

Multi-Drug X(2-12) Drugs Rapid Test Cassette

(Oral Fluid)

Package Insert

Instruction Sheet for testing of any combination of the following drugs:
AMP/MET/COC/THC/MOP/OPI/PCP/MTD/MDMA/BZO/OXY/COT/K2/KET/BAR/BUP/
6-MAM/TML/FYL/CFYL/MDPV/α-PVP/LSD/PGB/EDDP/ALC
A rapid test for the simultaneous, qualitative detection of multiple drugs and 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 Cassette for multiple drugs and drug metabolites is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Methamphetamine (MET)	d-Methamphetamine	50
Phencyclidine (PCP)	Phencyclidine	30/25/10
Cocaine (COC)	Benzoyllecgonine	50/30/20
Marijuana (THC Parent)	Δ ⁹ -THC	50/25/20/15
Opiates (OPI/MOP)	Morphine	50/40/25
Methadone (MTD)	Methadone	30
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Oxycodone (OXY)	Oxycodone	50/40/20
Cotinine (COT)	Cotinine	30/20
Benzodiazepines (BZO)	Oxazepam	50/30/20/10
Synthetic Marijuana (K2)	JWH -018, JWH- 073	25
Ketamine (KET)	Ketamine	50
Barbiturates (BAR)	Secobarbital	50
Buprenorphine (BUP)	Buprenorphine	10/5
Tramadol (TML)	Tramadol	30
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Fentanyl (FYL)	Fentanyl	50/20
Carfentanyl (CFYL)	Carfentanyl	50
3, 4-methylenedioxypyrovalerone (MDPV)	3, 4-methylenedioxypyrovalerone	300
alpha-Pyrrolidinovalerophenone (α-PVP)	alpha-Pyrrolidinovalerophenone	300
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	10
Pregabalin (PGB)	Pregabalin	500
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	50
Test	Calibrator	Cut-off
Alcohol (ALC)	Alcohol	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) and Liquid Chromatography-tandem mass spectrometry (LC-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

The Multi-Drug Rapid Test Cassette for multiple drugs 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 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.^{1,3} Amphetamine can be detected in oral fluid for up to 72 hours after use.^{1,3}

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.^{1,3} Methamphetamine can be detected in oral fluid for up to 72 hours after use.^{1,3}

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 benzoyllecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use.^{1,3} Cocaine and benzoyllecgonine can be detected in oral fluid for up to 24 hours after use.^{1,3}

Marijuana (THC)

THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. Users may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. THC 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.^{1,3} Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.^{1,3}

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.^{1,3} 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

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 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.^{1,3}

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.^{1,3}

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.^{1,3}

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 numbness, 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 days ²

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, glucuronidation or sulfation in the liver.

6-Monoacetylmorphine (6-MAM)

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) 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,⁵ 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 have 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.⁹

Carfentanyl (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.^{1,3} 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.¹³ 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 primarily 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 2A receptors 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.

Pregabalin (PGB)

Pregabalin, also known as β-isobutyl-γ-amino butyric acid (beta-isobutyl-GABA), is a medication used to treat epilepsy, neuropathic pain, fibromyalgia, and generalized anxiety disorder.²⁰ Common side effects include: sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, and weight gain. Potentially serious side effects include angioedema, drug misuse, and an increased suicide risk.²¹ Depending on the route of administration, Pregabalin can be detected in oral fluid as early as 5-10 minutes following use.^{1,3} Pregabalin can be detected in oral fluid for up to 48 hours after use.

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

Methadone is an unusual drug in that its primary urinary 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 urine 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 urine 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 Cassette for multiple drugs and their metabolites 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】

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 drug or and drug metabolites.

【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 collector and cassette 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 Cassette 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 pouch.

【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 tube should be used with this assay. Oral fluid collected at any time of the day may be used.

When testing cards 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 Cassettes	• Collectors	• Security Seals
• Collection Tubes	• Package Insert	• Color Chart (when applicable)
Materials Required But Not Provided		

- Timer

【DIRECTIONS FOR USE】

Allow the test, 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.

