Multi-Drug Rapid Test Cassette (Salivatracer) (Oral Fluid)

Package Insert

English

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human saliva. For healthcare professionals, including staff in healthcare facilities. Immunoassay for in vitro diagnostic use only.

【INTENDED USE】

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

Test	Calibrator	Cut-off (ng/mL)
6-Monoacetylmorphine(6-MAM)	6-Monoacetylmorphine	3/5/10
Amphetamine (AMP)	d-Amphetamine	25/50
Barbiturates (BAR)	Secobarbital	50
Buprenorphine (BUP)	Buprenorphine	5/10
Benzodiazepines (BZO)	Oxazepam	10/20
Cocaine (COC)	Benzoylecgonine	10/20/50
Cotinine (COT)	Cotinine	30/50
Fentanyl (FYL)	Fentanyl	10
Synthetic Marijuana (K2)	JWH-018 5-Pentanoic acid metabolite	25/30
AB-Pinaca (K2+)	AB-PINACA pentanoic acid metabolite	10
Ketamine (KET)	Ketamine	30/50
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Methamphetamine (MET)	d-Methamphetamine	25/50
Methadone (MTD)	Methadone	30
Opiates (OPI/MOP)	Morphine	10/30/40/50
Oxycodone (OXY)	Oxycodone	20/40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	d-Propoxyphene	30/50
Marijuana (THC)	Δ9-THC	15/40
Marijuana (THC)	11-or-9-THC-9Δ COOH	12/50
Tramadol (TML)	Cis-Tramadol	30/50
Zopiclone (ZOP)	Zopiclone	20

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 Cassette is a rapid saliva 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 saliva.

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 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.

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]. Amphetamine can be detected in oral fluids for up to 72 hours after use[1].

Barbiturates (BAR)

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 to tolerance and physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Buprenorphine(BUP)

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 usedas 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.

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.

Cocaine (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

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 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 30 ng/mL is expected to be up to 1-2 days after nicotine use.

Fentanyl (FYL)

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.

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.

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.

AB-Pinaca (K2+)

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 thebrain. 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 the aminoalkylindazole based drugs such as AB-PINACA, AB-FUBINACA and AB-CHMINACA.

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 ofcoordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blockedspeech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function butnot of the central nervous system, and cardiovascular function is maintained.The effects of Ketamine generally last 4-6 hours following use .

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.

Methamphetamine (MET)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use[1]. Methamphetamine can be detected in oral fluids for up to 72 hours after use[1].

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.

Opiates (OPI)

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, 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 excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

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.

Phencyclidine (PCP)

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

Propoxyphene (PPX)

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.

Marijuana (THC)

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 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 thesubsequent sequestering of the drug in the buccal cavity[5]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[5].

Tramadol(TML/TRA)

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. Largedoses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. The majorpathways appear to be N- and O-demethylation, glucoronidation or sulfation in the liver.

Zopiclone (ZOP)

Zopiclone is a non-benzodiazepine hypnotic (classified as a cyclopyrrolone) used in the treatment of insomnia. It is rapidly absorbed after oral administration, reaching its maximum concentration in plasma 1-1.5 hours later, the oral bioavailability is close to 80%.45%-80% of zopiclone binds to plasma protein and is widely distributed throughout the body. Its concentration in saliva is higher than in plasma. The bitter taste is proportional to the concentration in saliva. Since zopiclone was used in clinic in 1985, its abuse and dependence tendency has been a controversial topic. Some studies have pointed out that the risk is low or small, but at the same time, in different countries, there are more and more individual reports of abuse, dependence and withdrawal complications.

【ASSAY PRINCIPLE】

The Multi-Drug Rapid Test Cassette 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.

【REAGENTS】

Each test line contains anti-drug antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and cassette 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 test is stable through the expiration date printed on the sealed pouch. The test cassettes 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 cassettes should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

- Test cassettes
- Package insert
- Procedure Card(when applicable)

