	PI	CP	B2	20	0)	(Y	M	TD	B/	٩R	BI	JP	CO	OT	K	(2
Cut-off Range		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	- 1	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	29	1	30	0	27	3	27	3	30	0	28	2	28	2	29	1	29	1	27	3	29	1	29	1
Cut-off	30	13	17	16	14	19	11	18	12	14	16	20	10	13	17	12	18	10	20	12	18	16	14	20	10	21	9
+25% Cut-off	30	4	36	7	23	5	25	3	37	1	29	7	23	4	26	3	27	2	28	3	27	7	23	7	23	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	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 *First Sign® Oral Fluid Drug Screen Device* for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2 identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
β-Phenylethylamine	4,000
(+)3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
Tyramine	1,000
_	
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S)-(-)-Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE (COC)	
Benzoylecgonine	20
Cocaine HCI	20
Cocaethylene	25
Ecgonine HCI	1,500
Ecgonine Methyl Ester	12,500

OPIATE (OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
	100
Hydromorphone	
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
DUENCYCLIDINE (DCD)	
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
·	
BENZODIAZEPINES (BZO)	
	1,260
α-Hydroxyalprazolam	
Alprazolam	40
Bromazepam	400
Chlordiazepoxide	780
Chlordiazepoxide HCl	390
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam Glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	50
Oxazepam Temazepam	50
Temazepam	20
Temazepam Triazolam	20
Temazepam Triazolam OXYCODONE (OXY)	20 2,500
Temazepam Triazolam	20 2,500 50
Temazepam Triazolam OXYCODONE (OXY) Oxycodone	20 2,500 50
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine	20 2,500 50 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine	20 2,500 50 25,000 6,250
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine	20 2,500 50 25,000 6,250 12,500
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone	20 2,500 50 25,000 6,250 12,500 1,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone	20 2,500 50 25,000 6,250 12,500 1,000 6,250
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone	20 2,500 50 25,000 6,250 12,500 1,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydrocodone Oxymorphone Oxymorphone	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone	20 2,500 50 25,000 6,250 12,500 1,000 6,250
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydrocorphone Oxymorphone Thebaine  MARIJUANA (THC)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ <sup>9</sup> -THC-9-COOH	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydrocorphone Oxymorphone Thebaine  MARIJUANA (THC)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol  Δ³-THC	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 21 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 21 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC Δ³-THC METHADONE (MTD)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC  METHADONE (MTD) Methadone	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC  METHADONE (MTD) Methadone	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC Δ³-THC METHADONE (MTD)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC  METHADONE (MTD) Methadone Doxylamine	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC Δβ-THC METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydrocomphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75 75 75 12,500
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR)	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC Δ9 -THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital	20 2,500 50 25,000 6,250 12,500 1,000 6,250 1,000 25,000 12 3,000 75 75 75 12,500
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Aprobarbital	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  12 3,000 75 75 75 75 12,500  150 300 200
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Butabarbital	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  12 3,000 75 75 75 75 12,500  150 300 200 75
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC Δ9 -THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Aprobarbital Butabarbital Butabarbital Butabarbital Butabarbital	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  112 3,000 75 75 75 12,500  150 300 200 75 2,500
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC Δ9-THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Aprobarbital Butalbital Butalbital Butethal	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  12 3,000 75 75 75 12,500  150 300 200 75 2,500 100
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³ -THC-9-COOH Cannabinol Δ³ -THC Δ³ -THC Δ9 -THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Aprobarbital Butabarbital Butabarbital Butabarbital Butabarbital	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  112 3,000 75 75 75 12,500  150 300 200 75 2,500
Temazepam Triazolam  OXYCODONE (OXY) Oxycodone Codeine Dihydrocodeine Ethylmorphine Hydrocodone Hydromorphone Oxymorphone Thebaine  MARIJUANA (THC) 11-nor-Δ³-THC-9-COOH Cannabinol Δ³-THC Δ³-THC Δ9-THC  METHADONE (MTD) Methadone Doxylamine  BARBITURATES (BAR) Alphenol Amobarbital Aprobarbital Butalbital Butalbital Butethal	20 2,500  50 25,000 6,250 12,500 1,000 6,250 1,000 25,000  12 3,000 75 75 75 12,500  150 300 200 75 2,500 100

