ExactSign®

Multi-Drug Rapid Test Cup with Indicator and ALC Strip（Oral Fluid）
Package Insert
English

A rapid test for the simultaneous, qualitative detection of multiple drugs or drug metabolites in human oral fluid. For in vitro diagnostic use by healthcare professionals including professionals at point of care sites. Also applicable for workplace safety and law enforcement use.

【INTENDED USE】

The Multi-Drug Rapid Test Cup for AMP/BAR/BUP/BZO/COC/COT/FYL/KET/MDMA/MET/MTD/OPI/OXY/PCP/PPX/SMA/SMP/THC/TML/ZOP/6-MAM/ALC is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs or metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	25
Amphetamine (AMP)	d-Amphetamine	50
Barbiturates(BAR)	Secobarbital	50
Buprenorphine（BUP）	Buprenorphine	5
Buprenorphine（BUP）	Buprenorphine	10
Benzodiazepines(BZO)	Oxazepam	10
Benzodiazepines(BZO)	Oxazepam	20
Benzodiazepines(BZO)	Oxazepam	30
Cocaine (COC)	Cocaine	15
Cocaine (COC)	Cocaine	20
Cocaine (COC)	Cocaine	50
Cotinine(COT)	Cotinine	30
Cotinine(COT)	Cotinine	50
Fentanyl(FYL)	Fentanyl	10
Ketamine(KET)	Ketamine	30
Ketamine(KET)	Ketamine	50
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Methamphetamine (MET)	d-Methamphetamine	25
Methamphetamine (MET)	d-Methamphetamine	50
Methadone (MTD)	Methadone	30
Opiates (OPI)	Morphine	30
Opiates (OPI)	Morphine	40
Opiates (OPI)	Morphine	50
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	3
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	d-Propoxyphene	30
Propoxyphene (PPX)	d-Propoxyphene	50
Synthetic Marijuana(SMA/K2)	JWH-018 5-Pentanoic acid metabolite	25
Synthetic Marijuana(SMA/K2)	JWH-018 5-Pentanoic acid metabolite	30
Synthetic Marijuana K2+(AB-Pinaca)(SMP)	AB-PINACA pentanoic acid metabolite	10
Marijuana (THC15)	Δ9-THC	15
Marijuana (THC40)	Δ9-THC	40
Marijuana (THC50)	Δ9-THC	50
Tramadol(TML)	Cis-Tramadol	30
Tramadol(TML)	Cis-Tramadol	50
Zopiclone(ZOP)	Zopiclone	20
6-Monoacetylmorphine(6-MAM)	6-Monoacetylmorphine	3
6-Monoacetylmorphine(6-MAM)	6-Monoacetylmorphine	5
6-Monoacetylmorphine(6-MAM)	6-Monoacetylmorphine	10
Alcohol(ALC)	Alcohol	0.02%(20mg/dL)

This assay provides only a preliminary analytical test result. A more specific alternate chemical method should be used to confirm a preliminary positive analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse screen test result, particularly when preliminary positive results are indicated.

【SUMMARY】

The Multi-Drug Rapid Test Cup for AMP/BAR/BUP/BZO/COC/COT/FYL/KET/MDMA/MET/MTD/OPI/OXY/PCP/PPX/SMA/SMP/THC/TML/ZOP/6-MAM/ALC or 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 (AMP25)

Amphetamine is a sympathomimetic amine with therapeutic indications, especially for use in treating Attention Deficit Disorders. 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 and for as long as 72 hours after use. [1]

The AMP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the amphetamine concentration in oral fluid exceeds 25ng/mL.

Amphetamine (AMP50)

Amphetamine is a sympathomimetic amine with therapeutic indications, especially for use in treating Attention Deficit Disorders. 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 and for as long as 72 hours after use. [1]

The AMP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the amphetamine concentration in oral fluid exceeds 50ng/mL.

Barbiturates(BAR50)

Barbiturates are central nervous system 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 tootlerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months produce a clinically significant degree of physical dependence. A study of a single oral dose of one barbiturate: butalbital, phenobarbital or secobarbital showed the drug is detectable in oral fluid with 15-60 minutes of dosing and remained detectable in oral fluid for 52 hours.[5]

The BAR assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Secobarbital concentration in saliva exceeds50ng/mL.

Buprenorphine(BUP5)

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.

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.

The BUP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when Buprenorphine in saliva exceeds5 ng/mL**.**

Buprenorphine(BUP10)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is soldunder 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.

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The BUP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when Buprenorphine in saliva exceeds 10 ng/mL

Benzodiazepines (BZO10)

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, and loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

The BZO assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Oxazepam concentration in saliva exceeds 10ng/mL.

Benzodiazepines (BZO20)

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The BZO assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Oxazepam concentration in saliva exceeds 20ng/mL.

Benzodiazepines (BZO30)

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, and loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

The BZO assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Oxazepam concentration in saliva exceeds 30ng/mL.

Cocaine (COC15)

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.[2] Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use.[2]

The COC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the cocaine in oral fluid exceeds 15ng/mL.

Cocaine (COC20)

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The COC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the cocaine in oral fluid exceeds 20ng/mL.

Cocaine (COC50)

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.[2] Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use.[2]

The COC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the cocaine in oral fluid exceeds 50ng/mL.