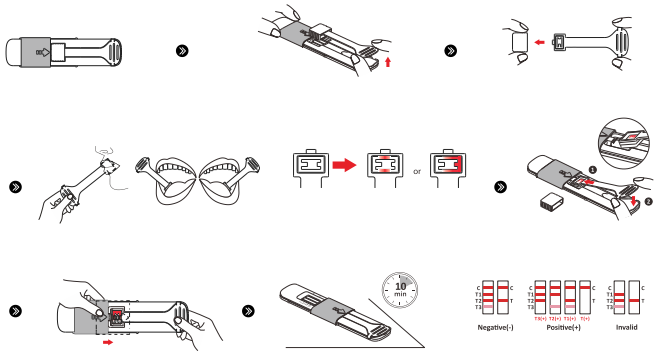
Materials Required but Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening. Remove the test from the sealed pouch and use within one hour of opening.
2. Instruct the donor to place the tongue against the root of the upper or lower jaw and collect saliva in the mouth.
3. Remove the swab from the cassette, then remove the cap from the swab.
4. Instruct the donor to place the swab between the lower cheek and gum and gently rub back and forth between the left and right cheeks and gums until the sponge is completely saturated with saliva. Do not bite, suck, or chew the sponge as it may break.
5. Remove the swab when two red/pink lines appear on the back of the swab or when the red/pink lines form a 3/4 turn,insert the swab into the cassette. If the saturation indicator has not turned red, place the swab back in the mouth and continue to collect saliva until the saturation indicator turns red.
   Note: When inserting the swab into the cassette, insert the protruding part of the swab head into the hole reserved at the sampling site, and then press down the tail of the swab to secure it.
6. Move the slider in the direction of the arrow until the slider is blocked.
7. Place the device on a flat surface while the test is running. Negative results can be read as soon as clear lines form in both the C and T zones of the test. Read presumptive positive results at 10 minutes. Do not read results after 20 minutes.



【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.

【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】

1. The Multi-Drug Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), 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.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

【PERFORMANCE CHARACTERISTICS】

Accuracy

Assemble each single test into the cassette before testing, and evaluate the cassette 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 Oral Fluid Drug Screen Test. 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 Screen Test		Positive	Negative		
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%	>99,0 %
	Negative	0	128	>99%	
AMP 25	Positive	56	2	96.6%	97.5%
	Negative	2	100	98.0%	
AMP50	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%	
BUP10	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%	
COC10	Positive	37	3	90.2%	95.3%
	Negative	4	106	97.2%	
COC20	Positive	38	2	95.0%	96.7%
	Negative	3	107	97.3%	
COC50	Positive	38	2	95.0%	96.7%
	Negative	3	107	97.3%	
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%	
K2（SMA）25	Positive	52	2	96.3%	96.0%
	Negative	4	92	95.8%	
K2（SMA）30	Positive	52	2	96.3%	96.0%
	Negative	4	92	95.8%	
K2+ 10	Positive	4	0	>99%	>99.0%
	Negative	0	40	>99%	
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 10	Positive	88	8	92.6%	92.9%
	Negative	7	107	93.0%	
OPI 30	Positive	61	3	95.3%	96.8%
	Negative	2	89	97.8%	
OPI 40	Positive	89	7	93,7 %	93.8%
	Negative	6	108	93.9%	
OPI 50	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%	
OXY 40	Positive	93	0	>99%	>99%
	Negative	0	137	>99%	
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%	
THC 15	Positive	43	0	95.6%	97.8%
	Negative	2	45	99%	
THC 40	Positive	45	0	95.7%	98.0%
	Negative	2	52	>99%	
THC12	Positive	75	5	96.2%	96.8%
	Negative	3	167	97,1 %	
THC 50	Positive	75	5	96.2%	96.8%
	Negative	3	167	97,1 %	
TML/TRA 30	Positive	89	0	>99%	>99%
	Negative	0	121	>99%	
TML/TRA 50	Positive	80	6	93.0%	95.7%
	Negative	3	121	97.6%	
ZOP 20	Positive	36	0	>99%	>99%
	Negative	0	114	>99%	

