

Multi-Drug Rapid Test (Oral Fluid) Package Insert

Instruction Sheet for testing of any combination of the following drugs:

AMP/MET/COC/OPI/MOP/THC/PCP/MTD/MDMA/BZO/OXY/COT/K2/KET/BAR/BUP/TML/ 6-MAM/FYL/CFYL/MDPV/α-PVP/LSD/EDDP/ALC

A rapid test for the simultaneous, qualitative detection of multiple drugs or drug metabolites and alcohol in human oral fluid. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

[INTENDED USE]

The Multi-Drug Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs or drug metabolites in human oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50/40/25/20
Methamphetamine (MET)	d-Methamphetamine	50/30/25
Marijuana (THC)	11-nor-∆9 -THC-9 COOH	50/40/30/25/20/15/12
Phencyclidine (PCP)	Phencyclidine	10
Cocaine (COC)	Benzoylecgonine	50/40/30/20
Opiates/Morphine (OPI/MOP)	Morphine	50/40/25/20/10
Methadone (MTD)	Methadone	50/30
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxyme- thamphetamine	75/50
Oxycodone (OXY)	Oxycodone	50/40/20
Cotinine (COT)	Cotinine	20
Benzodiazepines (BZO)	Oxazepam	50/30/20/10
Synthetic Marijuana (K2)	JWH -018, JWH- 073	25
Ketamine (KET)	Ketamine	150/100/50/30
Barbiturates (BAR)	Secobarbital	50
Buprenorphine (BUP)	Buprenorphine	10/5
Tramadol (TML)	Tramadol	30
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Fentanyl (FYL)	Fentanyl	50/30/20/10
Carfentanyl (CFYL)	Carfentanyl	50
3, 4-methylenedioxypyrovalerone (MDPV)	3, 4-methylenedioxy- pyrovalerone	300
alpha-Pyrrolidinovalerophenone (α-PVP)	alpha-Pyrrolidinovalerophenone	300
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	10
2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine	20
Test	Calibrator	Cut-off
Alcohol(ALC) This assay provides only a preliminary	7 7 7 m	0.02%

This assay provides only a preliminary 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) is the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

[SUMMARY]

The Multi-Drug Rapid Test 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 following use. Amphetamine can be detected in oral fluid for up to 72 hours after use.

Methamphetamine (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. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use. 1 Methamphetamine can be detected in oral fluid for up to 72 hours after use.

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 benzoylecgonine 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 fluid for up to 24 hours after use.1

Opiates (OPI/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 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 40ng/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. Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin.2

Marijuana (THC)

11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH), the metabolite of THC $(\Delta^9$ -tetrahydrocannabinol), 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.3 Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug

Phencyclidine (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in an Emergency Department, PCP was detected in the oral fluid of 79 patients at levels as low as 2ng/mL and as high as 600ng/mL.4

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).

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.1

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.1 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, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Although nicotine is excreted in oral fluid, the relatively short half-life of the drug makes it an unreliable maker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine bears a high correlation with plasma cotinine levels and has been found to be the best maker for smoking status compared with oral fluid nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing. The window of detection for cotinine in oral fluid test is expected to be up to 1-2 days after nicotine use.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception."

Synthetic Marijuana (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic

Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.6

Elevated levels of oral fluid metabolites are found within hours of exposure and remain detectable window up to 24-48 hours after smoking (depending on usage/dosage).

Ketamine (KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbress, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use.

Barbiturates (BAR)

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.8

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.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days²

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 drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. The elimination half-life of buprenorphine is 20-73 hours (mean 37). 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, intranasal and inhalation routes

Tramadol (TML)

Tramadol (TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in oral fluid as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver. 6-Monoacetylmorphine (6-MAM)

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the oral fluid. 6-MAM remains in the oral fluid for no more than 24 hours. So a oral fluid specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in oral fluid virtually guarantees that heroin has recently been consumed.

Fentanyl (FYL)

Fentanyl, belongs to powerful narcotics analgesics, and is a special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain.5 After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, 6,7 which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.8

Carfentanyi (CFYL)

Carfentanyl is an analog of the synthetic opioid analgesic fentanyl. It is 10,000 times more potent than morphine, making it among the most potent commercially used opioids. Carfentanyl was first synthesized in 1974.9 It is marketed under the trade name Wildnil as a general anaesthetic agent for large animals. 10 Side effects of carfentanyl are similar to those of fentanyl, which include itching, nausea and respiratory depression, which can be life-threatening. 11 Carfentanyl is classified as Schedule II under the Controlled Substances Act in the United States with a DEA ACSCN of 9743.

3, 4-methylenedioxypyrovalerone (MDPV)

3,4-methylenedioxypyrovalerone (MDPV) is a psychoactive recreational drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). It was first developed in the 1960s by a team at Boehringer Ingelheim. MDPV remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing MDPV were previously sold as recreational drugs in gas stations and convenience stores in the United States, similar to the marketing for Spice and K2 as incense. MDPV is the 3,4-methylenedioxy ring-substituted analog of the compound pyrovalerone,

developed in the 1960s, which has been used for the treatment of chronic fatigue and as an anorectic, but caused problems of abuse and dependence. However, despite its structural similarity, the effects of MDPV bear little resemblance to other methylenedioxy phenylalkylamine derivatives such as 3,4-methylenedioxy-N-methylamphetamine (MDMA), instead producing primarily stimulant effects with only mild entactogenic qualities. ¹²

MDPV undergoes CYP450 2D6, 2C19, 1A2, and COMT phase 1 metabolism (liver) into methylcatechol and pyrrolidine, which in turn are glucuronated (uridine 5'-diphospho-glucuronosyl-transferase) allowing it to be excreted by the kidneys, with only a small fraction of the metabolites being excreted into the stools. No free pyrrolidine will be detected in the oral fluid.

alpha-Pyrrolidinovalerophenone (α-PVP)

alpha-Pyrrolidinovalerophenone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes. α-PVP may be quantified in blood, plasma or urine to confirm a diagnosis of poisoning in hospitalized patients or to provide evidence in a medicolegal death investigation. ¹⁴ It generally comes in the form of either a crystalline powder or crystallized shards which users can ingest to produce powerful but short-lived euphoric stimulant effects which are comparable to those of methamphetamine and cocaine when insufflated or vaporized, α-PVP has been reported to be the cause, or a significant contributory cause of death in suicides and overdoses caused by combinations of drugs. ¹⁵ It has also been linked to at least one death where it was combined with pentedrone and caused heart failure.