Cotinine (COT 30)

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 saliva, 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 saliva nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing.

The window of detection for cotinine in saliva at a cutoff level of 30ng/mL is expected to be up to 1-2 days after nicotine use.

Cotinine (COT50)

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.

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The window of detection for cotinine in saliva at a cutoff level of 50ng/mL is expected to be up to 1-2 days after nicotine use.

Fentanyl(FYL10)

Fentanyl, belongs to powerful narcotics analgesics, and is a μ 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. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, 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.

The FYL assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the fentanyl concentration in saliva exceeds 10ng/mL.

Ketamine(KET30)

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.

The KET assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the ketamine concentration in saliva exceeds 30ng/mL.

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The KET assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the ketamine concentration in saliva exceeds 50ng/mL.

Methylenedioxymethamphetamine (MDMA50)

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 MDMA assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the d,l-Methylenedioxymethamphetamine concentration in saliva exceeds 50ng/mL.

Methamphetamine (MET25)

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 and for as long as 72 hours after use. [1]

The MET assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the methamphetamine concentration in oral fluid exceeds 25ng/mL.

Methamphetamine (MET50)

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 and for as long as 72 hours after use. [1]

The MET assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the methamphetamine concentration in oral fluid exceeds 50ng/mL.

Methadone (MTD30)

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 12-48hours. 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. A study 414 specimens collected from 16 donors taking therapeutic methadone at doses between 30-100 mg/day all showed saliva methadone concentrations exceeding 20 ng/mL.[4]

The MTD assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Methadone concentration in saliva exceeds 30ng/mL.

Opiates (OPI30)

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.[3] Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid than urine.

The OPI assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the morphine concentration in oral fluid exceeds 30ng/mL.

Opiates (OPI40)

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 oral fluid than urine.

The OPI assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the morphine concentration in oral fluid exceeds 40ng/mL.

Opiates (OPI50)

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 oral fluid than urine.

The OPI assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the morphine concentration in oral fluid exceeds 50ng/mL.

Oxycodone (OXY20)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying the baine, 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.

The OXY assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Oxycodone concentration in saliva exceeds 20ng/mL.

Phencyclidine (PCP10)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[3]

The PCP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Phencyclidine concentration in oral fluids exceeds 10ng/mL.

Phencyclidine (PCP3)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[3]

The PCP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Phencyclidine concentration in oral fluids exceeds 3ng/mL.

Propoxyphene (PPX30)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours).The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The PPX assay contained within The Multi-Drug Rapid Test Cup yields a positive result when propoxyphene in saliva exceeds 30ng/mL**.**

Propoxyphene (PPX50)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structuralsimilarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names forthe drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours).The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The PPX assay contained within The Multi-Drug Rapid Test Cup yields a positive result when propoxyphene in saliva exceeds 50ng/mL**.**

Synthetic Marijuana(SMA25)

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.

As of March 1, 2011, five cannabinoids, JWH -018, JWH- 073, CP- 47, JWH- 200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

The SMA assay contained within The Multi-Drug Rapid Test Cup yields a positive result when JWH-018 5-Pentanoic acid metabolite in saliva exceeds 25ng/mL**.**

Synthetic Marijuana(SMA30)

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The SMA assay contained within The Multi-Drug Rapid Test Cup yields a positive result when JWH-018 5-Pentanoic acid metabolite in saliva exceeds 30ng/mL**.**

Synthetic Marijuana K2+(AB-Pinaca)(SMP10)

Synthetic cannabinoids are designer drugs that are structurally different from THC (the active component of cannabis) but act in similar ways to affect the cannabinoid receptor system in the brain. Over the past few years, this class of designer drugs has mainstreamed to become globally popular and increasingly problematic. Synthetic cannabinoids fall into seven major structural groups:

1 .Naphthoylindoles (e.g. JWH-018, JWH-073)
2. Naphthylmethylindoles (JWH-175, JWH-184, JWH-185, JWH-199)
3 .Naphthoylpyrroles (JWH-145, JWH-146, JWH-147, etc)
4. Naphthylmethylindenes (JWH-176)
5. Phenylacetylindoles (JWH-250, JWH-251, JWH-302)
6. Cyclohexylphenols (e.g. CP 47,497)
7. Dibenzopyrans (classic cannabinoid structure such as. HU-210 and HU-211)

New structural group: Aminoalkylindazoles (AB-PINACA, AB-FUBINACA, AB-CHMINACA, etc)

In their original, chemical state, synthetic cannabinoids are liquid. The drugs are usually sold combined with dried herbs that emulate marijuana and are intended for smoking although powdered versions are also available. As laws are written to control these drugs with each new synthetic cannabinoid class as they are introduced to the market, the older versions (JWH-018,JWH-073) are seen less frequently than years past. The current trend shows theaminoalkylindazole based drugs such as AB-PINACA, AB-FUBINACA and AB-CHMINACA.

The SMP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the AB-PINACA pentanoic acid metabolite concentration in oral fluid exceeds 10ng/mL.

Marijuana (THC15)

THC (Δ9-tetrahydrocannabinol)is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slow learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders.