Analytical Sensitivity

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

Drug conc. (Cut-off range)	n	AMP50		MET50		THC15		THC40	
		-	+	-	+	-	+	-	+
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	28	2	27	3	26	4
Cut-off	30	15	15	16	14	12	18	12	18
+25% Cut-off	30	7	23	6	24	5	25	5	25
+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	PCP10		BZO20		OPI40		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	25	5	26	4	27	3	25	5
Cut-off	30	14	16	14	16	13	17	18	12
+25% Cut-off	30	10	20	5	25	7	23	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	MTD30		OXY20		COT30		MDMA50	
		-	+	-	+	-	+	-	+
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	25	5	26	4
Cut-off	30	15	15	20	10	20	10	19	11
+25% Cut-off	30	7	23	4	26	7	23	6	24
+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	BAR50		COC20		KET30		BUP10	
		-	+	-	-	-	+	-	+
0% Cut-off	30	30	0	30	30	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	23	7	25	5	25	5	27	3
Cut-off	30	16	14	15	15	16	14	15	15
+25% Cut-off	30	6	24	3	27	4	26	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	6-MAM10		TML/TRA30		FYL10		K2 25	
		-	+	-	+	-	+	-	+
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	25	5	24	6	26	4
Cut-off	30	14	16	14	16	15	15	15	15
+25% Cut-off	30	4	26	4	26	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**	**K2+ 10**		**BUP5**		**BZO10**		**COC50**	
		-	**+**	**-**	**+**	**-**	**+**	**-**	**+**
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	25	5
Cut-off	30	15	15	15	15	15	15	15	15
+25% Cut-off	30	3	27	7	23	7	23	3	27
+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**	**OPI50**		**OXY40**		**COC10**		**OPI10**	
		-	**+**	**-**	**+**	**-**	**+**	**-**	**+**
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	25	5	26	4	26	4
Cut-off	30	15	15	15	15	15	15	13	17
+25% Cut-off	30	8	22	7	23	3	27	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**	**AMP25**		**COT50**		**MET25**		**OPI30**	
		-	**+**	**-**	**+**	**-**	**+**	**-**	**+**
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	28	2	24	6	24	6
Cut-off	30	15	15	16	14	14	16	14	16
+25 % cut-off	30	4	26	6	24	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**	**THC12**		**THC50**		**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	27	3	25	5	25	5
Cut-off	30	12	18	12	18	15	15	15	15
+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**	**6-MAM 3**		**6-MAM 5**		**TML/TRA 50**		**SMA30**	
		-	**+**	**-**	**+**	**-**	**+**	**-**	**+**
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	25	5	26	4	26	4
Cut-off	30	15	15	14	16	14	16	15	15
+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

Drug conc. (Cut-off range)	**n**	**ZOP20**	
		-	**+**
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	26	4
Cut-off	30	14	16
+25 % cut-off	30	4	26
+50 % cut-off	30	0	30
+300% Cut-off	30	0	30

