

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

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

For Forensic Use Only

INTENDED USE

The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/OPI /THC/PC/BZO/OXY/MTD/BAR/BUP/ALC is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Alcohol 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-∆9-THC-9 COOH | 12 ng/mL |
| Manjuana (THC) | 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 |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL |
| Alcohol(ACL) | Alcohol | > 0.02 % B.A.C |

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 SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC /OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/ALC 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 use¹. The Amphetamine assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the Amphetamine concentration in oral fluid exceeds

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 use1.

The Methamphetamine assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol 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

and metabolites benzovlecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use. Cocaine and benzoylecgonine can be detected in oral fluids for up The Cocaine assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen

Device yields a positive result when the cocaine metabolite in oral fluid exceeds 20 ng/ml

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 dose². 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 SSTAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen **Device** yields a positive result when the concentration of Morphine in oral fluid exceeds the 40

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 cavity3. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use³

The Marijuana assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the 11-nor-\(\Delta^9\)-THC-9 COOH concentration exceeds 12

The Marijuana assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the Δ9-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/mL⁴. The Phencyclidine assay contained within The **STAT SWAB PLUS™ Oral Fluid Drug and Alcohol** Screen Device yields a positive result when the Phencyclidine concentration in oral fluids exceeds

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 SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the concentration of Oxazepam in oral fluids

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, OxyContir

consists solely of oxycodone hydrochloride in a time-release form. The Oxycodone assay contained within The **STAT SWAB PLUS™ Oral Fluid Drug and Alcohol** Screen Device yields a positive result when the concentration of oxycodone in oral fluid exceeds

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. The Methadone assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the Methadone concentration in oral fluids exceeds 75

BARBITURATES (BAR)

na/mL.

300 ng/mL

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. Secondiniar) for high PO (oral) 4.3 days⁵

The Barbiturates assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol

BUPRENORPHINE (BUP) Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care

offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the

Screen Device yields a positive result when the Barbiturates concentration in oral fluid exceeds

drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual,

The Buprenorphine assay contained within The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Deviceyields a positive result when the Buprenorphine concentration in oral fluid exceeds

ALCOHOL(ACL)

10 ng/mL.

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol

PRINCIPLE

(1) Drug tests: The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/ OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP 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

(2)Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

Alcohol Oxidase CH₂CH₂OH + O₂ CH₂C=O + H₂O Peroxidase

H,O, + DH, D + 2H₂O Blue

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidaze to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

REAGENTS

(1)Drug test: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, Barbiturates and Buprenorphine

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine

Alcohol Oxidaze, Peroxidase

Buffer and Stabilizing Proteins

PRECAUTION

- · 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. 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 Provide |
|----------------------------------|
| Test devices |

 Package insert Materials Required But Not Provided

Procedure Card

· Alcohol color chart

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 specime

DIRECTIONS FOR USE

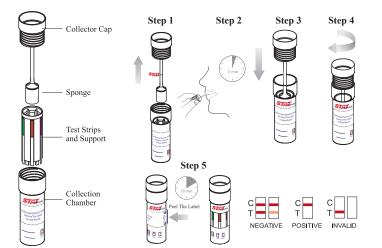
1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.

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

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 of alcohol test at 2 minutes and drug tests at 10 minutes. Do not read drug test results after 1 hour and alcohol test result after 5 m

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) **Drug Test Results**

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 lev

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

(Please refer to the color chart) **Alcohol Test Results**

Alcohol Negative Result: The alcohol pad shows no color change (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 repeated to ensure complete saturation of the 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 color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequa membrane wicking and correct procedural technique.

LIMITATIONS

1. The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol 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 a confirmed result. Gas chromatography/mass chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.

2. A positive test result does not indicate the concentration of drug or Alcohol in the specimen or

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 SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device . The results are summarized below.

AMP MAMP COC OPI THC PCP B70 OXY MTD BAR BUP

| 0 | 0 30 | _ |
|-----|-------|------|
| 0 | 0 30 | _ |
| - | - | 0 |
| 1 | | |
| 1 ' | 1 27 | 3 |
| 18 | 18 16 | 14 |
| 27 | 27 7 | 23 |
| 30 | 30 0 | 30 |
| | İ | 27 7 |

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02%, 0.08%, 0.15%, 0.30%,). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the OratectPlus™ Oral Fluid Drug and Alcohol Screen Device are summarized below:

| | Total # of Test/ | | 0.00% | | 0.02% | | 0.08% | | 0.15% | | 0.30% | |
|------------------------|------------------|---------------|-------|---|-------|----|-------|----|-------|----|-------|----|
| | | Concentration | - | + | - | + | - | + | - | + | - | + |
| | Alcohol | 15 | 15 | 0 | 1 | 14 | 0 | 15 | 0 | 15 | 0 | 15 |
| Analytical Specificity | | | | | | | | | | | | |

B.A.C.

