<table>
<thead>
<tr>
<th>Drug</th>
<th>Amount</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methamphetamine</td>
<td>50/100</td>
<td>This drug is often self-administered by nasal inhalation or oral ingestion.</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>5/10</td>
<td>This drug has a lower risk of abuse, addiction, and withdrawal symptoms.</td>
</tr>
<tr>
<td>Methadone</td>
<td>30/50</td>
<td>This drug is often prescribed for the short-term treatment of anxiety and insomnia.</td>
</tr>
<tr>
<td>Cannabis</td>
<td>25/50</td>
<td>This drug is becoming increasingly abused as a street drug.</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0.022k</td>
<td>Oral fluid drug and alcohol test are designed to detect various drugs and alcohol and their metabolites in oral fluid. For professional use only.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Cut-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>0.022k</td>
</tr>
<tr>
<td>Alcohol Metabolite</td>
<td>0.022k</td>
</tr>
</tbody>
</table>

**Oral Fluid Drug And Alcohol Test**

The Oral Fluid Drug And Alcohol Test is a lateral flow chromatographic immunoassay test designed to detect oral fluid drug and alcohol test. It is intended for screening for the presence of oral fluid drug and alcohol and their metabolites in oral fluid. For professional use only.

**Analytical Specificity**

This test will detect other related compounds, please refer to the Analytical Specificity table for details.

**Package Insert**

This test is intended for screening for the presence of oral fluid drug and alcohol and their metabolites in oral fluid. For professional use only.

**Results**

- **Positive**: The presence of oral fluid drug and alcohol and their metabolites in oral fluid.
- **Negative**: The absence of oral fluid drug and alcohol and their metabolites in oral fluid.

**Interpretation**

- **Positive**: The presence of oral fluid drug and alcohol and their metabolites in oral fluid.
- **Negative**: The absence of oral fluid drug and alcohol and their metabolites in oral fluid.

**Conclusion**

The Oral Fluid Drug And Alcohol Test is intended for screening for the presence of oral fluid drug and alcohol and their metabolites in oral fluid. For professional use only.
Opioids (MOP): 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 extended periods. 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.

*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 single dose.*

OX.: 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 opioid agonists, provides pain relief by acting on opioid receptors.

The States Department of Transportation (DOT) has established a BAG of 0.02% (20 confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Oxycodone is detectable for several days after a single dose.

TCA: The Oral Fluid Drug Test is an immunosassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody. During testing, a portion of each test specimen migrates along the test strip by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region (T). Oxycodone is detectable for sustained periods of time.

Morphine is detectable for 4-6 hours after a single oral dose. Morphine is detectable for 1-2 hours after a single intravenous dose.

REAGENTS

1. The Oral Fluid Drug Test contains mouse monoclonal antibody-coupled particles and corresponding drug-conjugates. A goat antibody is employed in each test strip.


MATERIALS

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. When using the provided collection swab, remove the collector from the sealed pouch. Place one drop of sample fluid onto the collection swab. Place the swab under the mouth and hold for 10 seconds. Remove the swab from the mouth and observe the results. Note: If after 7 minutes, color on the indicator indicator has not appeared in the indicator window, proceed with the test below. (See illustration 1)

3. Place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge first into the screening device, press until the collector cap sealed with the device tightly. Keep upright when the test is running. (See illustration 2)

4. Test device upright on flat surface and keep upright while test is running. Wait for the colored signal to appear in test results area. Read the results at 10 minutes. Read saliva alcohol pads at 3 minutes.

NOTE: 1. Once the collection sponge locks in place, the device is alg ide, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).

2. In the event of no flowening even with enough saliva specimen, or the saliva is too thin to run, please move the device but don’t tilt and keep upright back and forth on a flat and clean surface for several times. Do not tilt the device when the test is running before reading results.

INTERPRETATION OF RESULTS

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.