Lysergic Acid Diethylamide (LSD)

Lysergic acid diethylamide (LSD) is a white powder or a clear, colorless liquid. LSD is manufactured from lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a Schedule I controlled substance, available in liquid, powder, tablet (microdots), and capsule form. LSD is recreationally used as a hallucinogen for its ability to alter human perception and mood. LSD is primarity used by oral administration, but can be inhaled, injected, and transdermally applied. LSD is a non-selective 5-HT agonist, may exert its hallucinogenic effect by interacting with 5-HT 2Areceptors as a partial agonist and modulating the NMDA receptor-mediated sensory, perceptual, affective and cognitive processes. LSD mimics 5-HT at 5-HT 1A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD has a plasma half-life of 2.5-4 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD and 2-oxo-3-hydroxy-LSD. These metabolites are all inactive.

2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)

Methadone is an unusual drug in that its primary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.

Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better marker for methadone maintenance than unmetabolized methadone.

Alcohol (ALC)

Two-thirds of all adults drink alcohol. ¹⁶ The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions. ¹⁷

[ASSAY PRINCIPLE]

The Multi-Drug Rapid Test 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.

[ALCOHOL PRINCIPLE]

The oral fluid Alcohol Rapid Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

[REAGENTS]

Each 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 corresponding drug.

[ALCOHOL REAGENTS]

Tetramethylbenzidine/Alcohol Oxidase (EC 1.1.3.13)/Peroxidase (EC 1.11.1.7)/ Other additives

[PRECAUTIONS]

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.

- · Oral fluid is not classified as biological hazard unless derived from a dental procedure.
- The used Device should be discarded according to local regulations.

[ALCOHOL PRECAUTIONS]

Test materials that have been exposed to oral fluid should be treated as potentially infectious. Do not use the Oral fluid Alcohol Rapid Test after the expiration date marked on the foil package.

[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 Device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

[ALCOHOL STORAGE AND STABILITY]

The Alcohol Rapid Test is to be stored at 2-30 °C in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Oral fluid Alcohol Rapid Test must be brought to room temperature prior to opening the nouch.

[SPECIMEN COLLECTION AND PREPARATION]

The oral fluid specimen should be collected using the device with the kit. Follow the detailed Directions for Use below. No other collection device should be used with this assay. Oral fluid collected at any time of the day may be used.

When testing with Alcohol storage of oral fluid specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

[MATERIALS]

Materials Provided

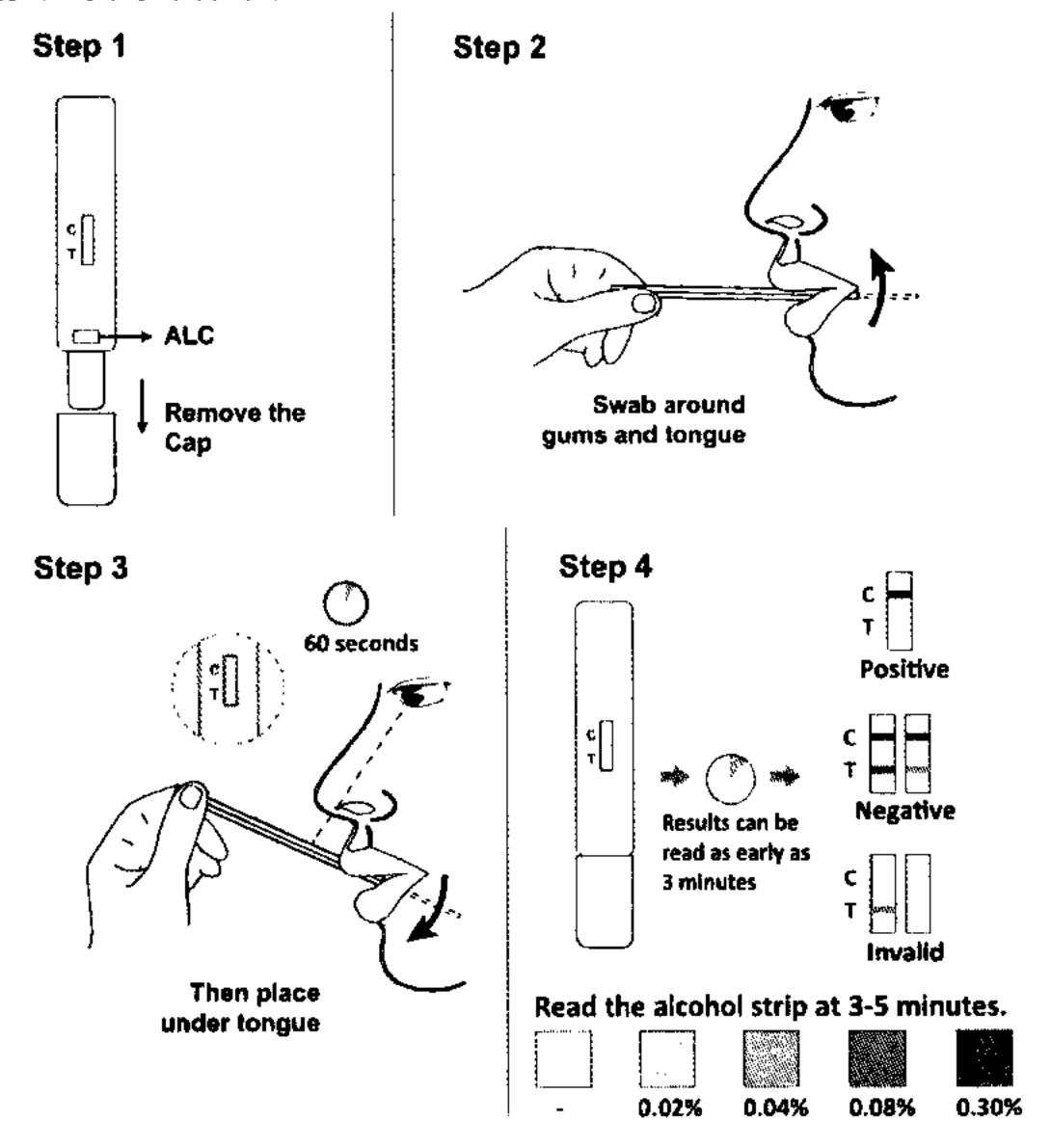
- Test Devices
- ALC color chart (when applicable)
 Materials Required but Not Provided
- Package insert

• 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 or tobacco products for at least 10 minutes prior to collection.