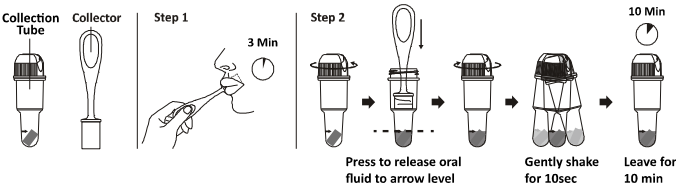
1. Sample Extraction

- ① Remove the collector from the sealed pouch and collect oral fluid specimen as follows:

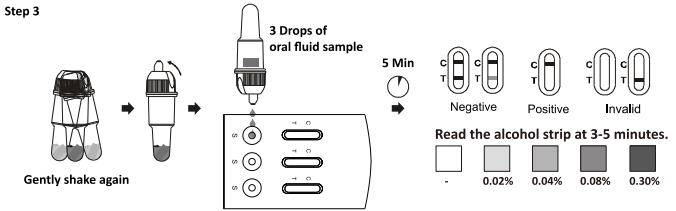
Important: Place the tongue against the upper, lower jaws and roots to enrich the oral fluid before oral fluid collection.

Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth and under the tongue and chew the sponge tenderly, place the sponge end under the tongue for a total of **2-3 minutes** until the sponge becomes fully saturated. Gently pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.

- ② Take the collection tube out of the sealed pouch and have it unscrewed. Remove the oral fluid saturated collector from the mouth and place it into the collection tube. Press sponge fully against the strainer to release oral fluid to the arrow point level and then screw it back tightly. Discard the collector.
- ③ Gently **shake the collection tube for 10 seconds** and then **leave it for 10 minutes**.



- 2. Test Reaction**
- ④ Take test cassette out from sealed pouch, place it on a clean and level surface.
- ⑤ **Again gently shake the collection tube for 10 seconds** and snap the tip open, invert it and then transfer **3 drops of oral fluid sample (approximately 120 µL)** into specimen well (S) of the test cassette. Start the timer.
- ⑥ Wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not read results after 15 minutes.
- ⑦ **For Alcohol strip, the results should be read at 3-5 minutes**. Compare the color of the reaction pad with the color chart provided separately/on foil to determine the relative alcohol level.
- ⑧ Apply a security seal over screw cap of the collection tube and send to the laboratory for confirmation if necessary.



【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 region (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 colored 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 card. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF ALCOHOL STRIP】

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 Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid chromatography-tandem mass spectrometry (LC-MS) is preferred confirmatory methods.¹⁸
- 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】

- 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 $\pm 50\%$ cut-off, $\pm 25\%$ cut-off and 300% cut-off and tested with the Multi-Drug Rapid Test Cassette. The results are summarized below.

Drug Concentration	AMP 50	MET 50	COC 30	COT 20	COT 30	BZO 50	PCP 10	THC 20
Cut-off Range	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	28	2	27	3	25	5
Cut-off	15	15	16	14	15	15	20	10
+25% Cut-off	7	23	6	24	8	22	7	23
+50% Cut-off	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30

Drug Concentration	TML 30	FYL 20	CFYL 50	BZO 30	MDPV 300	α -PVP 300	KET 50	THC 25
Cut-off Range	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	25	5	27	3
Cut-off	13	17	15	15	15	13	17	20
+25% Cut-off	7	23	3	27	7	23	4	26
+50% Cut-off	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30

Drug Concentration	OPI/ MOP 25	OPI/ MOP 40	OPI/ MOP 50	K2 25	MTD 30	OXY 20	MDMA 50	BZO 20
Cut-off Range	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	26	4	25	5
Cut-off	13	17	13	17	13	17	15	15
+25% Cut-off	7	23	7	23	7	23	4	26
+50% Cut-off	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30

Drug Concentration	BZO 10	FYL 50	COC 20	LSD 10	6-MAM 10	BAR 50	BUP 10	THC 50
Cut-off Range	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	27	3	26	4	28	2
Cut-off	13	17	15	15	15	16	14	20
+25% Cut-off	4	26	8	22	8	22	7	23
+50% Cut-off	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30

Drug Concentration	OXY 40	PGB 500	EDDP 50	PCP 30	BUP 5	PCP 25	OXY 50	COC 50	THC 15
Cut-off Range	- +	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30	0	30	0	30	0	30	0	30
-50% Cut-off	30	0	30	0	30	0	30	0	30
-25% Cut-off	27	3	25	5	27	3	25	5	26
Cut-off	20	10	15	15	14	16	14	16	15
+25% Cut-off	4	26	6	24	4	26	10	20	10
+50% Cut-off	0	30	0	30	0	30	0	30	0
300% Cut-off	0	30	0	30	0	30	0	30	0

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug Rapid Test Cassette for multiple drugs and their metabolites identified positive results at a read time of 5 minutes.

