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HIGHTOP Multi-Drug Urine Rapid Test Panel

FOR PROFESSIONAL USE ONLY

PRODUCT NAME

HIGHTOP Multi-Drug Urine Rapid Test Panel

Specification

1test/bag, 1test/kit, 20 tests/kit, 25 tests/kit, 40 tests/kit

INTENDED USE

Multi-Drug Urine Rapid Test panel tests are used for the qualitative detection of OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL in human urine according to the principle of gold immunochromatography assay.

The cutoff concentrations of the detected drugs are shown in the table below.

Drug (Identifier)	Cut-off level
Opiate (OPI)	2000ng/mL
Morphine (MOP)	300ng/mL
Oxazepam (BZO)	300ng/mL
Methamphetamine (MET)	1000ng/mL
Methylenedioxymethamphetamine (MDMA)	500ng/mL
Phencyclidine (PCP)	25ng/mL
Marijuana (THC)	50ng/mL
Secobarbital (BAR)	300ng/mL
Oxycodone (OXY)	100ng/mL
Nortriptyline (TCA)	1000ng/mL
Propoxyphene (PPX)	300ng/mL
Amphetamine (AMP)	1000ng/mL
Methadone (MTD)	300ng/mL
Cocaine (COC)	300ng/mL
Buprenorphine (BUP)	10ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300ng/mL
Tramadol (TML)	300ng/mL
Synthetic Marijuana(K2)	50ng/mL
Cotnine (COT)	200ng/mL
Fentanyl (FYL)	200ng/mL

SUMMARY

Multi-Drug Urine Rapid Test panel is a rapid urine screening test that can be performed without the use of an instrument. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

AMPHETAMINE (AMP)

Amphetamine is a central stimulant (phenethylamine central stimulant) and antidepressant. It can cause deep mental effects, including increased alertness, initiative and confidence, increased language and increased ability to concentrate. It can also treat hyperactivity and narcolepsy. Amphetamine can also cause adverse reactions such as restlessness, insomnia, tremor, nervousness and irritability. The physical tolerance of amphetamine appears very quickly, so long-term users must take more and more. The most serious consequence of taking high-dose amphetamine is a toxic neuropathy, whose symptoms are similar to paranoid schizophrenia. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine with a half-life of about 12 hours. It can be detected in the urine for 1 to 2 days after use. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

BUPRENORPHINE (BUP)

Buprenorphine is a semi-synthetic opioid derived from thebaine, a naturally occurring alkaloid of the opium poppy. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Buprenorphine is used as a substitution treatment for opioid addicts. In substitution therapy, buprenorphine is less addictive and side effects than strong agonists, and can better inhibit the appearance of withdrawal symptoms in opioid addicts. Most of a dose of buprenorphine is eliminated in the faeces, with approximately 10-30% excreted in urine. While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

SECOBARBITAL (BAR)

Barbiturates are a class of central nervous system depressions. Most of them are a long-acting hypnotic drug with different inhibitory effects on sedation, hypnosis, anticonvulsant and antiepileptic. Pentobarbital and secobarbital are two examples of a short acting barbiturate sedative. Large doses can inhibit the respiratory center, severe cases may cause respiratory paralysis and death. Only less than 5% of most barbiturates will be excreted in the urine intact. Barbiturates have a wide range of half-life of 2 to 40 hours and can be detected in the urine for 1 to 4 days after use.

OXAZEPAM (BZO)

Benzodiazepines are mostly 1,4-Benzodiazepine derivatives, which have sedative, hypnotic, antianxiety, central muscle relaxation and anticonvulsant effects. There are more than 20 commonly used clinically and have a wide range of half-life from 2 to 40 hours. 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. Benzodiazepines are mainly metabolized in the liver, and some benzodiazepines and their metabolites are excreted in the urine. The detection period for the benzodiazepines in the urine is 3-7 days.

COCAINE (COC)

Cocaine is the main alkaloid contained in coca leaves, which is the strongest natural central stimulant and a powerful local anesthetic or vasoconstrictor. Long-term use of cocaine can cause toxic psychosis, and its impact on the mental system is manifested as vivid vision, auditory hallucinations, tactile hallucinations, paranoid states, and personality disorders. Cocaine can be absorbed by the mucous membranes of the respiratory tract, digestive tract and anywhere else. Most of cocaine is hydrolyzed and metabolized in the liver and is excreted in the urine in a short time primarily as benzoylecgonme. Benzoylecgonme has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 1-2days after cocaine exposure.

METHAMPHETAMINE (MET)

Methamphetamine is a central nervous and sympathetic nerve stimulant. After Methamphetamine enters the body, it will lead to active thinking, energetic, increased intimacy between people, enhanced sensitivity to music and beat, and a series of unspeakable pleasures such as swinging head and twisting limbs with strong rhythmic music, which is called flash or rush. Excessive use of methamphetamine can cause acute poisoning, which is clinically manifested as irritation of the central nervous system and sympathetic nervous system. After taking methamphetamine, methamphetamine, amphetamine, p-hydroxymethamphetamine and p-hydroxyamphetamine can be tested in urine. Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

3,4-Methylenedioxymethamphetamine (ecstasy) is a synthetic amphetamine analogue that was originally synthesized in 1914. Excessive MDMA use is associated with greater self-report depression, obsessive and compulsive behaviors, anxiety, somatization, and loss of libido. The users also have problems with memory, attention, reasoning, impulse control, and sleep abnormalities. MDMA is readily absorbed from the intestinal tract, and the half-life is between 6 to 10 hours. MDMA is metabolized to MDA, HMMA and HHMA. The combination of MDMA and HHMA accounts for 58% of total drug in the urine. MDA accounts for less than 5% to 28% of MDMA.