- 1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
- 2. Take off the Device cap and collect oral fluid specimen as follows.
- Important: Place the absorbent wick against the upper, lower jaws and roots to enrich the oral fluid. Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth (10-15 times) to assist saturation.
- Put the absorbent wick under the tongue to collect oral fluid until the flow appear in the test windows (approximately 60 seconds) and then take out the device and start a timer.
- If no flow appeared repeat the procedure in steps above until the flow appear. If no flow appeared after triplicate of steps above, discard the device, review procedures with the donor and repeat the test using a new device.
- 3. Place the test device on a clean and level surface.
- 4. Read the test result at 3-10 minutes.
- If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. <u>If any lines are not visible at 3 minutes</u>, then the test should be re-read at 10 minutes.
- 5. Alcohol indicator, when applicable, the result should be read at 3-5 minutes. Compare the color of the reaction pad with the color chart provided separately/on foil pouch to determine the relative oral fluid alcohol level.



[INTERPRETATION OF RESULTS]

(Please refer to the previous illustration)

NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T). This negative result means that the concentrations in the oral fluid sample are below the designated cut-off levels for a particular drug tested.

*NOTE: The shade of the colored lines(s) in the Test regions (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the control region (C) and no line appears in the test region (T). The positive result means that the drug concentration in the oral fluid sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test device. If the result is still invalid, contact your manufacturer.

[ALCOHOL STRIP INTERPRETATION]

Positive: The Oral Fluid Alcohol Rapid Test will produce a color change in the presence of oral fluid alcohol. The color will range from light blue color at 0.02% relative oral fluid alcohol concentration to a dark blue color near 0.30% relative oral fluid alcohol concentration. Color pads are provided within this range to allow an approximation of relative oral fluid alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Oral fluid Alcohol Rapid Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in oral fluid.

Negative: When the oral fluid Alcohol Rapid Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying oral fluid sample, do not use the test. **NOTE:** A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with oral fluid. The test is not reusable.

[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.

[LIMITATIONS]

- The Multi-Drug Rapid Test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) is preferred confirmatory methods. 18
- 2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- 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.

[ALCOHOL LIMITATIONS]

- 1. The **Oral Fluid Alcohol Rapid Test** is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the **Oral Fluid Alcohol Rapid Test**. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
- Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

[PERFORMANCE CHARACTERISTICS]

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ±50% cut-off, ±25% cut-off and 300% cut-off and tested with the Multi-Drug Rapid Test. The results are summarized below

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Drug	Αλ	ΛP	M	ΞT	MI	ET	TH	J C	C	TC	BZ	O.	PC	CP	F	YĻ
Concentration	5	0	5	0	2	5	5	0	2	0	5	0	1	0	5	0
Cut-off Range	•	+	-	+	-	+	ı	+	•	+	ŧ	+	•	+	•	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	28	2	28	2	27	3	25	5	25	5	25	5	27	3
Cut-off	15	15	16	14	16	14	12	18	20	10	13	17	14	16	15	15
+25% Cut-off	7	23	6	24	6	24	8	22	7	23	4	26	10	20	8	22
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration		VIL O	F` 2	YL 0	F'	O 75	CF 5	о Ч		ZO 0		PV 20	a-P 30	PVP : 00		SD 0
Cut-off Range	-	+	-	+	_	+	•	+	•	+	1	+	•	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	26	4	25	5	25	5	27	က	26	4	26	4
Cut-off	13	17	15	15	15	15	15	15	13	17	20	10	19	11	16	14
+25% Cut-off	7	23	3	27	ფ	27	7	23	4	26	4	26	6	24	7	23
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug	0	PI/	K	2	M	ΓD	M	T D	0)	XY .	MD	MA	BZ	<u>20</u>	0	XY	O	PI/
Concentration	MO	P 40	2	5	3	0	5	0	2	0	5	0	2	0	5	0	MO	-
Cut-off Range	_	+	-	+	-	+	_	+	-	+		+	•	+	-	+		+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	Ö	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	25	5	25	5	27	3	26	4	25	5	26	4	27	3
Cut-off	13	17	15	15	15	15	15	15	20	10	19	11	13	17	15	15	13	17
+25% Cut-off	7	23	3	27	7	23	7	23	4	26	6	24	4	26	6	24	7	23
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	Ō	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	Ō	30	0	30	n	30

Drug	CC	OC	6-M	IAM [¯]	B	JP	Ti	НС	B/	4R	K	ET	B	ZO	T	IC	Το	PI/
Concentratio	2	0	1	0	1	0	1	2	5	iO	5	0] 1	0	•	20	_	P 50
n Cut-off Range	1	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	O	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	28	2	26	4	27	3	25	5	26	4	25	5	27	3	27	3
Cut-off	15	15	20	10	14	16	12	18	18	12	14	16	14	16	12	18	13	17
+25% Cut-off	8	22	2	28	10	20	8	22	8	22	10	20	4	26	8	22	7	23
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug		<u>oc</u>	l	IC		HC	_	ΧΥ		ET	MD	MA	KI	ΕT	T	I C	AN	ИP
Concentration		0	4	0	1 1	5	4	0	1(<u> 00</u>	7	<u>'5</u>	<u> </u>	50	2	5	2	0
Cut-off Range	•	+	-	+	-	_+	-	+	_	+] - ⁻	+	-	+	-	+	_	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	თ	27	3	26	4	26	4	26	4	26	4	27	3	29	1
Cut-off	15	15	12	18	12	18	15	15	14	16	19	11	14	16	12	18	15	15
+25% Cut-off	8	22	8	22	8	22	6	24	10	20	6	24	10	20	8	22	10	20
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	٥	30	0	30	0	30

Drug	O	PI/	CC	С	A	ΜP	M	ET	TH	I C	C	oc	O	PI/	ΑĬ	ИP	B	JP
Concentration		P 20	3	0	4	0	3	0	3	0	4	0	MO	P 10	2	5		5
Cut-off Range	•	+	•	+		+	-	+	-	+	_	+	-	+	-	+		+
0% Cut-off	30	0	30	Ö	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	Ö	30	0
-25% Cut-off	27	3	27	3	27	3	28	2	27	3	21	9	27	3	27	3	26	4
Cut-off	13	17	15	15	15	15	16	14	12	18	17	13	13	17	15	15	14	16
+25% Cut-off	7	23	8	22	7	23	6	24	8	22	8	22	7	23	7	23	10	20
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off	KE	T 30	FY	L 30	1	DP 20
Range	-	+	_	+		+
0% Cut-off	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0
-25% Cut-off	26	4	26	4	27	3
Cut-off	14	16	15	15	14	16
+25% Cut-off	10	20	3	27	4	26
+50% Cut-off	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30

Analytical Specificity
The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug
Rapid Test identified positive results at a read time of 3-10 minutes.