The following table lists the concentration of compounds (ng/mL) above which The STAT SWAB PLUS™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/OPI/THC/PCP/BZO/ OXY/MTD/BAR/BUP/ALC 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 HCI | 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 |
| | |

Concentration (ng/ml) Drug Morphine 3-ß-D-Glucuronide Nalorphine 10,000 Normorphine 12,500 Norcodeine 1,500 Oxycodone 25,000 Oxymorphone 25.000 Thebaine 1,500 PHENCYCLIDINE (PCP) Phencyclidine 50000 Tetrahydrozoline BENZODIAZEPINES (BZO) a-Hydroxyalprazolam 1.260 Alprazalam 40 Bromazepan 400 Chlordiazepoxide 780 Chlordiazepoxide HCI 390 Clobazam 100 Clonazepam 785 Clorazepate Dipotassium 195 Delorazepam 1,560 Desalkylflurazepan 390 Diazepam 195 2,500 Estazolam Flunitrazepam 385 1,560 (±) Lorazepam RS-Lorazepam glucuronide 160 Midazolam 12,500 Nitrazepam 95 Norchlordiazepoxide 200 Nordiazepan 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-Δ9 -THC-9 COOH Cannabinol 3,000 Δ^{8} -THC 75 Δ⁹ -THC 75 METHADONE(MTD) Methadone 75 12,500 Doxylamine BARBITURATES (BAR) Alphenol Amobarbita 300 Aprobarbital 200

| Drug | Concentration (ng/ml) |
|----------------------|-----------------------|
| Butabarbital | 75 |
| Butalbital | 2,500 |
| Butethal | 100 |
| Cyclopentobarbital | 600 |
| Pentobarbital | 300 |
| Phenobarbital | 100 |
| Secobarbital | 300 |
| | |
| BUPRENORPHINE(BUP) | |
| Norbuprenorphine | 10 |
| Buprenorphine | 20 |
| 3-D-glucuronide | 15 |
| Norbuprenglucuronide | 200 |
| | |

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, 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 STAT SWAB PLUS™ Oral Fluid Drug and Alcohol when tested with concentrations up to 100 µg/mL.

Acetaminophen Ervthromycin Quinacrine Acetophenetidin Fenoprofen Quinine Furosemide N-Acetylprocainamide Quindine Acetylsalicylic acid Gentisic acid Ranitidine Aminopyrine Hemoglobin Salicylic acid Amoxicillin Hvdralazine Serotonin Hydrochlorothiazide Ampicillin Sulfamethazine Sulindac L-Ascorbic acid Hydrocortisone O-Hydroxyhippuric acid Apomorphine Tetracycline p-Hydroxytyramine Tetrahydrocortisone 3-acetate Aspartame Atropine Ibuprofen Tetrahydrocortisone 3 Iproniazid (B-D-alucuronide) Cholesterol D/L-Isoproterenol Clonidine Thiamine Isoxsuprine Thioridazine Cortisone Ketamine L-Cotinine D/L-Tyrosine Ketoprofen Tolbutamide Benzoic acid Labetalol Triamterene Benzphetamine Loperamide Trifluoperazine D/L-Brompheniramine Meperidine Trimethoprim Caffeine Meprobamate D/L-Tryptophan Cannabidol Methylphenidate **Tvramine** Chloralhydrate Nalidixic acid Uric acid Chloramphenicol Naloxone Verapamil Chlorothiazide Naltrexone Zomepirac D/L-Chloropheniramine Naproxen Chlorpromazine Niacinamide Chloroquine Nifedipine Norethindrone Oxalic acid D-Norpropoxyphene Oxolinic acid Noscapine Oxymetazoline D/L-Octopamine Papaverine Creatinine Penicillin-G Deoxycorticosterone Pentazocine hydrochloride Dextromethorphan Perphenazine Diclofenac

Phenelzine

hydrochloride

Prednisolone

D/I -Propranolol

D-Propoxyphene

D-Pseudoephedrine

Prednisone

Phenylpropanolamine

Diflunisal

Diphenhydramine

Estrone-3-sulfate

L(-)-Epinephrine

Ethyl-p-aminobenzoate

L-Y-Ephedrine

ß-Estradiol

Digoxin

Trans-2-phenylcyclopropylamine

The following substances may interfere with the STAT SWAB PLUS™ 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: Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, and Uric acid

Bilirubin, L-dopa, L-methyldopa, and Methampyrone. 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 1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition

5. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735

and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998. 2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine 2. Nin, 1, et al., Prasina and oral mula praimatoximiteris and primariacoughannes after oral codeline administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.

3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9

4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201.



Manufactured for

Micro Distributing 620 Kennedy Court Belton, TX 76513 866-933-0964 www.micro-distributing.com

Effective date: 5/11/2010