MORPHINE (MOP)

Morphine is one of several important alkaloids derived from the papaver somniferum. Morphine is a very efficacious drug for the relief of moderate to severe pain and is also used preoperatively to reduce anxiety, cause sedation and reduce the dose of anesthetic. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Most of the morphine and its metabolites are excreted within 24 hours, 2% to 10% of morphine are excreted in urine as prototypes and up to 10% of a dose may eventually be excreted, as conjugates, through the bile into the feces.

OPIATE (OPI)

Opiates are substances derived from opium, as well as their chemical derivatives. The best known opiates are heroin, morphine and codeine. These drugs are used clinically for treating mild to severe pain in patients. Due to their intensely calming effects, opioids have tremendously high rates of abuse which, in many cases, can lead to addiction. The drugs also alleviate anxiety; induce relaxation, drowsiness, and sedation; and may impart a state of euphoria. Opiates are highly addictive due to the way they bind to receptors in the brain that drive feelings euphoria. Overdose can cause respiratory depression and eventually death. In the body, all of the opiates are ultimately converted to morphine, and morphine is converted to morphine-3-glucuronide and morphine-6-glucuronide. 2% to 10% of morphine are excreted in urine as prototypes.

METHADONE (MTD)/2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP)

Methadone is an opioid receptor agonist, which belongs to narcotic analgesics. Its analgesic effect is similar to that of morphine, and can produce respiratory inhibition, pupil constriction, sedation and other effects. Compared with morphine, it has the characteristics of longer acting time, less tolerance and lower drug dependence. Taking methadone for long periods and at large doses, can lead to a very long withdrawal period and the withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation. Methadone is mainly metabolized in the liver, and the biological half-life is 15 to 60 hours. Methadone and it's main metabolite EDDP are excreted through urine, so the detection of methadone and EDDP in urine can be used as evidence to determine methadone consumption and the types of drugs abused.

OXYCODONE (OXY)

Oxycodone, semisynthetic drug with potent pain-relieving effects that is derived from thebaine, an alkaloid that occurs naturally in the opium poppy. Oxycodone was synthesized from thebaine in 1916 and was first used clinically the following year. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Oxycodone is metabolized by N- and O-demethylation. After taking oxycodone, 13-19% of morphine are excreted in urine as prototypes and the detection time window of oxycodone is 1-3 days following use.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as Angel Dust, that was originally used as an anesthetic agent and a veterinary tranquilizer. PCP can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. Self-injurious behavior is one of the devastating effects of PCP. It is metabolized in the liver and that can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.

PROPOXYPHENE (PPX)

Propoxyphene, a synthetic opiate agonist, is a narcotic analgesic used to relieve mild to moderate pain. Propoxyphene was FDA approved in August 1957 and banned for medical purpose in 2010. Buse of propoxyphene can lead nausea, vomit, astriction, illusion, hallucination, heart poisoning, lung dropsy and even death. In human, propoxyphene is metabolized in the liver and excreted in urine as nordextropropoxyphene. 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.

TRICYCLIC ANTIDEPRESSANTS (TCA)

Tricyclic antidepressant is one of the most commonly used drugs in clinical treatment of depression, mainly including tertiary amine and secondary amine tricyclic antidepressant. Tricyclic antidepressant is suitable for the treatment of various mental disorders mainly with depressive symptoms, and can also be used for the prevention of migraine and adjuvant treatment of drug addiction withdrawal treatment. Tricyclic antidepressant can be fatal when taken at more than 10 times the daily dose, arrhythmias is the most common cause of death. Tricyclic antidepressant has a half-life of about 18-48 hours and is mainly metabolized in the liver. 5% of the ingested dose is excreted through bile, 5-16% through gastric juice, and 3-10% through urine.

MARIJUANA (THC)

Natural cannabis products and single cannabinoids are usually inhaled or taken orally and Δ9-Tetrahydrocannabinol (THC) is the primary psychoactive constituent of cannabis. Users have impaired short term memory and slowed learning, they may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The most important nonpsychotropic metabolite of THC is THC-COOH with a half-life of 24 hours. They can be detected for 1 to 5 days after use.

Tramadol (TML)

Tramadol (TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors.Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug,whereas 60% is excreted as metabolites.The major pathways appear to be N- and 0-demethylation, glucoronidation or sulfation in the liver.

Synthetic Marijuana(K2)

Synthetic Marijuana or K2 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 Mariana 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.Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for72hours after smoking(depending on usage/dosage). As of March 1,2011,five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol 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.

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.In a 24-hour urine,approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite,it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney, the window of detection for cotinine in urine at a cutoff level of 200ng/mL isexpected to be up to2-3days after nicotine use.

Fentanyl(FYL)

Fentanyl, belongs to powerful narcotics analgesics, and is a special opiates receptor stimulant.Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain. 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 along 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.