Compound	ng/mL
Amphetamine (AMP 50)	
d-Amphetamine	50
d/l-Amphetamine	100
p-Hydroxyamphetamine	100
l-Amphetamine	25,000
Methamphetamine (MET 50)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
Mephentermine	1,500
Benzphetamine	25,000
Cocaine (COC 20)	
Benzoylcegonine	20
Cocaine	20
Cocaethylene	30
Cocaine (COC 30)	
Benzoylcegonine	30
Cocaine	30
Cocaethylene	45
Cocaine (COC 50)	
Benzoylcegonine	50
Cocaine	50
Cocaethylene	75
Marijuana (THC 15)	
Δ^9 -THC	15
Cannabinol	2,000
Marijuana (THC 20)	
Δ^9 -THC	20
Cannabinol	2,000
Marijuana (THC 25)	
Δ^9 -THC	25
Cannabinol	2,000
Marijuana (THC 50)	
Δ^9 -THC	50
Cannabinol	2,000

Δ ⁹ -THC	50	11-nor-Δ ⁹ -THC-9 COOH	4
Cannabinol	3,000	Δ ⁸ -THC	80
Opiates (OPI/MOP 50)			
Morphine	50	Morphine 3-β-D-Glucuronide	50
Codeine	25	Norcodeine	6,250
Ethylmorphine	25	Normorphine	25,000
Hydromorphine	100	Nalorphine	10,000
Hydrocodone	100	Oxymorphone	25,000
Levorphanol	400	Thebaine	2,000
Oxycodone	25,000	Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine	25		
Opiates (OPI/MOP 40)			
Morphine	40	Morphine 3-β-D-Glucuronide	50
Codeine	25	Norcodeine	6,250
Ethylmorphine	25	Normorphine	25,000
Hydromorphine	100	Nalorphine	10,000
Hydrocodone	100	Oxymorphone	25,000
Levorphanol	400	Thebaine	2,000
Oxycodone	25,000	Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine	25		
Opiates (OPI/MOP 25)			
Morphine	25	Morphine 3-β-D-Glucuronide	40
Codeine	20	Norcodeine	4,250
Ethylmorphine	20	Normorphine	17,000
Hydromorphine	70	Nalorphine	7,000
Hydrocodone	70	Oxymorphone	17,000
Levorphanol	300	Thebaine	1,500
Oxycodone	17,000	Diacetylmorphine (Heroin)	40
6-Monoacetylmorphine	20		
Phencyclidine (PCP 10)			
Phencyclidine	10	4-Hydroxyphencyclidine	2,500
Phencyclidine (PCP 25)			
Phencyclidine	25	4-Hydroxyphencyclidine	6250
Phencyclidine (PCP 30)			
Phencyclidine	30	4-Hydroxyphencyclidine	7,500
Oxycodone (OXY 20)			
Oxycodone	20	Hydromorphone	10,000
Oxymorphone	40	Naloxone	5,000
Levorphanol	10,000	Naltrexone	5,000
Hydrocodone	1,500		
Oxycodone (OXY 40)			
Oxycodone	40	Hydromorphone	20,000
Oxymorphone	80	Naloxone	10,000
Levorphanol	20,000	Naltrexone	10,000
Hydrocodone	3,000		
Oxycodone (OXY 50)			
Oxycodone	50	Hydromorphone	25,000
Oxymorphone	100	Naloxone	12,500
Levorphanol	25,000	Naltrexone	12,500
Hydrocodone	3,750		
Cotinine (COT 20)			
(-)-Cotinine	20	(-)-Nicotine	300
Cotinine (COT 30)			
(-)-Cotinine	30	(-)-Nicotine	450
Synthetic Marijuana (K2-25)			
JWH-018 5-Pentanoic acid metabolite	25	JWH-018 5-Hydroxypentyl metabolite	250
JWH-073 4-butanoic acid metabolite	25	JWH-073 4-Hydroxybutyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200		
Benzodiazepines (BZO 50)			
Alprazolam	25	Flunitrazepam	25