Compound	ng/mL	Compound	ng/mL
Amphetamii			
d-Amphetamine	50	ß-Phenylethylamine	25,000
d/I-Amphetamine	100	-Amphetamine	25,000
p-Hydroxyamphetamine	100	Methoxyphenamine	12,500
(+)3,4-Methylenedioxyamphetamine (MDA)	100	Tryptamine	12,500
Amphetamir	ne (AMP 40)		
d-Amphetamine	40	ß-Phenylethylamine	20,000
d/I-Amphetamine	80	-Amphetamine	20,000
p-Hydroxyamphetamine	80	Methoxyphenamine	10,000
(+)3,4-Methylenedioxyamphetamine (MDA)	80	Tryptamine	10,000
Amphetamir	ne (AMP 25)		<u> </u>
d-Amphetamine	25	ß-Phenylethylamine	12,500
d/l-Amphetamine	50	I-Amphetamine	12,500
p-Hydroxyamphetamine	50	Methoxyphenamine	6,250
(+)3,4-Methylenedioxyamphetamine (MDA)	50	Tryptamine	6,250

d-Amphetamine	(AMP 20		1 2= -
d/l-Amphetamine	20	ß-Phenylethylamine	10,00
	40	l-Amphetamine	10,00
p-Hydroxyamphetamine	40	Methoxyphenamine	5,00
(+)3,4-Methylenedioxyamphetamine (MDA) Methamphetami	40	Tryptamine	5,00
d-Methamphetamine			
Fenfluramine	50	Procaine	2,000
p-Hydroxymethamphetamine	60,000		
Methoxyphenamine	400	Ephedrine	400
3,4-Methylenedioxymethamphetamine (MDMA)	25,000		25,00
I-Phenylephrine (R)-(-)-Phenylephrine	50	Mephentermine	1,500
Methamphetami	6,250	<u> </u>	
d-Methamphetamine			
Fenfluramine	36,000	Procaine (AP 20)	1,200
p-Hydroxymethamphetamine	36,000	V	250
Methoxyphenamine	250	Ephedrine	250
3,4-Methylenedioxymetham-	15,000	Benzphetamine	15,00
phetamine (MDMA)	30	Mephentermine	900
I-Phenylephrine (R)-(-)-Phenylephrine	2.750	- 	<u> </u>
Methamphetamic	3,750		
d-Methamphetamine			1 2 2 2 2
Fenfluramine	25	Procaine	1,000
p-Hydroxymethamphetamine	30,000	<u> </u>	200
Methoxyphenamine	200	Ephedrine	200
3,4-Methylenedioxymetham-	12,500	Benzphetamine	12,500
phetamine (MDMA)	25	Mephentermine	750
-Phenylephrine (R)-(-)-Phenylephrine	2 500	-	
	3,500	_ _	<u> </u>
Marijuana (T 11-nor-Δ ⁹ -THC-9 COOH	-,	1.8	T
Cannabinol	50	Δ ⁸ -THC	25,000
	50,000	Δ ⁹ -THC	40,000
11-nor-Δ ⁸ -THC-9 COOH	40	<u> </u>	<u> </u>
Marijuana (T		1.8	
11-nor-Δ ⁹ -THC-9 COOH	40	Δ ⁸ -THC	20,000
Cannabinol	40,000	Δ ⁹ -THC	32,000
1-nor-Δ ⁸ -THC-9 COOH	32		
Marijuana (T	HC 30)		
1-nor-Δ ⁹ -THC-9 COOH	30	Δ ⁸ -THC	15,000
Cannabinol	30,000	Δ ⁹ -THC	24,000
1-nor-Δ ⁸ -THC-9 COOH	25	·	
Marijuana (T	HC 25)		-
1-nor-Δ ⁹ -THC-9 COOH	25	Λ ⁸ -THC	10,000
Cannabinol	20,000	Δ ⁹ -THC	17,000
1-nor-Δ ⁸ -THC-9 COOH	25		17,000
Marijuana (T			<u> </u>
1-nor-Δ ⁹ -THC-9 COOH	20	Δ ⁸ -THC	10,000
annabinol	20,000	Δ ⁹ -THC	
1-nor-Δ ⁸ -THC-9 COOH	 	A -1 TC	17,000
Marijuana (T	15	<u> </u>	<u></u>
1-nor-Δ ⁹ -THC-9 COOH		1.8	T
annabinol	15	Δ ⁸ -THC	6,000
1-nor-Δ ⁸ -THC-9 COOH	12,500	Δ ⁹ -THC	10,000
	12		
Marijuana (TI 1-nor-Δ ⁹ -THC-9 COOH	1		···········
	12	Δ ⁸ -THC	6,000
annabinol	12,500	Δ ⁹ -THC	10,000
1-nor-Δ ⁸ -THC-9 COOH	12	<u></u>	
Cocaine (CO	C 50)		
enzoylecgonine	50	Ecgonine	3,750
ocaine		Ecgonine methyl ester	30,000
ocaethylene	75		
Cocaine (CO			
enzoylecgonine	_	Ecgonine	3,000
ocaine		Ecgonine methyl ester	25,000
ocaethylene	30		
Cocaine (CO			
enzoylecgonine		Ecgonine	2,250
ocaine		Ecgonine methyl ester	18,750
ocaethylene	45		
Cocaine (CO			
enzoylecgonine	20	Ecgonine	1,500
ocaine	-	Ecgonine methyl ester	12,500
ocaethylene	30		- , -
Oplates/Morphine (C	PI/MOP 5	iO)	-
ambiae		Norcodeine	6,500
orphine odeine		1 10 0000110	ບ,ວນປ ເ