Alcohol (ALC)

When contacting with the solution of alcohol, the test will rapidly turn colors depending on the concentration of alcohol. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

Adulteration

Adulteration is the tampering of the urine sample with the intention of altering the test results. The use of adulterants in the urine can cause false negative results by either interfering the test or destroying the drugs contained. Dilution also can produce false negative drug test results. To determine certain urinary characteristics such as specific gravity, pH, oxidants, nitrite, glutaraldehyde and creatinine in urine, that are considered to be the best ways to test for adulteration or dilution.

PRINCIPLE

Multi-Drug Strips: The Test uses antigen-antibody reaction, combining Colloidal gold immunochromatography technology,

highly specific and sensitive competition method to detect the OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL in urine. When testing, urine moving forward under the action of chromatography. If the concentration of the above products in urine is below the cut-off level, colloidal gold antibodies can not be combined with the above products in the urine completely, and the rest of colloidal gold antibodies will be captured by the above products conjugated on the NC membrane, appearing a visible red precipitate line (test line T). If the concentration of the above products in urine is higher than the cut-off level, the above products in urine can combine all of colloidal gold antibodies, thus no colloidal gold antibodies can combine with the above products conjugated on the NC membrane, so no red line appeared in the test area (T).Whether the above products exists in the urine or not, a red line (control line C) will always appear in the control area (C) to serve as a procedure control.

Alcohol Strip and Adulteration Strips: The tests contain different chemical substances, which produce chemical and enzymatic reactions with the corresponding substances in the urine, so that the color of the tests change according to the proportion of the components in the urine.

MATERIALS

Materials Provided

Drug Test Panel

Materials Required But Not Provided

Timer

REAGENTS

Multi-Drug Urine Rapid Test panel offers any combinations of 20 drugs and alcohol but only one cutoff concentration under same drug condition will be included per device. Meanwhile, Adulteration strips, including Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine also can be selected.

Multi-Drug Strips: The test contains a membrane strip coated with drug-BSA conjugates on the test line and goat anti-mouse IgG on the control line. The gold conjugate pad which contains colloidal gold particles coated with monoclonal antibody specific to drug respectively.

Alcohol Strip: The cutoff concentrations of alcohol is 20mg/mL.The test contains a reaction pad coated with 3,3',5,5'-Tetramethylbenzidine, Alcohol Oxidase, Peroxidase, buffer and non-reaction additives.

Adulteration Strips:

Oxidants: Sodium tetraborate, Tetramethyl benzidine

Specific Gravity: Bromothymol blue, Polyacid

pH: Methyl red, Bromothymol blue

Nitrite: N-(1-naphthyl)-ethylenediamine dihydrochloride

Glutaraldehyde: Sodium sulfite, Glycine

Creatinine: Sulfate, Benzidine

PRECAUTIONS

For in vitro diagnostic use only.

Do not re-use the test.

Do not use the test if the pouch is punctured or not well sealed.

Do not use after expiration date.

Keep out of the reach of children.

The used test device and urine sample should be thrown away according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. See expiration date on package label. The test is stable through the expiration date. The test must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

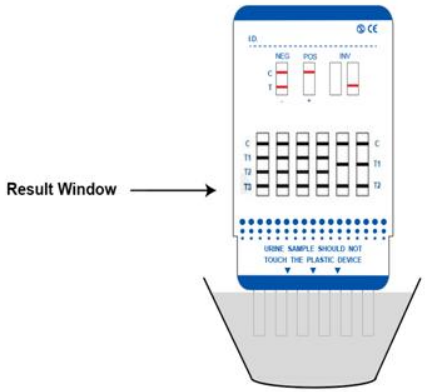
SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

DIRECTIONS FOR USE

Allow the test cup to equilibrate to room temperature (10-30°C) for 30 minutes prior to test. Do not open the inner package until ready, it must be used within one hour if opened (Humidity≤60%). Please use immediately when the humidity exceeded to 60%.

1. Remove the cap from the end of the test card. With arrows pointing toward the urine sample, immerse the sample pad area of the test card vertically in the urine sample for at least 5-10seconds. Dip the test card in the urine, but not above the arrow(s) on the test card. See the illustration below, that listed one type of combinations.
2. Place the test card on a non-absorbent flat surface.
3. Start the timer and the result should be read after 5 minutes. Do not interpret the result after 10 minutes.
4. Positive test results must be confirmed by another test. Please transport the panel and urine sample intact to a toxicology laboratory for confirmation.
5. We recommend not to interpret the drug test results in case of any positive result for any adulteration test. Please collect another sample to test.



Note: The diagram is for reference only. See the real object for details.

The appearance and color of cassette may be different from the actual product, which has no effect on normal use.

INTERPRETATION OF RESULTS

Multi-Drug Strips:

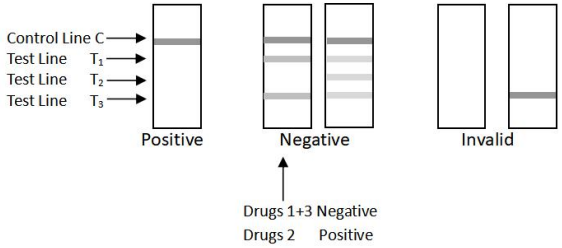
Preliminary positive(+): One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the cut-off level.

Negative(-): Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the drug concentration is below the cut-off level.

Note: The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

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.

Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line shows. (DO NOT compare lines within the same test strip or between different test strips).



Alcohol Strip:

POSITIVE: A color change appears on the reaction pad. The color on the reaction pad varying from light blue to dark blue, falling on or between the corresponding color blocks on the color chart.