The parent THC also known as Δ9-THC is present in oral fluid after use.

The THC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Δ9-THC concentration in oral fluid exceeds 15ng/mL.

Marijuana (THC40)

THC (Δ9-tetrahydrocannabinol)is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slow learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders.

The parent THC also known as Δ9-THC is present in oral fluid after use.

The THC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Δ9-THC concentration in oral fluid exceeds 40ng/mL.

Marijuana (THC50)

THC (Δ9-tetrahydrocannabinol)is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slow learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders.

The parent THC also known as Δ9-THC is present in oral fluid after use.

The THC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the Δ9-THC concentration in oral fluid exceeds 50ng/mL.

Tramadol(TML30)

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. The major pathways appear to be N- and O- demethylation, glucuronidation or sulfation in the liver.

The TML assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the tramadol concentration in oral fluid exceeds 30ng/mL.

Tramadol(TML50)

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. The major pathways appear to be N- and O- demethylation, glucuronidation or sulfation in the liver.

The TML assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the tramadol concentration in oral fluid exceeds 50ng/mL.

Zopiclone(ZOP20)

Zopiclone is a kind of benzodiazepines sedative hypnotics, tell from the chemistry, it belongs to cyclopyrrolidone, it combines with Benzodiazepine receptor in part of GABA receptor, it is absorbed rapidly after oral administration, reaches its peak concentration in plasma 1-1.5 hours later, the oral bioavailability is close to 80%.45%-80% of zopiclone binds with plasma protein and is widely distributed throughout the body. Its concentration in saliva is higher than that in plasma. Its bitter taste is proportional to the concentration in saliva. Since zopiclone was applied in clinic in 1985, its abuse and addiction tendency have been a controversial topic. Some studies have pointed out that its risk is low or small, but at the same time, in different countries, there are more and more individual reports of abuse, addiction and withdrawal complications.

The ZOP assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the zopiclone concentration in oral fluid exceeds 20ng/mL.

6-Monoacetylmorphine (6-MAM3)

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 active3-Monoacetylmorphine (3-MAM). 6-MAM occurs as a metabolite of heroin, which is rapidly created from heroin in the body. Heroin is rapidly metabolized by esterase enzymes in the brain and has an extremely short half-life. It has also relatively weak affinity to μ-opioid receptors because the 3-hydroxy group, essential for effective binding to the receptor, is masked by the acetyl group. Therefore, heroin acts as a pro-drug, serving as a lipophilic transporter for the systemic delivery of morphine, which actively binds with μ-opioid receptors.

The 6-MAM assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the 6-Monoacetylmorphine concentration in oral fluid exceeds 3ng/mL.

6-Monoacetylmorphine (6-MAM5)

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 active3-Monoacetylmorphine (3-MAM). 6-MAM occurs as a metabolite of heroin, which is rapidly created from heroin in the body. Heroin is rapidly metabolized by esterase enzymes in the brain and has an extremely short half-life. It has also relatively weak affinity to μ-opioid receptors because the 3-hydroxy group, essential for effective binding to the receptor, is masked by the acetyl group. Therefore, heroin acts as a pro-drug, serving as a lipophilic transporter for the systemic delivery of morphine, which actively binds with μ-opioid receptors.

The 6-MAM assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the 6-Monoacetylmorphine concentration in oral fluid exceeds 5ng/mL.

6-Monoacetylmorphine (6-MAM10)

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 active3-Monoacetylmorphine (3-MAM). 6-MAM occurs as a metabolite of heroin, which is rapidly created from heroin in the body. Heroin is rapidly metabolized by esterase enzymes in the brain and has an extremely short half-life. It has also relatively weak affinity to μ-opioid receptors because the 3-hydroxy group, essential for effective binding to the receptor, is masked by the acetyl group. Therefore, heroin acts as a pro-drug, serving as a lipophilic transporter for the systemic delivery of morphine, which actively binds with μ-opioid receptors.

The 6-MAM assay contained within The Multi-Drug Rapid Test Cup yields a positive result when the 6-Monoacetylmorphine concentration in oral fluid exceeds 10ng/mL.

Alcohol(ALC)

Two-thirds of all adults drink alcohol. However, alcohol intoxication can lead to loss of alertness, coma, death and birth defects. The blood alcohol concentration (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02%(20mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids.

The ALC assay contained within The Multi-Drug Rapid Test Cup yields a positive result when ethyl alcohol in saliva exceeds 0.02%(20mg/dL).

【ASSAY PRINCIPLE】

The Multi-Drug Rapid Test Cup for AMP/BAR/BUP/BZO/COC/COT/FYL/KET/MDMA/MET/MTD/OPI/OXY/PCP/PPX/SMA/SMP/THC/TML/ZOP/6-MAM 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.

The Alcohol Strip (Saliva) is based on the high specificity of alcohol oxidase (ALOx)/peroxidaseact on ethyl alcohol and enzyme substrate such as tetramethylbenzidine (TMB). The principle are showed below:

$$EtOH + TMB \xrightarrow{ALOx/Peroxidase} CH3CHO + Colored\ TMB.$$

【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 Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Cotinine, Fentanyl, Ketamine, Methylenedioxymethamphetamine, Methamphetamine, Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Synthetic Marijuana, AB-Pinaca, THC, Tramadol, Zopiclone and 6-Monoacetylmorphinerespectively.