Analytical Specificity

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

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		
METHAMPHETAMINE (MET25)			
d-Methamphetamine	25	(1R,2S) - (-) Ephedrine	200
Fenfluramine	30,000	Procaine	1,000
p-Hydroxymethamphetamine	200	l-Phenylephrine (R)-(-)-Phenylephrine	3,125
Methoxyphenamine	12, 500	Ephedrine	200
Mephentermine	750	Benzphetamine	12, 500
3,4-Methylenedioxymethamphetamine (MDMA)	25	L-Methamphetamine	5,000
D,L - Methamphetamine	100		
METHAMPHETAMINE (MET50)			
d-Methamphetamine	50	(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000	Procaine	2,000
p-Hydroxymethamphetamine	400	l-Phenylephrine (R)-(-)-Phenylephrine	6,250
Methoxyphenamine	25,000	Ephedrine	400
Mephentermine	1,500	Benzphetamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50	L-Methamphetamine	10,000
D,L - Methamphetamine	200		
MARIJUANA (THC15)			
Δ9 -THC	15	11- nor -Δ9-THC-9 COOH	12.5
Cannabinol	20,000	(-) Δ8 -THC	100
(±)-11-Hydroxy-Δ 9-THC	400	(±) Δ8 -THC	40
MARIJUANA (THC40)			
Δ9 -THC	40	11- nor -Δ9-THC-9 COOH	32
Cannabinol	40,000	(-) Δ8 -THC	250
(±)-11-Hydroxy-Δ 9-THC	800	(±) Δ8 -THC	80
MARIJUANA (THC12)			
11- nor -Δ9-THC-9 COOH	12	Δ9- THC	15
Cannabinol	20,000	(±)-11-Hydroxy-Δ9-THC	400
Δ8 -THC	100	(±) Δ8 -THC	40
MARIJUANA (THC50)			
11- nor -Δ9-THC-9 COOH	50	11- nor -Δ9-THC-9 COOH	40
Cannabinol	50,000	Δ8 -THC	300
(±)-11-Hydroxy-Δ9-THC	1000	(±) Δ8 -THC	100
COCAINE (COC10)			
Cocaine HCl	10	EcgonineHCl	7.5
Benzoylecgonine	10	Cocaethylene	15
COCAINE (COC20)			
Cocaine HCl	20	EcgonineHCl	15
Benzoylecgonine	20	Cocaethylene	30
COCAINE (COC50)			
Cocaine HCl	50	EcgonineHCl	37.5
Benzoylecgonine	50	Cocaethylene	75
OPIATES (OPI10)			
Morphine	10	Morphine 3-β-D-Glucuronide	20
Codeine	5	Normorphine	10,000
Ethylmorphine	25	Nalorphine	700
Hydromorphine	70	Oxymorphone	＞10,000
Hydrocodone	270	Thebaine	＞10,000
Levorphanol	1,000	Diacetylmorphine (Heroin)	25
Oxycodone	＞10,000	6-Monoacetylmorphine	10
Dihydrocodeine	10,000	6-Acetylcodeine	30
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)	40
Oxycodone	45,000	6-Monoacetylmorphine	100
Dihydrocodeine	30,000	6-Acetylcodeine	90
OPIATES (OPI40)			
Morphine	40	Morphine 3-β-D-Glucuronide	70
Codeine	50	Normorphine	70,000
Ethylmorphine	50	Nalorphine	10,0000
Hydromorphine	200	Oxymorphone	50,000
Hydrocodone	100	Thebaine	25,000
Levorphanol	800	Diacetylmorphine (Heroin)	50
Oxycodone	60,000	6-Monoacetylmorphine	125
Dihydrocodeine	40,000	6-Acetylcodeine	120
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
Dihydrocodeine	50,000	6-Acetylcodeine	150
PHENCYCLIDINE (PCP10)			
Phencyclidine	10	4-Hydroxyphencyclidine	2,500
PROPOXYPHENE(PPX30)			
D-Propoxyphene	30	D-Norpropoxyphene	30
PROPOXYPHENE(PPX50)			
D-Propoxyphene	50	D-Norpropoxyphene	50
METHAQUALONE (MQL100)			
Methaqualone	100		
METHADONE (MTD30)			
Methadone	30	LAAM	200
Disopyramide	400	Doxylamine	12,500
(+)-Chlorpheniramine	6,250	Nor-LAAM	12,500
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
OXYCODONE (OXY40)			
Oxycodone	40	Codeine	50,000
Oxymorphone	80	Dihydrocodeine	12,500
Levorphanol	20,000	Naloxone	10,000
Hydrocodone	3,000	Naltrexone	10,000
Hydromorphone	20,000	Thebaine	50,000
COTININE (COT30)			
(-)-Cotinine	30	(-)-Nicotine	450
COTININE (COT50)			
(-)-Cotinine	50	(-)-Nicotine	750
METHYLENEDIOXYMETHAMPHETAMINE (MDMA50)			
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)			50
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)			300
3,4-Methylenedioxyethyl-amphetamine (MDE)			30
l-Methamphetamine			25,000
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(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		
KETAMINE(KET50)			
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
KETAMINE(KET30)			
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
BARBITURATES(BAR50)			
Amobarbital	200	Pentobarbital	60
Aprobarbital	100	Phenobarbital	140
Butabarbital	50	Secobarbital	50
Butalbital	600	Primidone	95,000
Alphenal	200	Barbital	50
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
6-MONOACETYLMORPHINE(6-MAM3)			
6-Monoacetylmorphine	3	Diacetylmorphine (heroine)	10
6-MONOACETYLMORPHINE(6-MAM5)			
6-Monoacetylmorphine	5	Diacetylmorphine (heroine)	15
6-MONOACETYLMORPHINE(6-MAM10)			
6-Monoacetylmorphine	10	Diacetylmorphine (heroine)	25
TRAMADOL(TML/TRA30)			
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
TRAMADOL(TML/TRA50)			
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
FENTANYL(FYL10)			
Fentanyl	10	Norfentanyl	4
Perphenazine	20,000		
SYNTHETIC MARIJUANA (K2/SMA 25)			
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 (K2 /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
AB-Pinaca (K2+ 10)			
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
ZOPICLONE(ZOP20)			
Zopiclone	20		

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Multi-Drug Rapid Test Cassette 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	

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Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative within the European Community
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2–30 °C	LOT	Lot Number	REF	Catalog Number
	Do not use if package is damaged	CE	CE Marking		Manufacturer
	Importer		Distributor	UDI	Unique Device Identification

Manufacturer

Hangzhou Biotest Biotech Co., Ltd.
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Yuhang District, Hangzhou, P. R. China

CE

EC REP

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