

Express Check™ Oral Fluid Drug Test

Product Insert / Instructions

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Express Check™ Oral Fluid Drug Test Device

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

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine and Benzodiazepine and their metabolites in human oral fluid. For professional and in-vitro diagnostic use only.

INTENDED USE

The Express Check™ Oral Fluid Drug Test Device for AMP/mAMP/COC/OPI/THC/PCP/BZO is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepine 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)	Benzoyllecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Benzodiazepine (BZO)	Oxazepam	50 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 TEST

The Express Check™ Oral Fluid Drug Test Device for AMP/mAMP/COC/OPI/THC/PCP/BZO 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 use.

The Amphetamine assay contained within the Express Check™ Oral Fluid Drug Test 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.

The Methamphetamine assay contained within the Express Check™ Oral Fluid Drug Test 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 benzoyllecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use. Cocaine and benzoyllecgonine can be detected in oral fluids for up to 24 hours after use.

The Cocaine assay contained within the Express Check™ Oral Fluid Drug Test 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. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the

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 Express Check™ Oral Fluid Drug Test Device when tested with concentrations up to 100 µg/mL.

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

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- Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
- Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9
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Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Express Check™ Oral Fluid Drug Test Device for AMP/mAMP/COC/OPI/THC/PCP/BZO identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
b-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)	
Benzoylcegonine	20
Cocaine HCl	20
Cocaine ethylene	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
Hydromorphone	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-b-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
MARIJUANA (THC)	
11-Nor-D9-THC-9 COOH	12
Cannabinol	12,500
11-Nor-D8-THC-9 COOH	2
D8 -THC	6,000
D9 -THC	10,000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
BENZODIAZEPINES (BZO)	
Clobazam	12.5
Triazolam	2000
Chlordiazepoxide	2500
Nitrazepam	50
Lorazepam	1000
Estazolam	157
Clonazepam	495

major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiates assay contained within the Express Check™ Oral Fluid Drug Test 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. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use.

The Marijuana assay contained within the Express Check™ Oral Fluid Drug Test Device yields a positive result when the 11-nor- Δ^9 -THC-9 COOH concentration exceeds 12 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.

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

PRINCIPLE

The Express Check™ Oral Fluid Drug Test Device for AMP/mAMP/COC/OPI/THC/PCP/BZO 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, Benzoylcegonine, Morphine, 11-nor- Δ^9 -THC-9 COOH and Phencyclidine.

PRECAUTIONS

- For professional use only.
- Do not use after the expiration date.
- The Oral Fluid Drug Test Device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- 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 Provided

- Test devices
- Package insert
- Procedure Card

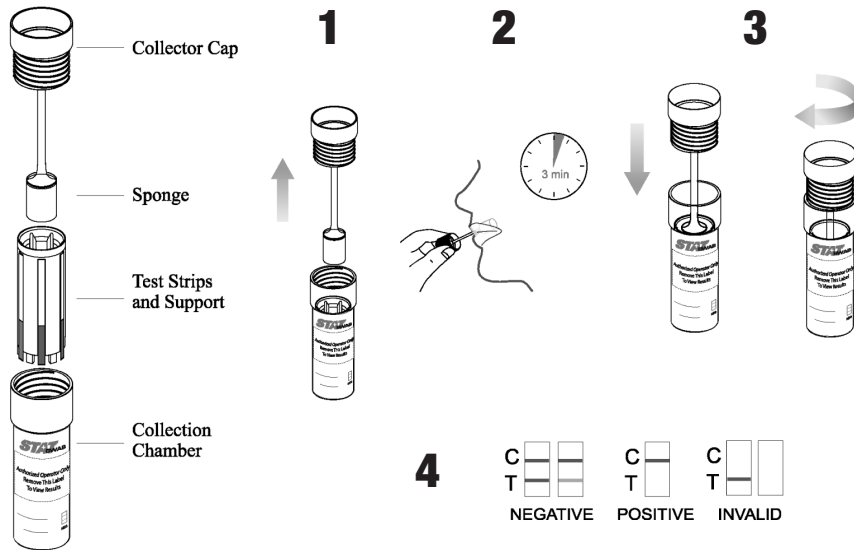
Materials Required But Not Provided: • Timer

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.



- 1 Remove swab from test cylinder
- 2 Have donor swab mouth for 3 minutes
- 3 Place swab back in cylinder and tighten cap
- 4 Read results at 5 minutes

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 Express Check™ Oral Fluid Drug Test 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 $\pm 50\%$ cut-off and $\pm 25\%$ cut-off and tested with the Express Check™ Oral Fluid Drug Test Device. The results are summarized below.

		PCP		AMP	
Drug Concentration Cut-off Range	n	-	+	-	+
0 % Cut-off	30	30	0	30	0
-50 % Cut-off	30	30	0	30	0
-25 % Cut-off	30	28	2	29	1
Cut-off	30	13	17	16	14
+25 % Cut-off	30	4	26	7	23
-50 % Cut-off	30	0	30	0	30

		mAMP		COC	
Drug Concentration Cut-off Range	n	-	+	-	+
0 % Cut-off	30	30	0	30	0
-50 % Cut-off	30	30	0	30	0
-25 % Cut-off	30	30	0	27	3
Cut-off	30	19	11	18	12
+25 % Cut-off	30	5	25	3	27
-50 % Cut-off	30	0	30	0	30

		OPI		THC	
Drug Concentration Cut-off Range	n	-	+	-	+
0 % Cut-off	30	30	0	30	0
-50 % Cut-off	30	30	0	30	0
-25 % Cut-off	30	25	5	30	0
Cut-off	30	15	15	20	10
+25 % Cut-off	30	2	28	7	23
-50 % Cut-off	30	0	30	0	30

		BZO	
Drug Concentration Cut-off Range	n	-	+
0 % Cut-off	30	30	0
-50 % Cut-off	30	30	0
-25 % Cut-off	30	25	5
Cut-off	30	14	16
+25 % Cut-off	30	7	23
-50 % Cut-off	30	0	30