NEGATIVE: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

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

Adulteration Strip:

Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.

Note: Interpret alcohol strip and adulteration strips at 5min, Please refer to the color chart for interpretation.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even thought here is an internal procedural control line in the test device in the Control Region(C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly.

LIMITATIONS

Multi-Drug Strips:

1. Multi-Drug Urine Rapid Test panel provides only a qualitative preliminary result. You must use a further method to get a confirmed result. GC/MS or LC/MS is the preferred confirmatory method.
2. There is a possibility that technical or procedural error, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Substances, such as bleach and/or other chemicals, in urine sample may produce wrong results.
4. A positive result does not indicate drug concentration in the urine, or drug administration route.
5. A negative result may not necessarily mean drug-free urine. When drug is in the urine but the concentration is lower than cut-off value of the test, it can get negative results.
6. The test does not distinguish between drugs of abuse and certain medications.
7. Certain foods or food supplements may get a positive test result.

Adulteration strip:

1. The adulteration tests are meant to aid in the determination of abnormal samples. While comprehensive, these tests are not meant to be an"all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the sample, such as ascorbic acid, may lead to false negative results for the oxidants/PCC.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Glutaraldehyde is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
6. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Multi-Drug Strips:

1. Accuracy

80 clinical urine specimens (40 negative and 40 positive) were analyzed by LC/MS and by the Multi-Drug Urine Rapid Test panel. The samples will be marked and randomized by the person who prepares the samples and won't take part in the sample testing. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, < -50% cut-off, -50% cut-off ~ cut-off, cut-off ~ +50% cut-off, > +50% cut-off. All samples were masked and randomized. Results were as follows:

Drug test	Results		Drug -free	Low Negative by LC/MS (less than -50%)	Near cut-off Negative by LC/MS (Between -50% and the cut-off)	Near cut-off Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)	% Agreement with LC/MS
AMP 1000	ViewerA	+	0	0	0	17	21	95.0%
		-	8	17	15	2	0	100%
	ViewerB	+	0	0	0	18	21	97.5%
		-	8	17	15	1	0	100%
	ViewerC	+	0	0	1	17	21	95.0%
		-	8	17	14	2	0	97.5%
BUP 10	ViewerA	+	0	0	1	18	21	97.5%
		-	8	15	16	1	0	97.5%
	ViewerB	+	0	0	2	19	21	100%
		-	8	15	15	0	0	95.0%
	ViewerC	+	0	0	0	18	21	97.5%
		-	8	15	17	1	0	100%
BAR 300	ViewerA	+	0	0	2	19	20	97.5%
		-	8	16	14	1	0	95.0%
	ViewerB	+	0	0	1	20	20	100%
		-	8	16	15	0	0	97.5%
	ViewerC	+	0	0	2	18	20	95.0%
		-	8	16	14	2	0	95.0%
BZO 300	ViewerA	+	0	0	1	15	23	95.0%
		-	8	16	15	2	0	97.5%
	ViewerB	+	0	0	1	16	23	97.5%
		-	8	16	15	1	0	97.5%
	ViewerC	+	0	0	2	16	23	97.5%
		-	8	16	14	1	0	95.0%
COC	ViewerA	+	0	0	2	18	21	97.5%