For alcohol strip, the reagents contain Tetramethylbenzidine(TMB), Alcohol Oxidase, Peroxidase Alcohol Oxidase and other additives.

【PRECAUTIONS】

1. Do not use after the expiration date.
2. The test should remain in the sealed pouch until use.
3. Saliva is not classified as biological hazard unless derived from a dental procedure.
4. The used collector and cup should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C. The product contains alcohol strip should be stored in the sealed pouch at 2-27°C, if storage temperature exceeds 27°C, the test performance may degrade. The test is stable through the expiration date printed on the sealed pouch. The test cups must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

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

【MATERIALS】

Materials Provided

Test cups	Collectors	Package insert
Procedure Card	Color card(When for alcohol strip)	

Materials Required but Not Provided

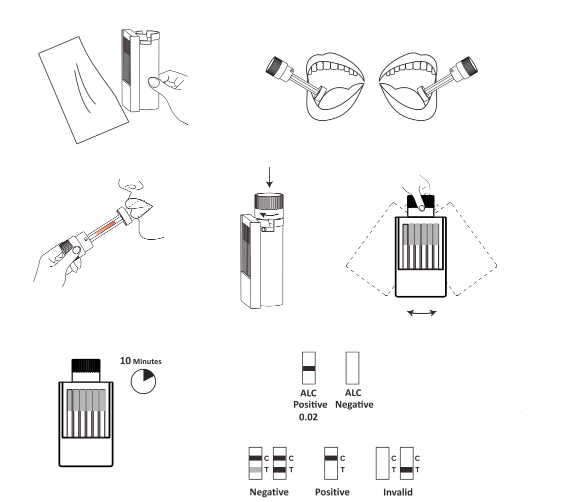
Timer

【DIRECTIONS FOR USE】

Allow the test cup, specimen, and/or controls to reach room temperature (15-27°C) prior to testing. Instruct the donor do 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 of opening.
2. Remove the test cup from the sealed pouch and instruct the donor to place the tongue against the root of the upper or lower jaw , pool saliva in mouth.
3. Instruct the donor to place the sponge between their lower cheek and gums and rub it back and forth between the left and right cheeks and gums respectively until the sponge is fully saturated with saliva. Do not bite, suck, or chew on the sponge, or it may break.
4. Approximately 4 minutes the sponge becomes fully saturated. At the same time, the color of indicator will be changed from colorless to pink.
5. Remove the collector from the mouth. Place saturated oral fluid collector into chamber and press sponge fully against the strainer to collect oral fluid.
6. Secure the cap, shake three times, and start the timer.See illustration below.
7. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not read results after 20 minutes.
8. For alcohol strip, read the result at two(2) minutes, compare the color of the reaction pad with the color card to determine the relative saliva alcohol level.

Note:The saliva collector may have a slight taste that varies from person to person because it has been pre-treated to stimulate saliva secretion.



【INTERPRETATION OF RESULTS】

(Please refer to the previous illustration)

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE**: The shade of color in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

Alcohol Strip:

Positive: Alcohol Strip (Saliva) produce a color change based on the presence of saliva alcohol. The color ranges from light blue color(0.02%(20mg/dL))to dark blue(0.30%).

NOTE: Alcohol Strip (Saliva) is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as positive but less than 0.02%(20mg/dL).

Negative: Alcohol Strip (Saliva) shows no color change. It means alcohol is not detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

【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 adequate membrane wicking.

【LIMITATIONS】

1. The Multi-Drug Rapid Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method should be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
2. 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 Strip

1. The saliva sample should be collected 15 minutes after in taking food, drink, or other materials (including smoking), the residual may affect the test results.
2. Some household products, such as disinfectant, deodorizers, perfumes, and glass cleaners, contain alcohol, these factors should be excluded before testing.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

【EXPECTED VALUES】

This negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

Assemble each single test into the cup before testing, and evaluate the cup with approximately 44-280 specimens per drug type previously collected from subjects presenting for Drug Screen Testing which were confirmed by GC/MS. These specimens were randomized and tested using The Multi-Drug Rapid Test Cup. Specimens were rated as either positive or negative at 10 minutes. The test results are shown in table below.