Ethylmorphine	30	Nalorphine	12,50
Hydromorphine	125	Oxymorphone	30,00
Hydrocodone	125	Thebaine	2,500
Diacetylmorphine(Heroin)	50	Levorphanol	600
Oxycodone	30,000		
Morphine 3-β-D-Glucuronide	50		
Morphine Opiates/Morph			
Codeine	40	Norcodeine	6,250
Ethylmorphine	25 25	Normorphine Nalorphine	25,00
Hydromorphine	100	Oxymorphone	10,00 25,00
Hydrocodone	100	Thebaine	2,000
Diacetylmorphine (Heroin)	50	Levorphanol	400
Oxycodone	25,000	6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50		
Opiates/Morpl Morphine			1
	25	Morphine 3-β-D-Glucuronide	40
Codeine	20	Norcodeine	4,250
Ethylmorphine	20	Normorphine	17,000
Hydromorphine	70		
Hydrocodone	70	Nalorphine Oxymorphone	7,000
Levorphanol	300	Thebaine	17,000
Oxycodone	17,000		40
		(Heroin)	"
6-Monoacetylmorphine	20		
Opiates/Morph Morphine			
INIOI DI III IE	20	Morphine	25
Codeine	15	3-β-D-Glucuronide	0.000
Ethylmorphine	15	Norcodeine Normorphine	3,200
Hydromorphine	50	Nalorphine	12,500 5,000
Hydrocodone	50	Oxymorphone	12,500
Levorphanol	200	Thebaine	1,000
Oxycodone	12,500	Diacetylmorphine	25
6-Monoacetylmorphine		(Heroin)	<u> </u>
Opiates/Morph	15 Inc (ODI/MOD	40)	<u>L </u>
Morphine	10	10) Morphine	20
·	'0	3-β-D-Glucuronide	20
Codeine	12	Norcodeine	2,500
Ethylmorphine	12	Normorphine	10,000
Hydromorphine	30	Nalorphine	3,000
-tydrocodone -evorphanol	30	Oxymorphone	10,000
Dxycodone		Thebaine	800
JAYOOGOI IG	10,000	Diacetylmorphine (Heroin)	20
-Monoacetylmorphine	12	(meroin)	
Phencyclid	ine (PCP 10)	<u> </u>	
I-Hydroxyphencyclidine	2,500	Phencyclidine	10
Oxycodor	ne (OXY 20)		
Oxycodone Oxymorphone		Hydromorphone	10,000
evorphanol		Naloxone	5,000
lydrocodone	10,000 1,500	Naltrexone	5,000
	ne (OXY 40)		
Oxycodone		Hydromorphone	20,000
Dxymorphone	T	Naloxone	10,000
evorphanol		Naltrexone	10,000
·	3,000		
	- INVV EN		···
Oxycodon			25,000
xycodone	50		20,000
Oxycodone Oxymorphone	50 100	Naloxone	12,500
Oxycodone Oxymorphone evorphanol	50 100 25,000		
Oxycodone Oxymorphone evorphanol lydrocodone	50 100 25,000 3,750	Naloxone	12,500
Oxycodone Oxymorphone evorphanol lydrocodone Cotinine	50 100 25,000 3,750 (COT 20)	Naloxone Naltrexone	12,500 12,500
Oxycodone Oxymorphone evorphanol lydrocodone Oxymorphone Synthetic Mar	50 100 25,000 3,750 (COT 20)	Naloxone	12,500
Oxycodone Oxymorphone evorphanol lydrocodone Cotinine Cotinine Synthetic Mar	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25)	Naloxone Naltrexone (-)-Nicotine	12,500 12,500
Oxycodone Oxymorphone evorphanol lydrocodone Cotinine Cotinine Synthetic Mar	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25)	Naltrexone (-)-Nicotine JWH-018 4-Hydroxypentyl	12,500 12,500
Oxycodone Oxycodone Oxymorphone evorphanol Oydrocodone	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25)	Naltrexone Naltrexone -)-Nicotine JWH-018 4-Hydroxypentyl metabolite	12,500 12,500 300
Oxycodone Oxymorphone evorphanol lydrocodone Oxymorphone Synthetic Mar WH-018 5-Pentanoic acid metabolite	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25)	Naltrexone (-)-Nicotine JWH-018 4-Hydroxypentyl metabolite JWH-018	12,500 12,500 300 200
Oxycodone Oxymorphone evorphanol lydrocodone Cotinine	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25) 25	Naloxone Naltrexone -)-Nicotine JWH-018 4-Hydroxypentyl metabolite JWH-018 5-Hydroxypentyl	12,500 12,500 300
Oxycodone Oxymorphone evorphanol lydrocodone Oxymorphone Synthetic Mar WH-018 5-Pentanoic acid metabolite	50 100 25,000 3,750 (COT 20) 20 ijuana (K2-25) 25	Naltrexone (-)-Nicotine JWH-018 4-Hydroxypentyl metabolite JWH-018	12,500 12,500 300 200