300		-	8	17	13	1	0	95.0%
	ViewerB	+	0	0	2	19	21	100%
		-	8	17	13	0	0	95.0%
	ViewerC	+	0	0	1	18	21	97.5%
		-	8	17	14	1	0	97.5%
EDDP 300	ViewerA	+	0	0	1	20	19	97.5%
		-	8	16	15	1	0	97.5%
	ViewerB	+	0	0	1	21	19	100%
		-	8	16	15	0	0	97.5%
	ViewerC	+	0	0	1	21	19	100%
		-	8	16	15	0	0	97.5%
MET 1000	ViewerA	+	0	0	0	20	18	95.0%
		-	8	17	15	2	0	100%
	ViewerB	+	0	0	0	21	18	97.5%
		-	8	17	15	1	0	100%
	ViewerC	+	0	0	0	21	18	97.5%
		-	8	17	15	1	0	100%
MDMA 500	ViewerA	+	0	0	1	20	18	95.0%
		-	8	16	15	2	0	97.5%
	ViewerB	+	0	0	1	21	18	97.5%
		-	8	16	15	1	0	97.5%
	ViewerC	+	0	0	0	21	18	97.5%
		-	8	16	16	1	0	100%
MOP 300	ViewerA	+	0	0	2	21	19	100%
		-	8	14	16	0	0	95.0%
	ViewerB	+	0	0	0	20	19	97.5%
		-	8	14	18	1	0	100%
	ViewerC	+	0	0	1	21	19	100%
		-	8	14	17	0	0	97.5%
OPI 2000	ViewerA	+	0	0	1	18	20	95.0%
		-	8	17	14	2	0	97.5%
	ViewerB	+	0	0	1	20	20	100%
		-	8	17	14	0	0	97.5%
	ViewerC	+	0	0	1	19	20	97.5%
		-	8	17	14	1	0	97.5%
MTD 300	ViewerA	+	0	0	1	18	20	95.0%
		-	8	17	14	2	0	97.5%
	ViewerB	+	0	0	2	19	20	97.5%
		-	8	17	13	1	0	95.0%
	ViewerC	+	0	0	1	20	20	100%
		-	8	17	14	0	0	97.5%
OXY 100	ViewerA	+	0	0	2	18	20	95.0%
		-	8	16	14	2	0	95.0%
	ViewerB	+	0	0	1	19	20	97.5%
		-	8	16	15	1	0	97.5%
	ViewerC	+	0	0	1	19	20	97.5%
		-	8	16	15	1	0	97.5%
PCP 25	ViewerA	+	0	0	1	18	20	95.0%
		-	8	16	15	2	0	97.5%
	ViewerB	+	0	0	0	19	20	97.5%
		-	8	16	16	1	0	100%
	ViewerC	+	0	0	1	18	20	95.0%
		-	8	16	15	2	0	97.5%
PPX 300	ViewerA	+	0	0	2	14	24	95.0%
		-	8	16	14	2	0	95.0%
	ViewerB	+	0	0	0	15	24	97.5%
		-	8	16	16	1	0	100%
	ViewerC	+	0	0	2	15	24	97.5%
		-	8	16	14	1	0	95.0%
TCA 1000	ViewerA	+	0	0	1	17	21	95.0%
		-	8	17	14	2	0	97.5%
	ViewerB	+	0	0	2	18	21	97.5%
		-	8	17	13	1	0	95.0%
	ViewerC	+	0	0	2	18	21	97.5%
		-	8	17	13	1	0	95.0%
THC 50	ViewerA	+	0	0	2	20	19	97.5%
		-	8	16	14	1	0	95.0%
	ViewerB	+	0	0	1	19	19	95.0%
		-	8	16	15	2	0	97.5%
	ViewerC	+	0	0	1	20	19	97.5%
		-	8	16	15	1	0	97.5%
TML 300	ViewerA	+	0	0	1	21	19	100%
		-	8	16	15	0	0	97.5%
	ViewerB	+	0	0	0	21	19	100%
		-	8	16	16	0	0	100%
	ViewerC	+	0	0	1	20	18	95.0%
		-	8	17	14	2	0	97.5%
K2 50	ViewerA	+	0	0	0	20	18	95.0%
		-	8	17	15	2	0	100%
	ViewerB	+	0	0	1	21	18	97.5%
		-	8	16	15	1	0	97.5%
	ViewerC	+	0	0	0	21	18	97.5%
		-	8	17	15	1	0	100%
COT 200	ViewerA	+	0	0	0	18	20	95.0%
		-	8	17	15	2	0	100%
	ViewerB	+	0	0	0	19	20	97.5%
		-	8	17	15	1	0	100%
	ViewerC	+	0	0	2	19	21	100%
		-	8	17	13	0	0	95.0%
FYL 200	ViewerA	+	0	0	0	14	24	95.0%
		-	8	16	16	2	0	100%
	ViewerB	+	0	0	1	20	20	100%
		-	8	16	15	0	0	97.5%
	ViewerC	+	0	0	2	16	24	100%
		-	8	16	14	0	0	95.0%

2. Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. All concentrations were confirmed with LC/MS. The study was performed 2 runs/day and lasted 20 days with three different lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 40 determinations by each operator, at each concentration, were made.

Drug test	Approximate concentration (ng/ml)	n	Lot1		Lot2		Lot3	
			+	-	+	-	+	-
AMP 1000	0	40	0	40	0	40	0	40
	250	40	0	40	0	40	0	40
	500	40	0	40	0	40	0	40
	750	40	0	40	0	40	0	40
	1000	40	28	12	29	11	28	12
	1250	40	40	0	40	0	40	0
	1500	40	40	0	40	0	40	0
	1750	40	40	0	40	0	40	0
	2000	40	40	0	40	0	40	0
BUP 10	0	40	0	40	0	40	0	40
	2.5	40	0	40	0	40	0	40
	5	40	0	40	0	40	0	40
	7.5	40	0	40	0	40	0	40
	10	40	28	12	29	11	27	13
	12.5	40	40	0	40	0	40	0
	15	40	40	0	40	0	40	0
	17.5	40	40	0	40	0	40	0
	20	40	40	0	40	0	40	0
BAR 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	27	13	28	12	26	14
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
BZO 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	25	15	27	13	24	16
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
COC 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	29	11	30	10	27	13
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
EDDP 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	29	11	27	13	26	14
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
MET 1000	0	40	0	40	0	40	0	40
	250	40	0	40	0	40	0	40
	500	40	0	40	0	40	0	40
	750	40	0	40	0	40	0	40
	1000	40	27	13	30	10	29	11
	1250	40	40	0	40	0	40	0
	1500	40	40	0	40	0	40	0
	1750	40	40	0	40	0	40	0
	2000	40	40	0	40	0	40	0
MDMA 500	0	40	0	40	0	40	0	40
	125	40	0	40	0	40	0	40
	250	40	0	40	0	40	0	40
	375	40	0	40	0	40	0	40
	500	40	26	14	29	11	29	11
	625	40	40	0	40	0	40	0
	750	40	40	0	40	0	40	0
	875	40	40	0	40	0	40	0
	1000	40	40	0	40	0	40	0
MOP 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	30	10	29	11	27	13
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
OPI 2000	0	40	0	40	0	40	0	40
	500	40	0	40	0	40	0	40
	1000	40	0	40	0	40	0	40
	1500	40	0	40	0	40	0	40
	2000	40	27	13	28	12	29	11
	2500	40	40	0	40	0	40	0
	3000	40	40	0	40	0	40	0
	3500	40	40	0	40	0	40	0
	4000	40	40	0	40	0	40	0
MTD 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	28	12	26	14	29	11
	375	40	40	0	40	0	40	0