a-hydroxylprazolam	250	(±) Lorazepam	500
Bromazepam	130	RS-Lorazepamglucuronide	25
Chlordiazepoxide	130	Midazolam	1,000
Clobazam	25	Nitrazepam	25
Clonazepam	65	Norchlordiazepoxide	25
Clorazepatedipotass	65	Nordiazepam	130
Delorazepam	130	Oxazepam	50
Desalkylflurazepam	25	Temazepam	25
Diazepam	250	Triazolam	500
Estazolam	1,000		
Benzodiazepines (BZO 30)			
Alprazolam	15	Flunitrazepam	15
a-hydroxylprazolam	150	(±) Lorazepam	300
Bromazepam	75	RS-Lorazepamglucuronide	15
Chlordiazepoxide	75	Midazolam	600
Clobazam	15	Nitrazepam	15
Clonazepam	40	Norchlordiazepoxide	15
Clorazepatedipotass	40	Nordiazepam	75
Delorazepam	75	Oxazepam	30
Desalkylflurazepam	15	Temazepam	15
Diazepam	150	Triazolam	300
Estazolam	600		
Benzodiazepines (BZO 20)			
Alprazolam	10	Flunitrazepam	10
a-hydroxylprazolam	100	(±) Lorazepam	200
Bromazepam	50	RS-Lorazepamglucuronide	10
Chlordiazepoxide	50	Midazolam	400
Clobazam	10	Nitrazepam	10
Clonazepam	25	Norchlordiazepoxide	10
Clorazepatedipotass	25	Nordiazepam	50
Delorazepam	50	Oxazepam	20
Desalkylflurazepam	10	Temazepam	10
Diazepam	100	Triazolam	200
Estazolam	400		
Benzodiazepines (BZO 10)			
Alprazolam	10	Flunitrazepam	10
a-hydroxylprazolam	80	(±) Lorazepam	150
Bromazepam	40	RS-Lorazepamglucuronide	10
Chlordiazepoxide	40	Midazolam	300
Clobazam	10	Nitrazepam	10
Clonazepam	20	Norchlordiazepoxide	10
Clorazepatedipotass	20	Nordiazepam	40
Delorazepam	40	Oxazepam	10
Desalkylflurazepam	10	Temazepam	10
Diazepam	80	Triazolam	150
Estazolam	300		
Methadone (MTD 30)			
Methadone	30	LAAM	200
Disopyramide	400	Doxylamine	12,500
(+)-Chlorpheniramine	6,250	Nor-LAAM	12,500
Methylenedioxyamphetamine (MDMA 50)			
(±)3,4-Methylenedioxy-Methamphetamine HCl (MDMA)	50	3,4-Methylenedioxyethyl- amphetamine (MDE)	30
(±) 3,4-Methylenedioxyam- phetamine HCl (MDA)	300	-Methamphetamine	25,000
Ketamine (KET 50)			
Ketamine	50	(1R, 2S) - (-)-Ephedrine	5,000
Tetrahydrozoline	20	Promazine	1,250
Benzphetamine	1,250	4-Hydroxyphencyclidine	2,500
d-Methamphetamine	1,250	Promethazine	1,250
(+)-Chlorpheniramine	1,250	Levorphanol	2,500
l-Methamphetamine	2,500	Thioridazine	2,500