a-hydroxyalprazolam				<u> </u>
Signate Sign	Alprazolam	25	Estazolam	1,000
Chrodiazepoxide		• 		+
Ciobazam		 		+
Cionazepam			· <u>·</u> ·	
Ciorazepatedipolass	· · ·			+
Delorazepam				+
Desaltyfflurazepam				+
Diazepam				+
RS-Lorazepamg Curonide 25			 	
Aprazolam			mazolam	500
Aprazolam			<u> </u>	<u> </u>
Section			· · · · · · · · · · · · · · · · · · ·	T 600
Bromazepam	· · · · · · · · · · · · · · · · · · ·		*** <u>*</u>	
Chlordiazepoxide		7		+
Ciobazam				· }
Clonazepatedipotass				
Clorazepatedipotass				
Delorazepam	· · · · · · · · · · · · · · · · · · ·			
Desalkylflurazepam	· · · · · · · · · · · · · · · · · · ·		+	
Diazepam	Y - ' - '			
RS-Lorazepamglucuronide			. T	+
Benzodlazepines (BZO 20)			IIIazoraiii	300
Aprazolam			<u>L</u>	
2-hydroxyalprazolam	· · · · · · · · · · · · · · · · · · ·	 	}**	400
Bromazepam			}	
Chlordiazepoxide				
10			 	+
Clorazepatedipotass 25				
Solid	· · · · · · · · · · · · · · · · · · ·		**	
Desalkyflurazepam	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·	
Desalkyffurazepam	· · · · · · · · · · · · · · · · · · ·			
Diazepam				
RS-Lorazepamglucuronide	······································			
Benzodiazepines (BZO 10)	\$		THEZOIGHT	200
Alprazolam				<u>'</u>
a-hydroxyaiprazolam 80 Flunitrazepam 10 Bromazepam 40 (±) Lorazepam 150 Chlordiazepoxide 40 Midazolam 300 Clobazam 10 Nitrazepam 10 Clonazepatedipotass 20 Norchlordiazepoxide 10 Delorazepam 40 Oxazepam 40 Delorazepam 10 Temazepam 10 Desalkyffurazepam 10 Temazepam 10 Diszepam 80 Triazolam 150 RS-Lorazepamglucuronide 10 Triazolam 150 RS-Lorazepamglucuronide 10 Triazolam 150 Methadone Methadone (MTD 30) Methadone 150 Methadone Methadone (MTD 30) Mor-LAAM 20 Methadone Methadone (MTD 50) Methadone Mor-LAAM 12,500 Methadone 50 LAAM 350 20,000 Methadone 50 LAAM 350 350 Disopyramid	**************************************		Estazolam	300
Bromazepam	· · · · · · · · · · · · · · · · · · ·			
Chlordiazepoxide 40 Midazolam 300 Clobazam 10 Nitrazepam 10 Clonazepam 20 Norchlordiazepoxide 10 Clorazepatedipotass 20 Nordiazepam 40 Delorazepam 40 Oxazepam 10 Desalkylflurazepam 10 Ternazepam 10 RS-Lorazepamglucuronide 10 Triazolam 150 RS-Lorazepamglucuronide 10 Triazolam 150 Methadone 30 LAAM 200 Methadone 30 LAAM 200 Disopyramide 400 Doxylamine 12,500 Methadone 50 LAAM 350 Disopyramide 700 Doxylamine 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM				
Clonazepam				
Clonazepam			174	 -
Clorazepatedipotass 20 Nordiazepam 40	· · · · · · · · · · · · · · · · · · ·			·····
Desalkylflurazepam			· · · · · · · · · · · · · · · · · · ·	
Desalkylflurazepam		· •		
Diazepam 80 Triazolam 150 RS-Lorazepamglucuronide 10			<u> </u>	
Methadone Meth				
Methadone (MTD 30) Methadone 30 LAAM 200 Disopyramide 400 Doxylamine 12,500 (+)-Chlorpheniramine 6,250 Nor-LAAM 12,500 Methadone (MTD 50) Methadone (MTD 50) LAAM 350 Disopyramide 700 Doxylamine 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 (±) 3,4-Methylenedioxy-methamphetamine (MDMA) 50 3,4-Methylenedioxyethylamphetamine (MDE) 30 (±) 3,4-Methylenedioxy-methamphetamine (MDE) 25,000 25,000 (±) 3,4-Methylenedioxy-methamphetamine (MDE) 45 45 (±) 3,4-Methylenedioxy-methamphetamine (MDE) 45 -Methamphetamine (MDE) 45 (±)			11102012111	
Methadone 30 LAAM 200 Disopyramide 400 Doxylamine 12,500 (+)-Chlorpheniramine 6,250 Nor-LAAM 12,500 Methadone (MTD 50) Methadone 700 Doxylamine 20,000 LAAM 350 Disopyramide 700 Doxylamine 20,000 Methylenedioxy-amine 10,000 Nor-LAAM 20,000 Methylenedioxy-methamphetamine (MDMA 50) (±) 3,4-Methylenedioxy-amphetamine HCI (MDA) 300 I-Methamphetamine (MDE) 30 Methylenedioxy-amphetamine HCI (MDMA) 75 3,4-Methylenedioxyethylamphetamine (MDE) 45 (±) 3,4-Methylenedioxy-amphetamine HCI (MDA) 450 I-Methamphetamine (MDE) 45 (±) 3,4-Methylenedioxy-amphetamine HCI (MDA) 450 I-Methamphetamine (MDE) 37,500 Ketamine (KET 30) Ketamine 20 Phencyclidine 350 Benzphetamine 625 (1R, 2S) - (-)-Ephedrine 2500 d-Methamphetamine 625 EDDP	· · · · · · · · · · · · · · · · · · ·	_	<u> </u>	<u> </u>
Disopyramide			LAAM	200
(+)-Chlorpheniramine 6,250 Nor-LAAM 12,500 Methadone Methadone (MTD 50) LAAM 350 Disopyramide 700 Doxylamine 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 Methylenedioxymethamphetamine (MDMA 50) 3,4-Methylenedioxyethylamphetamine (MDE) 3,4-Methylenedioxyethylamphetamine (MDE) 30 (±) 3,4-Methylenedioxyamphetamine HCI (MDA) 75 3,4-Methylenedioxyethylamphetamine (MDE) 45 (±) 3,4-Methylenedioxyamphetamine HCI (MDA) 450 I-Methamphetamine (MDE) 37,500 Ketamine (KET 30) Ketamine (KET 30) Ketamine (KET 30) I-Methamphetamine (MDE) 25 Clohaline (HCI (MDA) 20 Phencyclidine (MDE) 2500 25 Methoxypheniramine (MDE) 625 EDDP (Depheniramine (MDE) 2500 25 </td <td></td> <td></td> <td>· · · · · · · · · · · · · · · · · · ·</td> <td></td>			· · · · · · · · · · · · · · · · · · ·	
Methadone (MTD 50) Methadone 50 LAAM 350 Disopyramide 700 Doxylamine 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 Methylenedioxymethamphetamine (MDMA 50) (±) 3,4-Methylenedioxymethamphetamine (MDE) 30 -Methamphetamine (MDE) 30 (±) 3,4-Methylenedioxymethamphetamine (MDA) 75 3,4-Methylenedioxyethylamphetamine (MDE) 45 (±) 3,4-Methylenedioxymethamphetamine (MDE) 45 -Methamphetamine (MDE) 45 (±) 3,4-Methylenedioxymethamphetamine (MDE) -Methamphetamine (MDE) 45 -Methamphetamine (MDE) 45 (±) 3,4-Methylenedioxymethamphetamine (KET 30) -Methamphetamine (KET 30) -Methamphetamine (MDE) 37,500				
Methadone 50 LAAM 350 Disopyramide 700 Doxylamine 20,000 (+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 Methylenedioxy-methamphetamine (MDMA 50) 3,4-Methylenedioxyethyl-amphetamine (MDE) 30 -Methamphetamine (MDE) 30 (±) 3,4-Methylenedioxy-amphetamine HCI (MDA) 75 3,4-Methylenedioxyethyl-amphetamine (MDE) 45 (±) 3,4-Methylenedioxy-methamphetamine HCI (MDMA) 450 I-Methamphetamine (MDE) 45 (±) 3,4-Methylenedioxy-amphetamine HCI (MDA) 450 I-Methamphetamine (MDE) 37,500 Ketamine (KET 30) Ketamine (KET 30) Mephentermine 625 625 Ketamine (KET 30) Phencyclidine 350 350 Benzphetamine 625 20 Phencyclidine 2500 2500 G-Methamphetamine 625 250 1250 1250 I-Methamphetamine 625 2500 1250 1250 I-Methamphetamine 625 2500 1250 1250 I-Methamphetamine 625 2500 1250 1250 I-Methylenedioxy-methamphetamine 625		· · · · · · · · · · · · · · · · · · ·		12,000
Disopyramide 700			LAAM	350
(+)-Chlorpheniramine 10,000 Nor-LAAM 20,000 Methylenedioxymethamphetamine (MDMA 50) (±) 3,4-Methylenedioxymethamphetamine HCl (MDMA) 50 3,4-Methylenedioxyethylamphetamine (MDE) 30 (±) 3,4-Methylenedioxymethamphetamine HCl (MDA) 75 3,4-Methylenedioxyethylamphetamine (MDE) 45 (±) 3,4-Methylenedioxymethamphetamine HCl (MDA) 450 I-Methamphetamine (MDE) 45 (±) 3,4-Methylenedioxymethamphetamine HCl (MDA) 450 I-Methamphetamine (MDE) 37,500 Ketamine (KET 30) Ketamine (KET 30) Ketamine (KET 30) 50 50 50 50 625				
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Amphetamine HCI (MDA) 300 -Methamphetamine 25,000			· · · · · · · · · · · · · · · · · · ·	<u> </u>
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Ketamine 30 Mephentermine 625 Tetrahydrozoline 20 Phencyclidine 350 Benzphetamine 625 (1R, 2S) - (-)-Ephedrine 2500 d-Methamphetamine 625 Promazine 625 (+)Chlorpheniramine 625 EDDP 1250 I-Methamphetamine 1250 Promethazine 625 Clonidine 2500 Levorphanol 1250 Methoxyphenamine 350 Thioridazine 1250 Disopyramide 350 MDE 1250		T 30)		L
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Methoxyphenamine350Thioridazine1250Disopyramide350MDE1250	Clonidine			·-·-
Disopyramide 350 MDE 1250				
				