	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
OXY 100	0	40	0	40	0	40	0	40
	25	40	0	40	0	40	0	40
	50	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	100	40	29	11	27	13	30	10
	125	40	40	0	40	0	40	0
	150	40	40	0	40	0	40	0
	175	40	40	0	40	0	40	0
	200	40	40	0	40	0	40	0
PCP 25	0	40	0	40	0	40	0	40
	6.25	40	0	40	0	40	0	40
	12.5	40	0	40	0	40	0	40
	18.75	40	0	40	0	40	0	40
	25	40	30	10	28	12	28	12
	31.25	40	40	0	40	0	40	0
	37.5	40	40	0	40	0	40	0
	43.75	40	40	0	40	0	40	0
	50	40	40	0	40	0	40	0
PPX 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	28	12	29	11	26	14
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
TCA 1000	0	40	0	40	0	40	0	40
	250	40	0	40	0	40	0	40
	500	40	0	40	0	40	0	40
	750	40	0	40	0	40	0	40
	1000	40	28	12	28	12	29	11
	1250	40	40	0	40	0	40	0
	1500	40	40	0	40	0	40	0
	1750	40	40	0	40	0	40	0
	2000	40	40	0	40	0	40	0
THC 50	0	40	0	40	0	40	0	40
	12.5	40	0	40	0	40	0	40
	25	40	0	40	0	40	0	40
	37.5	40	0	40	0	40	0	40
	50	40	26	14	25	15	24	16
	62.5	40	40	0	40	0	40	0
	75	40	40	0	40	0	40	0
	87.5	40	40	0	40	0	40	0
	100	40	40	0	40	0	40	0
TML 300	0	40	0	40	0	40	0	40
	75	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	225	40	0	40	0	40	0	40
	300	40	27	13	30	10	28	12
	375	40	40	0	40	0	40	0
	450	40	40	0	40	0	40	0
	525	40	40	0	40	0	40	0
	600	40	40	0	40	0	40	0
K2 50	0	40	0	40	0	40	0	40
	12.5	40	0	40	0	40	0	40
	25	40	0	40	0	40	0	40
	37.5	40	0	40	0	40	0	40
	50	40	29	11	25	15	27	13
	62.5	40	40	0	40	0	40	0
	75	40	40	0	40	0	40	0
	87.5	40	40	0	40	0	40	0
	100	40	40	0	40	0	40	0
COT 200	0	40	0	40	0	40	0	40
	50	40	0	40	0	40	0	40
	100	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	200	40	26	14	28	12	27	13
	250	40	40	0	40	0	40	0
	300	40	40	0	40	0	40	0
	350	40	40	0	40	0	40	0
	400	40	40	0	40	0	40	0
FYL 200	0	40	0	40	0	40	0	40
	50	40	0	40	0	40	0	40
	100	40	0	40	0	40	0	40
	150	40	0	40	0	40	0	40
	200	40	25	15	29	11	28	12
	250	40	40	0	40	0	40	0
	300	40	40	0	40	0	40	0
	350	40	40	0	40	0	40	0
	400	40	40	0	40	0	40	0

3. Specificity

To investigate the specificity, 30 drug-free urine samples were collected from normal people. The drug-free samples were tested by three different lots. The results of each lot were read and recorded by an independent viewer who was blind to the samples. The results demonstrate that the drug-free urine samples produced negative results with the test.