Table: Specimen Correlation

Method		GC/MS		% agreement with GC/MS	% Total agreement with GC/MS
Multi-Drug Rapid Test Cup		Positive	Negative		
AMP 25	Positive	56	2	96.6%	97.5%
	Negative	2	100	98.0%	
AMP 50	Positive	90	6	94.7%	94.8%
	Negative	5	109	94.8%	
BAR50	Positive	80	6	96.4%	95.7%
	Negative	3	121	95.3%	
BUP5	Positive	86	5	95.6%	95.7%
	Negative	4	115	95.8%	
BUP 10	Positive	86	5	95.6%	95.7%
	Negative	4	115	95.8%	
BZO10	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
BZO20	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
BZO 30	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
COC15	Positive	41	0	>99%	>99%
	Negative	0	109	>99%	
COC20	Positive	38	2	92.7%	96.7%
	Negative	3	107	98.2%	
COC50	Positive	38	2	92.7%	96.7%
	Negative	3	107	98.2%	
COT30	Positive	131	2	99.2%	98.7%
	Negative	1	96	98.0%	
COT 50	Positive	131	2	99.2%	98.7%
	Negative	1	96	98.0%	
FYL10	Positive	53	1	98.1%	96.7%
	Negative	4	92	95.8%	
KET 30	Positive	49	3	94.2%	94.5%
	Negative	5	88	94.6%	
KET 50	Positive	90	6	93.8%	94.8%
	Negative	5	109	95.6%	
MDMA50	Positive	96	1	97.0%	98.3%
	Negative	3	130	99.2%	
MET 25	Positive	43	2	95.6%	96.4%
	Negative	3	92	96.8%	
MET 50	Positive	126	4	99.2%	98.2%
	Negative	1	149	97.4%	
MTD 30	Positive	116	3	97.5%	97.4%
	Negative	3	108	97.3%	
OPI 30	Positive	61	3	95.3%	96.8%
	Negative	2	89	97.8%	
OPI40	Positive	89	7	93.7%	93.8%
	Negative	6	108	93.9%	
OPI50	Positive	89	7	93.7%	93.8%
	Negative	6	108	93.9%	
OXY 20	Positive	91	1	97.8%	98.7%
	Negative	2	136	99.3%	
PCP 3	Positive	107	2	96.4%	97.4%
	Negative	4	117	98.3%	
PCP 10	Positive	107	2	96.4%	97.4%
	Negative	4	117	98.3%	
PPX 30	Positive	92	3	95.8%	96.7%
	Negative	4	111	97.4%	
PPX 50	Positive	92	3	95.8%	96.7%
	Negative	4	111	97.4%	
SMA 25	Positive	52	2	92.9%	96%
	Negative	4	92	97.9%	
SMA 30	Positive	52	2	92.9%	96%
	Negative	4	92	97.9%	
SMP 10	Positive	4	0	>99%	>99%
	Negative	0	40	>99%	
THC 15	Positive	75	5	96.2%	96.8%
	Negative	3	167	97.1%	
THC 40	Positive	84	1	>99%	99.6%
	Negative	0	165	99.4%	
THC 50	Positive	75	5	96.2%	96.8%
	Negative	3	167	97.1%	
TML 50	Positive	80	6	96.4%	95.7%
	Negative	3	121	95.3%	
TML 30	Positive	89	0	>99%	>99%
	Negative	0	121	>99%	
ZOP 20	Positive	36	0	>99%	>99%
	Negative	0	114	>99%	
6-MAM 3	Positive	36	0	>99%	>99%
	Negative	0	128	>99%	
6-MAM 5	Positive	36	0	>99%	>99%
	Negative	0	128	>99%	
6-MAM 10	Positive	36	0	>99%	>99%
	Negative	0	128	>99%	

Alcohol Strips

Alcohol Strip(Saliva)	Results	>0.02%(Spiked)	0	Total Results
	Positive	30	0	30
	Negative	1	29	30
Total Results		31	29	60

% Agreement	97%	100%	98%

Analytical Sensitivity

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

Drug conc. (Cut-off range)	n	AMP25		AMP50		BAR50		BUP5	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	26	4	27	3
Cut-off	30	15	15	15	15	19	11	15	15
+25% Cut-off	30	4	26	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	BUP 10		BZO10		BZO20		BZO30	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	27	3	27	3
Cut-off	30	15	15	15	15	15	15	15	15
+25% Cut-off	30	7	23	7	23	7	23	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	COC15		COC20		COC50		COT30	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	25	5	25	5	27	3
Cut-off	30	15	15	15	15	15	15	20	10
+25% Cut-off	30	5	25	3	27	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	COT50		FYL10		KET30		KET50	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	24	6	8	2	25	5
Cut-off	30	16	14	15	15	5	5	16	14
+25% Cut-off	30	6	24	3	27	1	9	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	MDMA50		MET25		MET50		MTD30	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	24	6	28	2	27	3
Cut-off	30	20	10	14	16	16	4	13	17
+25% Cut-off	30	7	23	4	26	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	OPI30		OPI40		OPI50		OXY20	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	27	3	25	5
Cut-off	30	14	16	15	15	15	15	15	15
+25% Cut-off	30	4	26	8	22	8	22	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	PCP3		PCP10		PPX30		PPX50	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	26	4	25	5	25	5
Cut-off	30	14	16	14	16	15	15	15	15
+25% Cut-off	30	5	25	5	25	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	SMA25		SMA30		SMP10		THC15	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	26	4	27	3	26	4
Cut-off	30	15	15	15	15	15	15	12	18
+25% Cut-off	30	4	26	4	26	3	27	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	THC40		THC50		TML30		TML50	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	27	3	25	5	26	4
Cut-off	30	12	18	12	18	14	16	14	16
+25% Cut-off	30	8	22	5	25	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	ZOP20		6-MAM 3		6-MAM 5		6-MAM10	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	25	5	25	5	27	3
Cut-off	30	14	16	15	15	14	16	14	16
+25% Cut-off	30	4	26	4	26	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the cutoff concentration of compounds (ng/mL) above which will be detected by The Multi-Drug Rapid Test Cup for AMP/BAR/BUP/BZO/COC/COT/FYL/KET/MDMA/MET/MTD/OPI/OXY/PCP/PPX/SMA/SMP/THC/TML/ZOP/6-MAM/ALC at a read time of 10 minutes, respectively.