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Mephentermine 1,22 Benzplatamine 1,250 Mephentermine 1,250 Benzplatamine 1,250 GR, 2,5) - (-)-Ephedrine 5,00 - Methamphetamine 1,250 EDDP 2,50 - Methamphetamine 2,500 Evorphanol 2,55 - Methamphetamine 2,500 Evorphanol 2,55 - Methamphetamine 6,25 Mine 2,50 - Morpropoxyphene 6,25 Mine 2,50 - Morpropoxyphene 6,25 Mine 1,25 - Mine 1,25 Mine 1,	4-Hydroxyphencyclidine 1250 Dextromethorphan 50								
Tetrahydrozoline	Ketamine (KET 50)								
Benzpitelamine				1,250					
Admentamphetamine		+		625					
Condina			-						
Methoxyphenamine				1,250					
Clonidine	· · · · · · · · · · · · · · · · · · ·			2,500					
Methoxyphenamine				1,250					
Dispoyramide				 					
All-proposyphene				· • · · · · · · · · · · · · · · · · · ·					
A-Hydroxyphencyclidine				+					
A-Methylendioxymethamphetamine (MDMA) 5,000 Pentazocine 1,28		+							
Retamine 100				1,250					
Tetrahydrozoline				.1					
Tetrahydrozoline	Ketamine	100	Mephentermine	2,500					
d.Methamphetamine	Tetrahydrozoline	40	Phencyclidine	1,300					
	· · · · · · · · · · · · · · · · · · ·	2,500	(1R, 2S) - (-)-Ephedrine	10,000					
Methamphetamine		2,500	Promazine	2,500					
Clonidine		2,500	EDDP	5,000					
Methoxyphenamine			Promethazine	2,500					
Disopyramide				5,000					
1,300 Meperidine 1,300 Meperidine 2,500				5,000					
A-Hydroxyphencyclidine				5,000					
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Netamine Netamine		 -	<u></u>	150					
Ketamine			Pentazocine	2,500					
Tetrahydrozoline			Manharter	10					
Benzphetamine		•		3,750					
Methamphetamine		<u> </u>							
(+)Chlorpheniramine									
Methamphetamine			<u></u>						
Displayments		· ·							
Methoxyphenamine									
Disopyramide	"								
d-Norpropoxyphene 2,000 Meperidine 3,75 4-Hydroxyphencyclidine 7,500 Dextromethorphan 225 (+)3,4-Methylendioxymethamphetamine (MDMA) 15,000 Pentazocine 3,75 Amobarbital 833 Alphenol 100 5,5-Diphenylhydantoin 1,333 Aprobarbital 83 Allobarbital 10 Butabarbital 13 Barbital 1,333 Butabitial 1,333 Fentobarbital 33 Butethal 83 Cyclopentobarbital 5,000 Phenobarbital 50 Pentobarbital 1,333 Secobarbital 50 Pentoparbitial 1,333 Secobarbital 50 Buprenorphine GBUP 10 10 Norbuprenorphine 10 Norbuprenorphine									
4-Hydroxyphencyclidine 7,500 Dextromethorphan 225 (+)3,4-Methylendioxymethamphetamine (MDMA) 15,000 Pentazocine 3,75 Barbiturates (BAR 50) 833 Alphenol 100 5,5-Diphenylhydantoin 1,333 Aprobarbital 83 Allobarbital 100 Butabarbital 33 Barbital 1,333 Butethal 83 Cyclopentobarbital 5,000 Phenobarbital 50 Pentobarbital 1,333 Secobarbital 50 Pentobarbital 1,333 Secobarbital 50 Pentobarbital 5,000 Phenobarbital 50 Buprenorphine (BUP 10) Buprenorphine (BUP 10) Buprenorphine 3-D-Glucuronide 50 Buprenorphine 10 Norbuprenorphine 3-D-Glucuronide 25 Buprenorphine 50 Norbuprenorphine 3-D-Glucuronide 25 Buprenorphine 5 Norbuprenorphine 3-D-Glucuronide 25 Buprenorphine 5 Norbuprenorphine 3-D-Glucuronide 50 Norbuprenorphine 5 </td <td></td> <td>· · · · · · · · · · · · · · · · · · ·</td> <td></td> <td>-</td>		· · · · · · · · · · · · · · · · · · ·		 -					
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Amobarbital 833		 	V OITELEOUTIO	0,700					
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Barbital	······································								
Talbutal	Barbital			1,333					
Cyclopentobarbital 5,000 Phenobarbital 50 Pentobarbital 1,333 Secobarbital 50 Buprenorphine (BUP 10) Buprenorphine 10 Buprenorphine 3-D-Glucuronide 100 Norbuprenorphine 50 Buprenorphine 3-D-Glucuronide 25 Buprenorphine 5 Norbuprenorphine 3-D-Glucuronide 25 Buprenorphine 5 Norbuprenorphine 3-D-Glucuronide 50 Norbuprenorphine 5 Norbuprenorphine 3-D-Glucuronide 60 Phencyclidine 30,00 50 Norbuprenorphine 15 30 6-D-Gurandia 15 30 30 30 6-Monoac	Talbutai	33	Butethal						
Buprenorphine (BUP 10)	Cyclopentobarbital	5,000	Phenobarbital						
Buprenorphine 3-D-Glucuronide	Pentobarbital	1,333	Secobarbital	50					
Norbuprenorphine 3-D-Glucuronide 100 Norbuprenorphine 50		BUP 10)							
Buprenorphine (BUP 5)				10					
Buprenorphine 3-D-Glucuronide 25 Buprenorphine 5 Norbuprenorphine 3-D-Glucuronide 50 Norbuprenorphine 25			Norbuprenorphine	50					
Norbuprenorphine 3-D-Glucuronide									
Tramadol (TML 30)				-					
n-Desmethyl-cis-tramadol 60 Phencyclidine 30,00 d,i-O-Desmethylvenlafaxine 15,000 Cis-tramadol 30 o-Desmethyl-cis-tramadol 3,000 Procyclidine 30 6-Monoacethylmorphine (6-MAM 10) 6-Monoacethylmorphine (6-MAM 10) Fentanyl (FYL 50) Alfentanyl (FYL 50) Alfentanyl (FYL 50) Fentluramine 125,000 Pentanyl (FYL 30) Fentluramine (FYL 30) Buspirone 22,50 Fentluramine (FYL 20) Alfentanyl (FYL 20) Alfentanyl (FYL 20) Alfentanyl (FYL 20) Alfentanyl (FYL 10) Alfentanyl (FYL 10) Alfentanyl (FYL 10) Alfentanyl (FYL 10)	**************************************		Norbuprenorphine	25					
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Fentanyl (FYL 50)				100.000					
Alfentanyl 1,500,000 Buspirone 37,50 Fenfluramine 125,000 Fentanylf 50 Norfentanyl 10 Sufentanyl 125,00 Fentanyl (FYL 30) Alfentanyl 900,000 Buspirone 22,50 Fenfluramine 75,000 Fentanylf 30 Norfentanyl 10 Sufentanyl 125,00 Fentanyl (FYL 20) Alfentanyl 600,000 Buspirone 37,50 Fenfluramine 50,000 Fentanyl 20 Norfentanyl 8 Sufentanyl 50,00 Fentanyl (FYL 10) Alfentanyl 300,000 Buspirone 18,75			inioi burie	100,000					
Tenfluramine 125,000 Fentanylf 50			Ruspisono	27 500					
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Norfentanyl 10 Sufentanyl 125,00	······································		·						
Fentanyl (FYL 20) Alfentanyl 600,000 Buspirone 37,50 Fentluramine 50,000 Fentanyl 20 Norfentanyl 8 Sufentanyl 50,00 Fentanyl (FYL 10) Alfentanyl 300,000 Buspirone 18,75	· · · · · · · · · · · · · · · · · · ·			125,000					
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Fenfluramine 50,000 Fentanyl 20 Norfentanyl 8 Sufentanyl 50,00 Fentanyl (FYL 10) Alfentanyl 300,000 Buspirone 18,75			Buspirone	37,500					
Norfentanyl 8 Sufentanyl 50,00			*						
Fentanyl (FYL 10) Alfentanyl 300,000 Buspirone 18,75	· · · · · · · · · · · · · · · · · · ·			50,000					
Alfentanyl 300,000 Buspirone 18,75									
			Buspirone	18,750					
			Fentanyl	10					
				25,000					