4. Cross Reactivity

To investigate the cross-reactivity, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
AMP 1000			
d-Amphetamine	1000	l-Amphetamine	1000
d l-Amphetamine	1000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	2000
Phentermine	10000	Hydroxyamphetamine	>100000
d-Methamphetamine	>100000	l-Methamphetamine	>100000
(+/-)3,4-Methylenedioxyethylamphetamine(MDE)	>100000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100000
d/l-Epinephrine	>100000	β-Phenylethylamine	100000
Tyramine	100000	p-Hydroxynorephedrine	100000
Phenylpropanolamine	>100000	(±)Phenylpropanolamine	>100000
p-Hydroxyamphetamine	100000	d/l-Norephedrine	>100000
Benzphetamine	>100000	l-Ephedrine	100000
l-Epinephrine	>100000	/	/
BUP 10			
Buprenorphine	10	Buprenorphine-3-D-Glucuronide	15
Norbuprenorphine-3-D-Glucuronide	250	Norbuprenorphine	20
Morphine	>100000	Oxymorphone	>100000
Hydromorphone	>100000	/	/
BAR 300			
Secobarbital	300	Butethal	300
Amobarbital	300	Alphenol	>100000
Butalbital	2500	Cyclopentobarbital	300
Aprobarbital	300	Pentobarbital	300
Butabarbital	300	Phenobarbital	300
BZO 300			
Oxazepam	300	Diazepam	100
Alprazolam	200	Estazolam	5000
a-Hydroxyalprazolam	1250	Flunitrazepam	50000
Bromazepam	500	Demoxepam	2000
Delorazepam	1250	Midazolam	12500
Clobazam	100	Nitrazepam	100
Clonazepam	2500	Norchlordiazepoxide	200
Clorazepate dipotassium	200	Flurazepam	500
Chlordiazepoxide	1250	Temazepam	50
Desalkylflurazepam	100	Triazolam	2500
D,L-Lorazepam	2000	Nordiazepam	500
COC 300			
Benzoylecgonine	300	Cocaine	1000
Ecgonine	50000	Ecgonine methyl Ester	>100000
Cocaethylene	12500	Norcocaine	>100,000
COT 200			
Continine	200	Norricotinine	＞100000
(R,S)-Norcotinine	＞100000	Hydroxycotinine	2500
EDDP 300			
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	Alpha Methadol	>100000
EMDP	>100000	Disopyramide	>100000
Doxylamine	>100000	LAAM (Levo-alpha-acetylmethadol) HCl	>100000
Methadone	>100000	/	/
FYL 200			
Fentanyl	200	Norfentanyl	300
Remifentanil	＞10000	Ocfentanil	＞10000
Carfentanil	＞10000	Isobutyryl fentanyl	400
Sufentanil	＞10000	4-Fluoro-isobutyryl fentanyl	400
Acetylfentanyl	300	Acetyl norfentanyl	5000
α-Methylfentanyl	300	(±)-β-Hydroxythiofentanyl-$^{13}C_6$	500
Parafluorofentanyl-$^{13}C_6$	300	Butyryl fentanyl-$^{13}C_6$	1000
K2 50			
JWH-018 5-Pentanoic acid	50	JWH-073 4-Butanoic acid	50
JWH-018	＞10000	JWH-073	＞10000
JWH-018 4-hydroxypentyl	400	JWH-018 5-hydroxypentyl	400
JWH-073 4-hydroxybutyl	500	/	/
MET 1000			
D(+)-Methamphetamine	1000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDE)	50000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	8000
D/L-Methamphetamine	1000	β-Phenylethylamine	>100000
p-Hydroxymethamphetamine	25000	Trimethobenzamide	>100000
D-Amphetamine	>100000	L-Amphetamine	>100000
d,l-Amphetamine	>100000	(+/-)-Ephedrine	50000
Chloroquine	50000	l-phenylephrine	>100000
Mephetermine	50000	(1R,2S)-(-)-Ephedrine	>100000
(-)-Methamphetamine	50000	L-Methamphetamine	100000
MDMA 500			
3,4-Methylenedioxymethamphetamine (MDMA)	500	d-amphetamine	>100000
3,4-Methylenedioxyamphetamine HCl (MDA)	50000	l- methamphetamine	50000
3,4-Methylenedioxyethylamphetamine (MDE)	2500	l-amphetamine	>100000
d-methamphetamine	>100000	/	/
MOP 300			
Morphine	300	Hydrocodone	10000
Normorphine	>100000	Hydromorphone	5000
Codeine	300	Morphinie-3-β-d-glucuronide	2500
Ethyl Morphine	200	Oxycodone	>100000
Heroin	1250	Oxymorphone	>100000
Thebaine	20000	Norcodeine	100000
Levorphanol	10000	Procaine	>100000
6-Monoacetylmorphine (6-MAM)	300	s-Monoacetylmorphine	300
OPI 2000			
Morphine	2000	6-Monoacetylmorphine (6-MAM)	25000
Codeine	5000	Morphine 3-β-D-glucuronide	2000
Ethyl Morphine	10000	Norcodeine	>100000
Hydrocodone	25000	Normorphine	>100000
Hydromorphone	25000	Oxycodone	>100000
Levorphanol	50000	Oxymorphone	>100000
Procaine	>100000	Heroin	>100000
Thebaine	>100000	s-Monoacetylmorphine	2000
MTD 300			
Methadone	300	EDDP	>100000

LAAM	>100000	Doxylamine	>100000
EMDP	>100000	Alpha-Methadol	>100000
OXY 100			
Oxycodone	100	Hydromorphone	50000
Dihydrocodeine	10000	Acetylmorphine	>100000
Codeine	10000	Buprenorphine	>100000
Oxymorphone	500	Ethylmorphine	10000
Hydrocodone	10000	Thebaine	>100000
Morphine	50000	/	/
PCP 25			
Phencyclidine	25	4-Hydroxyphencyclidine	12500
PPX 300			
d-Propoxyphene	300	d-Norpropoxyphene	5000
TCA 1000			
Nortriptyline	1000	Desipramine	3000
Nordoxepine	10000	Imipramine	1000
Trimipramine	20000	Clomipramine	40000
Amitriptyline	1250	Doxepin	5000
Promazine	>100000	Maprotiline	100000
Promethazine	>100000	Norclomipramine	12500
Cyclobenzaprine	10000	/	/
THC 50			
11-nor-Δ9-THC-9-COOH	50	(-)-11-nor-9-carboxy-Δ 9-THC	500
11-nor-Δ8-THC-9-COOH	30	11-nor-Δ9-THC-carboxy -glucuronide	100000
11-hydroxy-Δ9 -Tetrahydrocannabinol	100000	Cannabinol	100000
Δ8- Tetrahydrocannabinol	20000	Cannabidiol	100000
Δ9- Tetrahydrocannabinol	20000	/	/
TML 300			
Cis-tramadol	300	/	/

5. Effect of Urinary Specific Gravity

Seven urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The spiked, different specific gravity urine were tested by three lots. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

6. Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.0 to 9.0 in 1.0 pH unit increment and spiked with the target drug at 25% below and 25% above cut-off levels respectively. The spiked, pH-adjusted urine were tested by three lots. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

7. Interfering Substances

The following compounds were added to drug-free urine, urine with target drugs of -25% cut-off and +25% cut-off level. Except for the compounds of Albumin (100mg/dL) and Ethanol (1%), other compounds were added at a concentration of 100μg/mL. All compounds show no interference at the response concentration in the following table.