Clonidine	5,000	MDE	2,500
Methoxyphenamine	625	Meperidine	1,250
Disopyramide	625	Dextromethorphan	75
d-Norpropoxyphene	625	(+)-3,4-Methylendioxy-metham- phetamine (MDMA)	5,000
EDDP	2,500	Mephentermine	1,250
Pentazocine	1,250	Phencyclidine	625
Barbiturates (BAR 50)			
Amobarbital	833	Alphenol	100
5,5-Diphenylhydantoin	1,333	Aprobarbital	83
Allobarbital	100	Butabarbital	33
Barbital	1,333	Butalbital	1,333
Talbutal	33	Butethal	83
Cyclopentobarbital	5,000	Phenobarbital	50
Pentobarbital	1,333	Secobarbital	50
Buprenorphine (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
Buprenorphine (BUP 5)			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine 3-D-Glucuronide	25	Norbuprenorphine 3-D-Glucuronide	50
Tramadol (TML 30)			
n-Desmethyl-cis-tramadol	60	o-Desmethyl-cis-tramadol	3,000
Cis-tramadol	30	Phencyclidine	30,000
Procyclidine	30	d,l-O-Desmethylvenlafaxine	15,000
6-Monoacethylmorphine (6-MAM 10)			
6-Monoacethylmorphine	10	Morphine	100,000
Fentanyl (FYL 50)			
Alfentanyl	1500,000	Buspirone	37,500
Fenfluramine	125,000	Fentanylf	50
Norfentanyl	10	Sufentanyl	125,000
Fentanyl (FYL 20)			
Alfentanyl	600,000	Buspirone	37,500
Fenfluramine	50,000	Fentanyl	20
Norfentanyl	8	Sufentanyl	50,000
Carfentanyl (CFYL 50)			
Carfentanyl	50	Fentanyl	25
Sufentanil	300	(±)cis-3-Methylfentanyl	50,000
Ramifentanil	500	Butylfentanyl	200
3, 4-methylenedioxypropyvalerone (MDPV 300)			
3, 4-methylenedioxypropyvalerone			300
alpha-Pyrrolidinovalerophenone (α-PVP 300)			
alpha-Pyrrolidinovalerophenone			300
Lysergic Acid Diethylamide (LSD 10)			
Lysergic Acid Diethylamide			10
Pregabalin (PGB 500)			
Pregabalin			500
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 50)			
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			50

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 Cassette when tested with at concentrations up to 100 µg/mL.		
Acetaminophen	d/l-Chloropheniramine	Sulfamethazine
N-Acetylprocainamide	Chloroquine	Tetracycline
Aminopyrine	Clonidine	Tetrahydrocortisone 3 (β-D-glucuronide)
Ampicillin	I-Cotinine	Thioridazine
Apomorphine	Deoxycorticosterone	Tolbutamide
Atropine	Diclofenac	Trifluoperazine

Benzoic acid	Digoxin	d/l-Tryptophan
d/l-Brompheniramine	l -ψ-Ephedrine	Uric acid
Chloral-hydrate	Estrone-3-sulfate	Ketoprofen
Chlorothiazide	l(-)-Epinephrine	Loperamide
Chlorpromazine	Fenoprofen	Meprobamate
Cholesterol	Gentisic acid	Nalidixic acid
Cortisone	Hydralazine	Niacinamide
Creatinine	Hydrocortisone	Norethindrone
Dextromethorphan	p-Hydroxytyramine	Noscapine
Diflunisal	Iproniazid	Oxalic acid
Diphenhydramine	Isoxsuprine	Oxymetazoline
β-Estradiol	Labetalol	Penicillin-G
Ethyl-p-aminobenzoate	Meperidine	Perphenazine
Erythromycin	Methylphenidate	Trans-2-phenylcyclopropylamine hydrochloride
Furosemide	Naproxen	Prednisolone
Hemoglobin	Nifedipine	d/l-Propranolol
Hydrochlorothiazide	d-Norpropoxyphene	d-Pseudoephedrine
o-Hydroxyhippuric acid	d/l-Octopamine	Quinine
Ibuprofen	Oxolinic acid	Ranitidine
d/l-Isoproterenol	Papaverine	Serotonin
Acetophenetidin	Pentazocine hydrochloride	Sulindac
Acetylsalicylic acid	Phenelzine	Tetrahydrocortisone 3-acetate
Amoxicillin	Phenylpropanolamine	Thiamine
l-Ascorbic acid	Prednisone	d/l-Tyrosine
Aspartame	d-Propoxyphene	Triamterene
Benzilic acid	Quinacrine	Trimethoprim
Benzphetamine	Quindine	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】

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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Index of Symbols

	Consult instructions for use		Contains sufficient for <n> test		Authorized representative in the European Community/European Union
	In vitro diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30 °C		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		

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