Secobarbital	300
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine 3-D-Glucuronide	200
COTININE (COT)	
(-)-Cotinine	30
S-(-)-Nicotine	6,250
L-Glutathione Reduced	40,000
SYNTHETIC CANNABINOID (K2)	
JWH-018 5-Pentanoic Acid Metabolite	20
JWH-073 4-Butanoic Acid Metabolite	20
MAM2201 N-Pentanoic Acid Metabolite	200
JWH-398 N-Pentanoic Acid Metabolite	400
JWH-210 N-(5-Carboxypentyl) Metabolite	2,500
JWH-073 3-Hydroxybutyl Metabolite	2,500
JWH-018 N-4-Hydroxypentyl	8,000
JWH-073 4-Hydroxybutyl Metabolite	40,000
JWH-019 5-Hydroxyhexyl Metabolite	40,000
JWH-018 5-Hydroxypentyl Metabolite	45,000
JWH-122 5-Hydroxypentyl Metabolite	50,000
JWH-122 4-Hydroxypentyl Metabolite	50,000
JWH-019 6-Hydroxyhexyl Metabolite	50,000
RCS-4 N-(5-Carboxypentyl) Metabolite	50,000
Trifluoperazine Dihydrochloride	50,000
Trifluoperazine Hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000

### INTERFERENCE

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 First Sign® Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL

Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are: \*Parent compound only:

Labetalol

Loperamide

DL-Chlorpheniramine Chlorpromazine Meperidine Methylphenidate Chloroquine Chlorothiazide Nalidixic Acid Norethindrone Naloxone D-Norpropoxyphene Naltrexone Naproxen Noscapine DL-Octopamine Niacinamide Creatinine Nifedipine Deoxycorticosterone Oxalic Acid Oxolinic Acid Dextromethorphan Diclofenac Oxymetazoline Diflunisal Papaverine Penicillin-G Diaoxin Diphenhydramine Pentazocine Hydrochloride L-Ψ-Ephedrine Perphenazine **β-Estradiol** Phenelzine . Estrone-3-Sulfate Trans-2-Phenylcyclopropylamine Hydrochloride

L-(-)-Epinephrine Prednisolone Erythromycin Prednisone Fenoprofen Furosemide Gentisic Acid Hemoglobin Quinacrine Hydralazine Quinine Hydrochlorothiazide Quinidine Hydrocortisone Ranitidine o-Hydroxyhippuric Acid Salicylic Acid p-Hydroxytyramine Serotonin Ibuprofen Iproniazid Sulindac DL-Isoproterenol

Chlorothiazide

Ethyl-p-Aminobenzoate

Isoxsuprine

Ketamine

Ketoprofen

DL-Propranolol D-Propoxyphene D-Pseudoenhedrine Sulfamethazine Tetracycline Tetrahydrocortisone 3-Acetate Tetrahydrocortisone 3 (β-D-Glucuronide)

Phenylpropanolamine

Thioridazine DL-Tyrosine Tolbutamide Triamterene Trifluoperazine Trimethoprim DL-Tryptophan Uric Acid Verapamil Zomepirac

Cotinine Non-Cross-Reacting Compounds Are:

\*Parent compound only:

Acetaminophen Acetophenetidin Sulindac N-Acetylprocainamide Acetylsalicylic Acid Thiamine Amoxicillin Amphetamine Sulfate Ampicillin L-Ascorbic Acid Apomorphine Aspartame Atropine Tyramine Cholesterol Uric Acid Clonidine Verapamil Codeine Zomepirac Cortisone Benzovlecgonine Benzoic Acid