Alcohol Test Results

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

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

### QUALITY CONTROL

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, adequacy of 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 Oral Fluid Drug And Alcohol Test 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/laser mass spectrometry (GC/MS/MSC) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
3. A positive result does not indicate the concentration of drug in the specimen and to verify proper test performance.
4. The test does not distinguish between drugs of abuse and certain medications.
5. 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.
6. A positive result may be obtained from certain foods or food supplements.
7. The test does not distinguish between drugs of abuse and certain medications.
8. A positive test result does not indicate the concentration of drug in the specimen.
9. Drug may be present in the specimen below the cut-off level of the test.
10. The test does not distinguish between drugs of abuse and certain medications.
11. 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.
12. The test does not distinguish between drugs of abuse and certain medications.
13. A positive result does not indicate the concentration of drug in the specimen.
14. Drug may be present in the specimen below the cut-off level of the test.
15. The test does not distinguish between drugs of abuse and certain medications.
16. 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.
17. The test does not distinguish between drugs of abuse and certain medications.
18. A positive result does not indicate the concentration of drug in the specimen.
19. Drug may be present in the specimen below the cut-off level of the test.
20. The test does not distinguish between drugs of abuse and certain medications.
21. 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.
22. The test does not distinguish between drugs of abuse and certain medications.
23. A positive result does not indicate the concentration of drug in the specimen.
24. Drug may be present in the specimen below the cut-off level of the test.
25. The test does not distinguish between drugs of abuse and certain medications.
26. 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.
27. The test does not distinguish between drugs of abuse and certain medications.
28. A positive result does not indicate the concentration of drug in the specimen.
29. Drug may be present in the specimen below the cut-off level of the test.
30. The test does not distinguish between drugs of abuse and certain medications.
31. 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.
32. The test does not distinguish between drugs of abuse and certain medications.
33. A positive result does not indicate the concentration of drug in the specimen.
34. Drug may be present in the specimen below the cut-off level of the test.
35. The test does not distinguish between drugs of abuse and certain medications.
36. 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.
37. The test does not distinguish between drugs of abuse and certain medications.
38. A positive result does not indicate the concentration of drug in the specimen.
39. Drug may be present in the specimen below the cut-off level of the test.
40. The test does not distinguish between drugs of abuse and certain medications.
41. 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.
42. The test does not distinguish between drugs of abuse and certain medications.
43. A positive result does not indicate the concentration of drug in the specimen.
44. Drug may be present in the specimen below the cut-off level of the test.
45. The test does not distinguish between drugs of abuse and certain medications.
46. 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.
47. The test does not distinguish between drugs of abuse and certain medications.
48. A positive result does not indicate the concentration of drug in the specimen.
49. Drug may be present in the specimen below the cut-off level of the test.
50. The test does not distinguish between drugs of abuse and certain medications.

### 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 Oral Fluid Pipette Test. The results are summarized below.

<table>
<thead>
<tr>
<th>Drug Conc. (Cut-off range)</th>
<th>AMP</th>
<th>BAR 50</th>
<th>BZO 50</th>
<th>BZO 50</th>
<th>BUP 5</th>
<th>BUP 10</th>
<th>AMP</th>
<th>BAR 50</th>
<th>BZO 50</th>
<th>BZO 50</th>
<th>BUP 5</th>
<th>BUP 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>-50% Cut-off</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**AMPHETAMINE (AMP)**
- AMP: 50
- d-Amphetamine: 125
- d-Amphetamine: 4,000
- d-Amphetamine: 1,200
- d-Amphetamine: 800
- d-Amphetamine: 150

**BENZODIAZEPINES (BZO)**
- BZ0: 150
- BZ0: 150
- BZ0: 150
- BZ0: 150
- BZ0: 150

**BUTOXYHIDRAZINE (BUP)**
- BUP: 5
- BUP: 10
- BUP: 15
- BUP: 20
- BUP: 30
- BUP: 50
- BUP: 75
- BUP: 100
- BUP: 150
- BUP: 200
- BUP: 300
- BUP: 500
- BUP: 700
- BUP: 1,000
- BUP: 1,500
- BUP: 2,000
- BUP: 3,000
- BUP: 5,000

### Analytical Specificity

The following table lists the concentration of compounds (ng/ml) above which the Oral Fluid Drug Test identified positive results at 10 minutes.
BUPRENORPHINE (BUP 5)
Buprenorphine 5
Buprenorphine-3-D-Glucuronide 10
Norbuprenorphine 5
Buprenorphine-2-D-Glucuronide 10
Buprenorphine Glucuronide 20

KETAMINE (KET 100)
Ketamine 100
norketamine 1,000
Dextromethorphan 70
Dextrophenanthrastrate 70
D-Norpseudoxyphene 3,000

