Oral Fluid Drug Screen Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The ***STAT™ Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates 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
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12 ng/mL
	Δ^9-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

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.

SUMMARY AND EXPLANATION OF THE TEST

The ***STAT™ Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR 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 selfadministered 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 use[1].

The Amphetamine assay contained within the ***STAT™ 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 use[1].

The Methamphetamine assay contained within the ***STAT™ 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 to 24 hours after use[1].
The Cocaine assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the cocaine metabolite 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. Opiates 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 cutoff 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[2]. 6-monoacetylmorphine (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 Opiates assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the concentration of Morphine in oral fluid exceeds the 40 ng/mL cut-off level.

MARIJUANA (THC)
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[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

The Marijuana assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the 11-nor-Δ^9-THC-9 COOH concentration exceeds 12 ng/mL.

The Marijuana assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the Δ^9-THC concentration 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[4].

The Phencyclidine assay contained within the ***STAT™ 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 ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the concentration of Oxazepam in oral fluids exceeds 50 ng/mL.

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

The Oxycodone assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the concentration of oxycodone in oral fluid exceeds 50 ng/mL.

METHADONE(MTD)
Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists[5].

TheMethadone assay contained within the ***STAT™ 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 death.
Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.
The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days[5]

The Barbiturates assay contained within the ***STAT™ Oral Fluid Drug Screen Device*** yields a positive result when the Barbiturates concentration in oral fluid exceeds 300 ng/mL.

PRINCIPLE

The ***STAT™ Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR 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.

REAGENTS

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 and Barbiturates.

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.

STORAGTE 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.

PN: Y0311113901

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

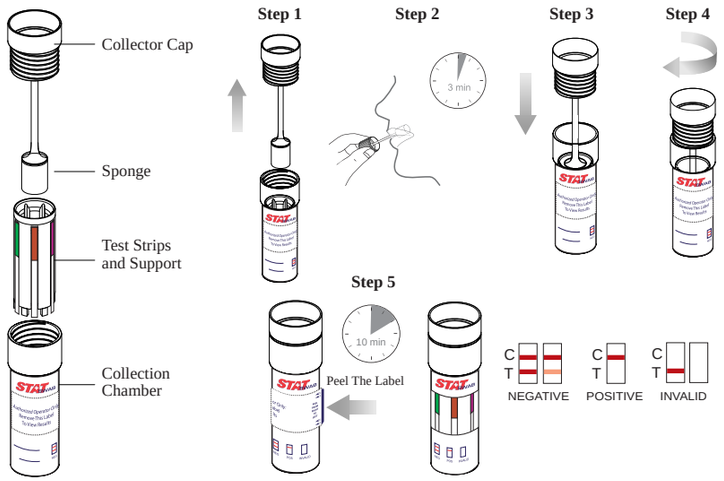
Materials Provided
• Test devices • Package insert • Procedure Card

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. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.
2. Remove the test device from the sealed pouch and screw the Collector Cap counterclockwise to pull out the whole piece of collection stick with Sponge from the Collection Chamber. (Step 1)
3. Insert the sponge end of the collection stick into the mouth. Close mouth and gently chew the sponge for saliva excretion. Soak sponge into saliva in mouth and swab the inside of the mouth and tongue to **collect oral fluid for a total of 3 minutes** until the sponge becomes completely soft and fully saturated with saliva. No hard spots should be felt on the sponge when saturated. (Step 2)
4. Remove the sponge from the mouth. With gentle pressure, place the collection stick with saturated sponge into Collection Chamber. (Step 3)
5. Screw the Collector Cap clockwise to secure the cap and start the timer. (Step 4)
6. Mark patient ID on the test device. Peel off the label to read test results. Wait for the color line(s) to appear on the test strips. **Read results at 10 minutes**. Do not read 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

1. The ***STAT™ 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.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the ***STAT™ Oral Fluid Drug Screen Device***. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		mAMP		COC		OPI		THC		PCP		BZO		OXY		MTD		BAR	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	28	2	29	1	30	0	27	3	27	3	30	0	28	2	28	2	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
+25% Cut-off	30	4	26	7	23	5	25	3	27	1	29	7	23	4	26	3	27	2	28	3	27
+50% Cut-off	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 ***STAT™ Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
ß-Phenylethylamine	4,000
(+)3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE (COC)	
Benzoylecogonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphine	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-ß-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50000
BENZODIAZEPINES (BZO)	
a-Hydroxyalprazolam	1,260
Alprazalam	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

Temazepam	20
Triazolam	2,500
OXYCODONE(OXY)	
Oxycodone	50
Codeine	25,000
Dihydrocodeine	6,250
Ethylmorphine	12,500
Hydrocodone	1,000
Hydromorphone	6,250
Oxymorphone	1,000
Thebaine	25,000
MARIJUANA (THC)	
11-nor-Δ^9 -THC-9 COOH	12
Cannabinol	3,000
Δ^8 -THC	75
Δ^9 -THC	75
METHADONE(MTD)	
Methadone	75
Doxylamine	12,500
BARBITURATES (BAR)	
Alphenol	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Secobarbital	300

Cross-Reactivity

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 ***STAT™ Oral Fluid Drug Screen Device*** when tested with concentrations up to 100 µg/mL.

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
L-Ascorbic acid
Apomorphine
Aspartame
Atropine
Cholesterol
Clonidine
Cortisone
L-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Benzoic acid
Benzphetamine
D/L-Brompheniramine
Caffeine
Cannabidol
Chloralhydrate
Chloramphenicol
Chlorothiazide
D/L-Chloropheniramine
Chlorpromazine
Chloroquine
Norethindrone
D-Norpropoxyphene
Noscapine
D/L-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Perphenazine
L-Ψ-Ephedrine
ß-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
L(-)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
D/L-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Meprobamate
Methylphenidate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Phenelzine
Trans-2-phenylcyclopropylamine hydrochloride
Phenylpropanolamine
Prednisolone
Prednisone
D/L-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinine
Quindine
Ranitidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (ß-D-glucuronide)
Thiamine
Thioridazine
D/L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
D/L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

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STAT TEST

Effective date: 10/29/2009

PN: Y0311113901