Compound	ng/mL	Compound	ng/mL
AMPHETAMINE (AMP25)			
D-Amphetamine	25	p-Hydroxyamphetamine	200
D,L-Amphetamine	500	(+)3,4-Methylenedioxyamphetamine (MDA)	250
L-Amphetamine	35,000		
AMPHETAMINE (AMP50)			
D-Amphetamine	50	p-Hydroxyamphetamine	400
D,L-Amphetamine	1,000	(+)3,4-Methylenedioxyamphetamine (MDA)	500
L-Amphetamine	70,000		
BARBITURATES(BAR50)			
Amobarbital	250	Pentobarbital	70
Aprobarbital	80	Phenobarbital	30
Butabarbital	25	Secobarbital	50
Butalbital	500		
BUPRENORPHINE(BUP5)			
Norbuprenorphine	90	Buprenorphine	5
Buprenorphine-3-β-D-glucuronide	50	Norbuprenorphine-3-β-D-glucuronide	300
BUPRENORPHINE(BUP10)			
Norbuprenorphine	180	Buprenorphine	10
Buprenorphine-3-β-D-glucuronide	100	Norbuprenorphine-3-β-D-glucuronide	600
BENZODIAZEPINES(BZO10)			
Oxazepam	10	7-Amino-clonazepam	5,000
Alprazolam	100	Bromazepam	10
Chlordiazepoxide	50	Clonazepam	1,000
Desalkylflurazepam	500	Diazepam	50
Estazolam	80	Flunitrazepam	500
Furosemide	5,000	Lorazepam	700
Midazolam	1,000	Midazolam Maleate	2,500
Nefopam	1,000	Nitrazepam	25
Norchlordiazepoxide	25	Oxolinic acid	50,000
Pheniramine	50,000	Theophylline	50,000
α-Hydroxyalprazolam	50		
BENZODIAZEPINES(BZO20)			
Oxazepam	20	7-Amino-clonazepam	10,000
Alprazolam	200	Bromazepam	20
Chlordiazepoxide	100	Clonazepam	2,000
Desalkylflurazepam	1,000	Diazepam	100
Estazolam	160	Flunitrazepam	1,000
Furosemide	10,000	Lorazepam	1,400
Midazolam	2,000	Midazolam Maleate	5,000
Nefopam	2,000	Nitrazepam	50
Norchlordiazepoxide	50	Oxolinic acid	100,000
Pheniramine	100,000	Theophylline	100,000
α-Hydroxyalprazolam	100		
BENZODIAZEPINES(BZO30)			
Oxazepam	50	7-Amino-clonazepam	25,000
Alprazolam	500	Bromazepam	50
Chlordiazepoxide	250	Clonazepam	5,000
Desalkylflurazepam	2,500	Diazepam	250
Estazolam	400	Flunitrazepam	2,500
Furosemide	25,000	Lorazepam	3,500
Midazolam	5,000	Midazolam Maleate	12,500
Nefopam	5,000	Nitrazepam	125
Norchlordiazepoxide	125	Oxolinic acid	250,000
Pheniramine	250,000	Theophylline	250,000
α-Hydroxyalprazolam	250		
COCAINE (COC15)			
Cocaine HCl	15	EcgonineHCl	45,000
Benzoylecgonine	15	Ecgonine methyl ester	75,000
Cocaethylene	550		
COCAINE (COC20)			
Cocaine HCl	20	EcgonineHCl	60,000
Benzoylecgonine	20	Ecgonine methyl ester	100,000
Cocaethylene	700		
COCAINE (COC50)			
Cocaine HCl	50	EcgonineHCl	60,000
Benzoylecgonine	50	Ecgonine methyl ester	100,000
Cocaethylene	1,750		
COTININE (COT 30)			
(-)-Cotinine	30	(-)-Nicotine	15,000
COTININE (COT 50)			
(-)-Cotinine	50	(-)-Nicotine	25,000
FENTANYL(FYL10)			
Fentanyl	10	Norfentanyl	4
Perphenazine	20,000		
KETAMINE(KET 30)			
Ketamine(KET)	30	Norketamine	400
(+/-)-Chlorpheniramine	50,000	Pantoprazole Sodium	50,000
Levorphanol	50	hydromorphpne	2,500
Meperidine（Pethidine）	50,000	Promethazine	50,000
Naloxone	10,000	d-Pseudoephedrine	100,000
Naltrexone	2,500	Phencyclidine	100
EDDP （2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine）	5,000	Tetrahydrozoline	5,000
Normorphine	50,000	Heroin (diacetylmorphine)	50,000
Oxymorphone	1,000	Methamphetamine Hydrochride	50,000
Pheniramine	50,000	R(-)-Methamphetamine	50,000
KETAMINE(KET 50)			
Ketamine(KET)	50	Norketamine	600
(+/-)-Chlorpheniramine	85,000	Pantoprazole Sodium	85,000
Levorphanol	85	hydromorphpne	4,000
Meperidine（Pethidine）	85,000	Promethazine	85,000
Naloxone	15,000	d-Pseudoephedrine	>100,000
Naltrexone	4,000	Phencyclidine	150
EDDP （2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine）	8,500	Tetrahydrozoline	8,500
Normorphine	85,000	Heroin (diacetylmorphine)	85,000
Oxymorphone	1,500	Methamphetamine Hydrochride	85,000
Pheniramine	85,000	R(-)-Methamphetamine	85,000
METHYLENEDIOXYMETHAMPHETAMINE(MDMA50)			
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)			50
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)			50
3,4-Methylenedioxyethylamphetamine (MDE)			250
METHAMPHETAMINE (MET25)			
d-Methamphetamine	25	Procaine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	250	L-Phenylephrine	1,250
(1R,2S) - (-) Ephedrine	200	Ephedrine	500
METHAMPHETAMINE (MET50)			