Carfent	anyl (CFYL 50)						
Carfentanyl	50	Fentanyl	25				
Sufentanil	300	(±)cis-3-Methylfentanyl 50,0					
Ramifentanil	500	Butylfentanyl 200					
3, 4-methylenedioxy	ypyrovalerone (MDPV 300)					
3, 4-methylenedioxypyrovalerone	300						
alpha-Pyrrolidinovalerophenone (α-PVP 300)							
alpha-Pyrrolidinovalerophenone	300	T					
Lysergic Acid I	Diethylamide (L	SD 10)					
Lysergic Acid Diethylamide	10						
2-ethylidene-1,5-dimethyl-	3,3-diphenylpyri	rolidine (EDDP20)					
2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP)	20						

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 Multi-Drug Rapid Test when tested with at concentrations up to 100 µg/mL.

Acetaminophen d/l-Chloropheniramine Sulfamethazine

N-Acetylprocainamide Chloroquine Tetracycline Aminopyrine Clonidine Tetrahydroco

Clonidine Tetrahydrocortisone 3 (β-D-glucuronide)
I-Cotinine Thioridazine

Ampicillin Deoxycorticosterone Tolbutamide Apomorphine Diclofenac Atropine Trifluoperazine Benzoic acid Digoxin d/l-Tryptophan d/l-Brompheniramine I -Ψ-Ephedrine Uric acid Chioral-hydrate Estrone-3-sulfate Ketoprofen Chlorothiazide I(-)-Epinephrine Loperamide Chlorpromazine Meprobamate Fenoprofen Nalidixic acid Cholesterol Gentisic acid Cortisone Hydralazine Niacinamide Creatinine Norethindrone Hydrocortisone Dextromethorphan p-Hydroxytyramine Noscapine Diflunisal Oxalic acid Iproniazid Diphenhydramine Isoxsuprine Oxymetazoline β-Estradiol Penicillin-G Labetalol

Erythromycin Methylphenidate Trans-2-phenylcyclopropylamine

Perphenazine

Furosemide Naproxen Prednisolone
Hemoglobin Nifedipine d/l-Propranolol
Hydrochlorothiazide d-Norpropoxyphene d-Pseudoephedrine
o-Hydroxyhippuric acid d/l-Octopamine Quinine

IbuprofenOxolinic acidRanitidined/l-IsoproterenolPapaverineSerotoninAcetophenetidinPentazocine hydrochloride Sulindac

Acetylsalicylic acid Phenelzine Tetrahydrocortisone 3-acetate

Amoxicillin Phenylpropanolamine Thiamine 1-Ascorbic acid Prednisone d/I-Tyrosine Aspartame Triamterene d-Propoxyphene Benzilic acid Quinacrine Trimethoprim Quindine Benzphetamine Tyramine Caffeine Salicylic acid Verapamil Chloramphenicol Zomepirac

[ALCOHOL PERFORMANCE CHARACTERISTICS]

The detection limit on the **Oral Fluid Alcohol Rapid Test** is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the **Oral Fluid Alcohol Rapid Test** can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

[ALCOHOL ASSAY SPECIFICITY]

Ethyl-p-aminobenzoate Meperidine

The Oral fluid Alcohol Rapid Test will react with methyl, ethyl and allyl alcohols. 19

[ALCOHOL INTERFERING SUBSTANCES]

The following substances may interfere with the **Oral fluid Alcohol Rapid Test** when using samples other than oral fluid. The named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test.

- A. Agents which enhance color development
- Peroxidases
- Strong oxidizers
- B. Agents which inhibit color development
 - Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

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		Inde	ex of Symbols		
i	Consult instructions for use	Σ	Contains sufficient for <n> test</n>	EC REP	Authorized representative in the European Community/European Union
IVD	In vitro diagnostic medical device	\subseteq	Use-by date	(2)	Do not reuse
11-11-11	Store between 2-30 °C	LOT	Batch code	REF	Catalogue number
®	Do not use if package is damaged and consult instructions for use		Manufacturer		



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> Number: 146064707 Revision date: 2025-05-15

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