Effective date: 2015-xx-xx

Number: 1156104801

# One Step Multi-Line Screen Test Device (Oral Fluid)

## Package Insert

*A rapid, screening test for the simultaneous, qualitative detection of multiple drugs and metabolites in human oral fluid.*
*For medical and other professional in vitro diagnostic use only.*

## INTENDED USE & SUMMARY

The SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Cocaine, Marijuana, Methamphetamine, Opiate, Methadone, Phencyclidine, Oxycodone and their metabolites in oral fluid at the following cut-off concentrations. The detection window, when drugs can be detected in oral fluid specimens using this test, is also indicated.

| Test | Calibrator | Cut-off (ng/mL) | Detection Time |
|---|---|---|---|
| Amphetamine (AMP) | d-Amphetamine | 50 | 10 min - 72 hrs |
| Cocaine (COC) | Benzoylecgonine | 20 | 10 min - 24 hrs |
| Marijuana (THC) | 11-nor-$\Delta^9$-THC-9 COOH | 30 | Up to 14 hrs |
| Methamphetamine (MET) | d-Methamphetamine | 50 | 10 min - 72 hrs |
| Opiate (OPI) | Morphine | 40 | 1 hr - several days* |
| Methadone (MTD) | Methadone | 45 | Up to 2 days |
| Phencyclidine (PCP) | Phencyclidine | 10 | / |
| Oxycodone (OXY) | Oxycodone | 20 | Up to 14 hrs |

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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

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

**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) and the subsequent sequestering of the drug in the buccal cavity.[2]

**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]

**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 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.

**MTD:** Methadone is an analgesic compound most frequently used for the treatment of opiate addiction. One clinical study suggested that the ratio of methadone to plasma was approximately 0.51.[4] Using known half life data for plasma, the detection window in saliva is expected to be up to 2 days after use.

**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]

**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.

**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.**

## PRINCIPLE

The SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) 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

Each test line in the test device contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

## PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- All specimens should be considered potentially biohazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.

## 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 using the collector provided with 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).

## MATERIALS

### Materials Provided

- Test devices
- Collectors
- Collection tubes
- Security seals
- Package insert

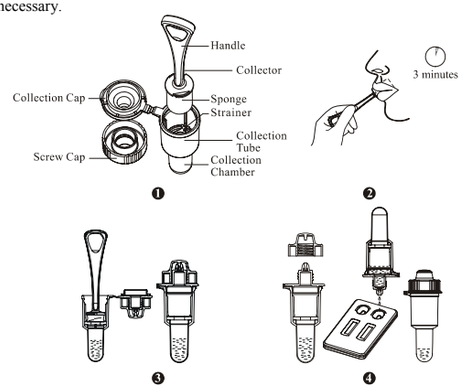
### Materials Required But Not Provided

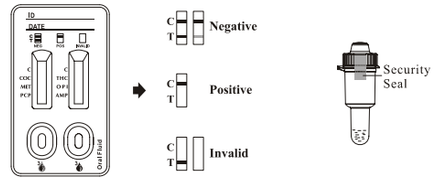
- Timer

## 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.
2. Remove the collector from the sealed pouch and **insert the sponge end of the collector into the mouth**. Actively swab the inside of the mouth and tongue to **collect oral fluid for a total of 3 minutes** until the sponge becomes fully saturated. Gentle pressing of the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated. See illustration 1 and 2.
3. Open the collection cap then remove the saturated oral fluid collector from the mouth and place into the collection chamber. **Press sponge fully against the strainer to express as much oral fluid as possible into the collection chamber.** Discard the collector. Snap the collection cap on the collection tube tightly. See illustration 3.
4. Place the test device on a clean and level surface. Twist open the screw cap from the collection tube.* Invert the collection tube and **transfer 3 drops of oral fluid** (approximately 100 µL) into each specimen well of the test device, and start the timer. Replace screw cap on the collection tube. Avoid trapping air bubbles in the specimen well. See illustration 4.
   *Note: When opening the screw cap, do not open the collection cap attached to the collection chamber.
5. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret results after 20 minutes.
6. Secure collection tube with security seal and send to laboratory for confirmation if necessary.