d-Methamphetamine	50	Procaine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	500	L-Phenylephrine	2,500
(1R,2S) - (-) Ephedrine	400	Ephedrine	1,000
METHADONE(MTD30)			
Methadone	30	Disopyramide	5,000
Doxylamine	50,000		
OPIATES (OPI30)			
Morphine	30	Morphine 3-β-D-Glucuronide	50
Codeine	40	Normorphine	52,500
Ethylmorphine	40	Nalorphine	75,000
Hydromorphine	150	Oxymorphone	37,500
Hydrocodone	75	Thebaine	18,750
Levorphanol	600	Diacetylmorphine (Heroin)	35
Oxycodone	45,000	6-Monoacetylmorphine	100
OPIATES (OPI40)			
Morphine	40	Morphine 3-β-D-Glucuronide	70
Codeine	50	Normorphine	70,000
Ethylmorphine	50	Nalorphine	100,000
Hydromorphine	200	Oxymorphone	50,000
Hydrocodone	100	Thebaine	25,000
Levorphanol	800	Diacetylmorphine (Heroin)	50
Oxycodone	60,000	6-Monoacetylmorphine	125
OPIATES (OPI50)			
Morphine	50	Morphine 3-β-D-Glucuronide	90
Codeine	65	Normorphine	90,000
Ethylmorphine	65	Nalorphine	>100,000
Hydromorphine	250	Oxymorphone	65,000
Hydrocodone	150	Thebaine	35,000
Levorphanol	1,000	Diacetylmorphine (Heroin)	65
Oxycodone	75,000	6-Monoacetylmorphine	150
OXYCODONE (OXY20)			
Oxycodone	20	Codeine	25,000
Oxymorphone	40	Dihydrocodeine	6,250
Levorphanol	10,000	Naloxone	5,000
Hydrocodone	1,500	Naltrexone	5,000
Hydromorphone	10,000	Thebaine	25,000
PHENCYCLIDINE(PCP3)			
Phencyclidine	3		
PHENCYCLIDINE(PPC10)			
Phencyclidine	10		
PROPOXYPHENE(PPX30)			
D-Propoxyphene	30	D-Norpropoxyphene	30
PROPOXYPHENE(PPX50)			
D-Propoxyphene	50	D-Norpropoxyphene	50
SYNTHETIC MARIJUANA (SMA25)			
JWH-018 5-Pentanoic acid	25	MAM2201 N-Pentanoic acid	35
JWH-073 4-Butanoic acid	25	JWH-210 N-5-Carboxypentyl	210
JWH-018 4-Hydroxypentyl	210	JWH-398 N-Pentanoic acid	175
JWH-018 5-Hydroxypentyl	300	JWH-200 6-Hydroxyindole	300
JWH-073 4-Hydroxybutyl	170	JWH-073 N-2-Hydroxybutyl	500
JWH-018 N-Propanoic acid	20	JWH-019 5-Hydroxyhexyl	500
JWH-019 6-Hydroxyhexyl	500	JWH-018	42,000
JWH-122 N-4-Hydroxypentyl	500	AM2201 N-(4-hydroxypentyl)	350
RCS4 N-5-Carboxypentyl	22,500	JWH-073 N-(3-hydroxybutyl)	225
SYNTHETIC MARIJUANA (SMA30)			
JWH-018 5-Pentanoic acid	30	MAM2201 N-Pentanoic acid	45
JWH-073 4-Butanoic acid	30	JWH-210 N-5-Carboxypentyl	300
JWH-018 4-Hydroxypentyl	300	JWH-398 N-Pentanoic acid	210
JWH-018 5-Hydroxypentyl	350	JWH-200 6-Hydroxyindole	360
JWH-073 4-Hydroxybutyl	200	JWH-073 N-2-Hydroxybutyl	600
JWH-018 N-Propanoic acid	25	JWH-019 5-Hydroxyhexyl	600
JWH-019 6-Hydroxyhexyl	600	JWH-018	50,000
JWH-122 N-4-Hydroxypentyl	600	AM2201 N-(4-hydroxypentyl)	420
RCS4 N-5-Carboxypentyl	27,000	JWH-073 N-(3-hydroxybutyl)	270
SYNTHETIC MARIJUANA K2+(AB-Pinaca)(SMP)			
AB-PINACA pentanoic acid metabolite	10	AB-PINACA N-(4-hydroxypentyl) metabolite	10
ADB-PINACA N-(4-hydroxypentyl) metabolite	15	ADB-PINACA N-(5-hydroxypentyl) metabolite	20
5-fluoro AB-PINACA N-(4-hydroxypentyl)	20	ADB-PINACA pentanoic acid metabolite	20
AB-PINACA N-(5-hydroxypentyl) metabolite	30	5-fluoro AB-PINACA	50
AB-PINACA	100	AB-FUBINACA	150
5-fluoro ADB-PINACA	250	5-chloro AB-PINACA	1000
MARIJUANA (THC15)			
Δ9 -THC	15	11- nor -Δ 9-THC-9 COOH	12.5
Cannabinol	20,000	(-)Δ 8 -THC	100
(+/-)-11-Hydroxy-Δ 9-THC	400	(±)Δ 8 -THC	40
MARIJUANA (THC40)			
Δ9 -THC	40	11- nor -Δ 9-THC-9 COOH	32
Cannabinol	40,000	(-)Δ 8 -THC	250
(+/-)-11-Hydroxy-Δ 9-THC	800	(±)Δ 8 -THC	80
MARIJUANA (THC50)			
Δ9 -THC	50	11- nor -Δ 9-THC-9 COOH	40
Cannabinol	5,000	(-)Δ 8 -THC	300
(+/-)-11-Hydroxy-Δ 9-THC	1,000	(±)Δ 8 -THC	100
TRAMADOL(TML50)			
Cis-tramadol	50	n-Desmethyl-cis-tramadol	25
Procyclidine	5,000	Phencyclidine	10,000
d,l-O-Desmethyl venlafaxine	25,000	o-Desmethyl-cis-tramadol	2,500
TRAMADOL(TML30)			
Cis-tramadol	30	n-Desmethyl-cis-tramadol	15
Procyclidine	3,000	Phencyclidine	6,000
d,l-O-Desmethyl venlafaxine	15,000	o-Desmethyl-cis-tramadol	1,500
ZOPICLONE(ZOP20)			
Zopiclone	20		
6-MONOACETYLMORPHINE(6-MAM 3)			
6-Monoacetylmorphine	3	Diacetylmorphine(herion)	10
6-MONOACETYLMORPHINE(6-MAM 5)			
6-Monoacetylmorphine	5	Diacetylmorphine(herion)	15
6-MONOACETYLMORPHINE(6-MAM10)			
6-Monoacetylmorphine	10	Diacetylmorphine(herion)	25