Benzphetamine Chloramphenicol

Chlorothiazide Chlorpromazine Chloroquine Cocaine Hydrochloride

Norethindrone D-Norpropoxyphene Noscapine DL-Octopamine Creatinine Dextromethorphan Diflunisal

Caffeine

Digoxin L-Ψ-Ephedrine β-Estradiol Estrone-3-Sulfate Ethyl-p-Aminobenzoate L-(-)-Epinephrine Erythromycin Fenoprofen Furosemide Gentisic Acid Hemoglobin Heroin

Hydralazine Hydrochlorothiazide Hydrocortisone Ibuprofen Isoxsuprine Ketamine Labetalol Loperamide

Methadone Methamphetamine Meperidine Menrohamate Methylphenidate Morphine Nalidixic Acid Naloxone Naltrexone Naproxen

Niacinamide Oxymetazoline Papaverine Penicillin-G Perphenazine Phencyclidine

Phenylpropanolamine Prednisolone Prednisone DL-Propranolol D-Propoxyphene D-Pseudoephedrine

Phenelzine Hydrochloride

Quinacrine Quinine Oxycodone Ranitidine Secobarbital Salicylic Acid Serotonin

Sulfamethazine Tetracycline Thioridazine DL-Tyrosine Tolbutamide Trifluoperazine Trimethoprim DL-Tryptophan

Synthetic Cannabinoid

Non-Cross-Reacting Compounds Are:

\*Parent compound only:

Acepromazine-d6 Hydrochloride Acetylcysteine Effervescent Tablets

Acetaminophen o6-Acetylmorphine Acetazolamide Tablets N-Acetylprocainamide Acetone

Acetophenetidin Alprenolol Hydrochloride Alprazolam

Allopurinol Tablets Alphenal

Amiloride Hydrochloride Tablets Amiodarone Hydrochloride Tablets

Amoxicillin Capsule Ampicillin Caps (Ampicinine)

Amitriptyline Hydrochloride Tablets Aminophylline Tablets

Amantadine Hydrochloride Tablets

Amphotericin B Ammonium Chloride Amobarbital Amphetamine Sulfate Amikacin Hydrate Amikacin Sulfate Injection 4-Aminobenzoic Acid DL-Aminoglutethimide Aniline Hydrochloride

Antipyrine Aprobarbital Aspartame L-Ascorbic Acid L-Aspartic Acid D-Aspartic Acid DL-Aspartic Acid Atropine Sulfate Injection **Baclofen Tablets** Benzphetamine Barbituric Acid

Betamethasone Injection

Berberine Hydrochloride Tablets Benzilic Acid

Benzocaine Benzyl alcohol Benzoylecgonine Bendroflumethiazide Benzylamine Hydrochloride

Benzoic Acid

Bisacodyl

Bromazepam

Bromocriptine Mesylate Tablets

Bupivacaine Hydrochloride

Buprenorphine

Buspirone Hydrochloride Butacaine

Butalbital Butabarbital

Butyrophenone Butethal

Cannabidiol Caffeine

Carbamazepine Tablets

Carisoprodol Cefaclor

Cefradine Capsules

Ceftriaxone Sodium for Injection

Cefotaxime Sodium for Injection

Cefoxitin

Cefadroxil Capsule

Cephradine

Chlordiazepoxide HCL Chloroquine Phosphate

Chlorpheniramine Maleate Tablets

Chlorpromazine Hydrochloride Tablets

Chlorpropamide

Chlorprothixene Hydrochloride

Chlorthalidone

Chlorzoxazone Tablets

Cimetidine (Tablets)

(-)-Cinchonidine

Cinoxacin

Ciclosporin Soft Capsule Citric acid

Clenbuterol Hydrochloride

Clindamycin

Clobetasone Butyrate

Clomipramine Hydrochloride Tablets Clorazepate Dipotassium

Kanamycin Sulfate

2,4,6-Trmethylbezamide

Triflupromazine Hydrochloride

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