## INTERPRETATION 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) for a specific drug indicate 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.

## QUALITY CONTROL

A procedural control is included in the test. A colored 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. 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 SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) 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 the preferred confirmatory method.
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 cut-off level of the test.

## 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 SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid). The results are summarized below.

| Drug Conc. (Cut-off range) | AMP | | COC | | THC | | MET | | OPI | | MTD | | PCP | | OXY | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 |
| -50% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 | 0 |
| +50% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 90 |

### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) identified positive results at 10 minutes.

| | |
|---|---|
| **AMPHETAMINE (AMP)** | |
| d-Amphetamine | 50 |
| d,l-Amphetamine | 125 |
| β-Phenylethylamine | 4,000 |
| Tryptamine | 1,500 |
| p-Hydroxyamphetamine | 800 |
| (+) 3,4-Methylenedioxyamphetamine (MDA) | 150 |
| l-Amphetamine | 4,000 |
| **COCAINE (COC)** | |
| Benzoylecgonine | 20 |
| Cocaine | 20 |
| Cocaethylene | 25 |
| Ecgonine | 1,500 |
| Ecgonine methylester | 12,500 |
| N-Acetylprocainamide | 12,500 |
| Chlordiazepoxide | 12,500 |
| **MARIJUANA (THC)** | |
| 11-nor-$\Delta^9$-THC-9 COOH | 30 |
| Cannabinol | 31,500 |
| 11-nor-$\Delta^8$-THC-9 COOH | 2 |
| $\Delta^8$-THC | 6,000 |
| $\Delta^9$-THC | 20,000 |
| **METHAMPHETAMINE (MET)** | |
| 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 |
| l-Ephedrine | 400 |
| Mephentermine | 800 |
| (-) Deoxyephedrine, L-Methamphetamine | 3,000 |
| Ephedrine | 800 |

| | |
|---|---|
| **OXYCODONE (OXY)** | |
| Hydrocodone | 6,250 |
| Levorphanol | 12,500 |
| Naloxone | 12,500 |
| Naltrexone | 6,250 |
| Oxycodone | 20 |
| Secorbarbital | 50,000 |
| Oxymorphone | 100 |
| Hydromorphone | 25,000 |
| **OPIATE (OPI)** | |
| Morphine | 40 |
| Codeine | 10 |
| Ethylmorphine | 24 |
| Hydromorphine | 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 |
| Diacetylmorphine (Heroin) | 50 |
| 6-Monoacetylmorphine (6-MAM) | 25 |
| Bilirubin | 3,500 |
| **METHADONE (MTD)** | |
| Methadone | 45 |
| Doxylamine | 50,000 |
| Estrone-3-sulfate | 50,000 |
| Phencyclidine | 50,000 |
| **PHENCYCLIDINE (PCP)** | |
| Phencyclidine | 10 |
| Tetrahydrozoline | 50,000 |

### 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 SureScreen Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) when tested at concentrations up to 100 µg/mL.

#### Non Cross-Reacting Compounds

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

## BIBLIOGRAPHY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2. Schramm W., et al. *Drugs of Abuse in Saliva: A Review*. J Anal Tox, 16 (1):1-9, 1992.
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4. Kang GI and Abbott FS. *Analysis of methadone and metabolites in biological fluids with gas chromatography-mass spectrometry*. J Chromatogr. 231(2); 311-319. Sept 1982.
5. McCarron MM, et al. *Detection of Phencyclidine Usage by Radioimmunoassay of Saliva*. J Anal Tox. 8 (5):197-201, 1984.


### Index of Symbols

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | | Tests per kit | | Manufacturer |
| IVD | For *in vitro* diagnostic use only | | Use by | 2 | Do not reuse |
| 2°C 30°C | Store between 2-30°C | LOT | Lot Number | REF | Catalog # |


Manufacturer

Breathalyser Direct Ltd
Units 1 & 2
Kingham Rd
Churchill
Oxon
OX7 6NE


CE