The following substances may interfere with Alcohol Strip(Saliva):

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic compopunds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds don't exist in saliva usually, and may not interfere with the test.

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 Cup when tested with at concentrations up to 10 μg/mL.

Acetaminophen	Acetophenetidin	N-Acetylprocainamide
Acetylsalicylic acid	Aminopyrine	Amoxicillin
Ampicillin	l-Ascorbic acid	Aspartame
Atropine	Benzilic acid	Benzoic acid
d/l-Brompheniramine	Caffeine	Chloral-hydrate
Chloramphenicol	Chlorothiazide	Cortisone
Chlorpromazine	Chloroquine	Cholesterol
Creatinine	Deoxycorticosterone	Diclofenac
Diflunisal	Digoxin	Diphenhydramine
l(−)-Epinephrine	Erythromycin	β-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate	Fenoprofen
Gentisic acid	Hydralazine	p-Hydroxytyramine
Hydrochlorothiazide	o-Hydroxyhippuric acid	Hydrocortisone
Ibuprofen	d/l-Isoproterenol	Isoxsuprine
Iproniazid	Ketoprofen	Labetalol
Loperamide	Meprobamate	Methylphenidate
Nalidixic acid	Naproxen	Niacinamide
Norethindrone	Nifedipine	d/l-Octopamine
Oxalic acid	Oxymetazoline	Penicillin-G
Papaverine	Phenelzine	Phenylpropanolamine
Trans-2-phenylcyclopropylamine hydrochloride	Prednisolone	Prednisone
d/l-Propranolol	d-Pseudoephedrine	Quinacrine
Quindine	Quinine	Ranitidine
Salicylic acid	Serotonin	Sulfamethazine
Sulindac	Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrocortisone3-(β-D-glucuronide)	Thiamine	Tolbutamide
Triamterene	Trifluoperazine	d/l-Tryptophan
Tyramine	d/l-Tyrosine	Uric acid
Verapamil	Zomepirac	

【BIBLIOGRAPHY】

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4. Gray, T, et al, "Methadone Disposition in Oral Fluid during Pharmacotherapy for Opioid-Dependence," *Forensic Scilnt*, 2011, March 20; 206(1-3): 98-102.
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Index of Symbols

	Consult Instruction for use		Tests per kit
IVD	For *in vitro* diagnostic use only		Use by
2-30°C	Store between 2-30°C	LOT	Lot Number
	Do not use if package is damaged		

EC REP	Authorized Representative
	Do not reuse
REF	Catalog #

Manufacturer Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhonglai Street,
Yuhang District, Hangzhou, P. R. China

EC REP Shanghai International Holding Corp. GmbH (Europe)
Effestraße 80,
20537 Hamburg, Germany

Number: RP5509300
Effective date: 2023-03-17