The drug class opiates refer to any drug that is derived from the opium poppy, including naturally occurring compounds, semi-synthetic, and fully synthetic forms. Opiates produce analgesia (pain reduction), and they may also cause respiratory depression, constipation, nausea and vomiting. Opiates can also produce euphoria, which is the most pervasive effect of MDMA, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of altered sensory experience, changes in time perception, and a sense of depersonalization. This effect can produce a feeling of euphoria and well-being. Methadone serves as a form of substitution therapy for individuals who are addicted to opioids. Methadone is a long-acting opioid that produces a more stable blood concentration following a single dose. Methadone is used for the treatment of opioid addiction because it is less likely to cause physical dependence and withdrawal symptoms compared with the use of opioids such as heroin. Methadone is a non-narcotic, non-addictive analgesic that is used to relieve pain. Methadone is effective in treating pain of all types, and it can be used to treat opioid dependence. Methadone is a potent analgesic often used in the treatment of opioid addiction. Methadone is also used as a maintenance therapy for individuals who have been addicted to opioids. Methadone is a non-narcotic, non-addictive analgesic that is used to relieve pain. Methadone is effective in treating pain of all types, and it can be used to treat opioid dependence. Methadone is a potent analgesic often used in the treatment of opioid addiction. Methadone is also used as a maintenance therapy for individuals who have been addicted to opioids. Methadone is a non-narcotic, non-addictive analgesic that is used to relieve pain. 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To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper testing conditions have been met.

MATERIALS
- Device
- QC Solution
- Drug Solution

DIRECTIONS FOR USE
- The test is intended for use by appropriately trained personnel.
- The test is approved for use with oral fluid specimens collected using the collector provided with the kit.
- The oral fluid specimen should be collected within 24 hours of testing.
- 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 use after the expiration date.
- The oral fluid drug screen device should remain in the sealed pouch until use.
- Do not use beyond the expiration date.
- The oral fluid specimen should be collected using the collector provided with the kit.
- Follow the detailed Directions for Use below.

How to Use

1. Open the device pack by pulling apart the two pieces on the top of the pack. The collection stick and test tube are inside the device pack.
2. Remove the collection stick and test tube from the sealed pouch.
3. Insert the collection stick into the mouth and direct the tip of the collection stick towards the tongue.
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.
5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results.
6. Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing.
7. Do not read drug test results after 1 hour.
8. Do not read drug test results after 1 hour.

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the STAT SWAP Oral Fluid Drug Screen Device can detect drugs at a rate of 10 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.

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.

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 SWAP Oral Fluid Drug Screen Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result.
2. Drug chromatography/mass spectrometry (GCMS) or gas chromatography/tandem mass spectrometry (GCMS/MS) is preferred confirmatory methods.
3. A positive test result does not necessarily indicate the concentration of drug in the specimen or the route of administration.
4. A negative result does not necessarily indicate a drug-free specimen.
5. Drug tests are intended for single use.

ERRORS IN READING TEST RESULTS

- Incorrect use of the collection stick: the collector tip is not inserted into the oral fluid specimen.
- Incorrect use of the device: the device is not used within the recommended time frame.
- Specimen volume: the specimen volume is too low or too high.
- Incorrect procedural technique: the procedural technique is not followed correctly.

ACCEPTABLE DRUG CONCENTRATIONS

- Benzodiazepines
- Opioids
- Barbiturates
- Amphetamines
- Caffeine
- Phencyclidine
- Methadone
- Ecgonine-based

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7. Do not read drug test results after 1 hour.
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Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and expressed into tube again. (Step 2)

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the STAT SWAP Oral Fluid Drug Screen Device can detect drugs at a rate of 10 minutes.

ERRORS IN READING TEST RESULTS

- Incorrect use of the collection stick: the collector tip is not inserted into the oral fluid specimen.
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3. Insert the sponge end of the collection stick into the mouth and direct the tip of the collection stick towards the tongue. (Step 1)
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 5)
6. Read results of drug tests at 10 minutes. (If there is a label over reading window, peel off the label to see text results.)
7. Send the test with collected oral fluid to the laboratory for GCMS confirmation if necessary.

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

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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.

VALID:
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 kit immediately and contact your supplier.

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

Amphetamine, Methamphetamine, Cocaine, Opium, Marijuana, Benzodiazepines, Oxycodeone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are:

- Parent compound only:
  - Chloroquine (Disulfate)
  - Chlorthalidone
  - Clonazepam
  - Clotrimazole
  - Cleocin
  - Cefadroxil
  - Cephalosporin
  - Cefazolin
  - Cefuroxime Axetil (Zinnat)
  - Cephalosporin (Roxithromycin)
  - Cefdinir
  - Cefpodoxime Proxetil
  - Ceftepime
  - Ceftriaxone Sodium
  - Ceftriaxone
  - Ceftazidime
  - Cefazolin
  - Cefuroxime
  - Cefoxitin
  - Cefotaxime Sodium
  - Cefotaxime
  - Cefoperazone
  - Cefuroxime Axetil
  - Cefotaxime
  - Cefamandole Nafate
  - Cefmenoxime
  - Cefotetan Disodium
  - Cefprozil
  - Cefmenoxime
  - Cefonicid
  - Cefoperazone
  - Cefodizime
  - Cefonicid
  - Cefquinome Sulfate
  - Ceftriaxone Sodium
  - Ceftriaxone
  - Cefuroxime Axetil
  - Cefuroxime
  - Cefuroxime Axetil
  - Cefpodoxime Proxetil
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