TRAMADOL [TRA]
Tramadol 50
N-desmethyl tramadol 260
O-desmethyl tramadol 12,000

SYNTHETIC CANNABINOID (K2)
JWH-018 N-Pentanoic acid metabolite 5
JWH-073 4-hydroxybutyl metabolite 250
JWH-250 4-hydroxyphenyl metabolite 25,000
JWH-210 5-hydroxyphenyl metabolite 50,000
JWH-073 4-hydroxybutyl metabolite 250
JWH-019 5-hydroxyhexyl metabolite 5,000
JWH-019 N-(4-hydroxyphenyl) metabolite solution 500
JWH-219 5-hydroxyhexyl 700
JWH-219 5-hydroxyhexyl 400

MAM201 40,000
JWH-122 5-hydroxyphenyl metabolite 700
APINACA 5-hydroxyphenyl metabolite 50,000

BUPRENORPHINE (BUP 10)
Buprenorphine 10
Buprenorphine-3-D-Glucuronide 10
Norbuprenorphine 20
Buprenorphine-2-D-Glucuronide 200
Buprenorphine Glucuronide 10

LYSERCIG ACID DIETHYLAMIDE (LSD)
D-lysergic acid diethylamide 25

METHAQUALONE (MQL 100)
Methaqualone 100

METHYLENEDIOXYPYROVALERONE (MDPV 50)
Methylenedioxyprovalerone 50
Butyline 4,000
Ethylone 50
Methione 11,000
Brompheniramine 800

METHYLENEDIOXYPYROVALERONE (MDPV 100)
Methylenedioxyprovalerone 10
Butyline 5,000
Ethylone 50
Methione 10,000
Brompheniramine 1,000
Methedrone 5,000
Naphydrex 100,000

Methedrone 5,000
Naphydrex 100,000

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

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 Oral Fluid Drug Test when tested at concentrations up to 100 µg/mL.

Non Cross-Reactive Compounds

Acetaminophen Diclofenac Lopramide 0-Pseudoephedrine
Acetaminophen Dicyclomine Meprobamate Quinine
Acetylsalicylic acid Dimethylphenidate Guanidine
Aspirin Diphenhydramine Naproxen Ranitidine
Ampicillin β-Estradiol Nicotinamide Salicylic acid
Antipyrine Ethyl-p-anisomenochrome Sulfathiazole
Ascorbic acid i-epinephrine Nimesulide Sulindac
Apomorphine Enphrosic Norephedrine Tetracycline
Aspartame Fenoprofen Noscapine Tetracyroprovalerone
Atropline Furosemide d-J-Octopamine 3-acetate
Benzilic acid Gentianic acid Oxalic acid Tetracyroprovalerone
Benzilic acid Hemoglobin Oxalic acid 5-(3-glucuronide)
Benzphetamine Hydromazine Oxyphenylalanine Thalidomide
Carfene Hydrocortisone Pipawrene Thymine
Chlorhydrate Hydrocortisone Penicillin G Toroidiazide
Chloroxymethanne 5-Hydroxypyrrolid acid Pentazzone d-J-Tyrosine
Chloroxymethanne 5-Hydroxypyrrolid acid Pentazzone Tobutamide
d-J Hydroxypyrrolid acid Phenazine Triclozone
Chloroxymethanne (Serotonin) Trans-2-phenylxylolo- Tribrantrene
Chloroxymethanne 3-Hydroxypyrrolid propyramine Triclozone
Chloroxymethanne 1-propranolol Phenindamine Triheximidrin
Clonidine lproniazid Phenylpropanolamine d-J-Tryptophan
Cortisone (d-1 -Tryptophan
Cortisone (-)lsoproterenol Phenolbarbital Phenylpropanolamine d-J-Tryptophan
Dextromethorphan Labelolol Labelolol d-J-Propranolol Zomepirac

Alcohol Test
The following substances may interfere with the Oral Fluid Drug and Alcohol Screen Device when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers
(2) Agents which inhibit color development:
Reducing Agents: such as Ascorbic acid, Tannic acid, Pyrogallol, Mercaptaolanics and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methylene, L-dopa, L-dimethylnol, and Methamphetamine, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

BIBLIOGRAPHY