Acetaminophen	Effexor	Nimodipine
Acetophenetidin	Enalapril Maleate	Nitroglycerin
Acetylsalicylic Acid	Erythromycin	Norethindrone
Acyclovir	Esomeprazole Magnesium	N-Acetylprocain-amide
Afrin	β-Estradiol	O-Hydroxyhippuric Acid
Albumin (100mg/dL)	1% Ethanol	Olanzapine
Aminophylline	Fenofibrate	Omeprazole
Aminopyrine	Fenoprofen	Oxalic Acid
Amiodarone Hydrochloride	Fentanyl Citrate	Oxolinic Acid
Amlodipine Mesylate	Fluoxetine Hydrochloride	Oxymetazoline
Amoxicillin	Fluvoxamine	Ondansetran
Ampicillin	Furosemide	Paliperidone
Apomorphine	Gabapentin	Pantoprazole
Aripiprazole	Gentisic Acid	Papaverine
Aspartame	Glibenclamide	Paroxetine Hydrochloride
Atomoxetine	Gliclazide	Penfluridol
Atorvastatin Calcium	Glipizide	PenicillinV Potassium
Atropine	Glucose	Penicillin-G
Benzilic Acid	Haloperidol	Phenelzine
Benzoic Acid	Hemoglobin	Pioglitazone Hydrochloride
Bilirubin	Hydrochlorothiazide	Piracetam
Bupropion	Hydrocortisone	Pravastatin Sodium
Captopril	3-Hydroxytyramine	Prednisone
Carbamazepine	Isosorbide Dinitrate	Propylthiouracil
Cefradine	Isoxsuprine	Quetiapine Fumarate
Cephalexin	Ibuprofen	Quinine
Chloral Hydrate	Ketoconazole	Ranitidine
Chloramphenicol	Ketoprofen	Rifampicin
Chlorothiazide	Ketamine	Risperidone
Cholesterol	Kratom powder	Salicylic Acid
Ciprofloxacin Hydrochloride	Labetalol	Serotonin
Citalopram	Lamotrigine	Sertraline Hydrochloride
Clarithromycin	Levofloxacin Hydrochloride	Sildenafil Citrate
Clonidine	Levonorgestrel	Simvastatin
Clopidogrel Hydrogen Sulphate	Levothyroxine Sodium	Sodium Valproate
Clozapine	Lidocaine Hydrochloride	Spironolactone
Conjugated Estrogens	Lisinopril	Sulfamethazine
Cortisone	Lithium Carbonate	Sulindac
Creatinine	Liverite	Tetracycline
(-) Cotinine	Loperamide	Tetrahydrocortsone 3 -acetate
chlorpheniramine	Loratadine	Tetrahydrocortisone 3-(β-D glucuronide)
D,L-Octopamine	Magnesium	Tetrahydrozoline
D,L-Propranolol	Meperidine	Thiamine
D,L-Tyrosine	Meprobamate	Thioridazine
Deoxy- corticosterone	Metoprolol Tartrate	Topiramate
Dextromethorphan	Mifepristone	Tramadol Hydrochloride
Diclofenac	Mirtazapine	Trazodone Hydrochloride
Diflunisal	Montelukast Sodium	Triamterene
Digoxin	Mosapride Citrate	Trifluoperazine
Diphenhydramine	Minocycline	Trimethoprim
Dirithromycin	Nalidixic Acid	Uric Acid
Domperidone	Naproxen	Valproate
D-Pseudoephedrine	Niacinamide	Verapamil
Duloxetine	Nifedipine	Vitamin B2
Dicyclomine	Nikethamide	Vitamin C

Alcohol Strip and Adulteration Strips

1. Detecion range

Alcohol Strip: The detection limit of the Alcohol Test is from 0.02% to 0.30%.

Adulteration Strips:

Oxidants (OXI.): Tests for the presence of oxidants such as bleach and peroxide in the urine.

Specific Gravity (S.G.): Tests for sample dilution. Normal level for specific gravity will range from 1.003 to 1.030. Specific gravity level of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.

pH: Tests for the presence of acidic or alkaline adulterants in the urine. Normal pH level should be in the range of 4.0 to 9.0. Values that below 4.0 or above 9.0 may indicate the sample has been altered.

Nitrite (NIT.): Tests for commercial adulterants. The normal urine should not contain nitrite. Positive results for nitrite usually indicate the sample has been altered.

Glutaraldehyde (GLUT.): Tests for the presence of Glutaraldehyde. Glutaraldehyde is normally not found in the urine. Positive results for glutaraldehyde usually indicate the sample has been altered.

Creatinine (CREA.): Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate the sample has been diluted. Test results can be compared to reference levels of the color chart.

2. Accuracy

The difference between the detection result and the marked value of the corresponding reference solution shall not exceed one order of magnitude, and no reverse difference shall be allowed. Positive reference solutions shall not produce negative results, and negative reference solutions shall not produce positive results.

3. Repeatability: The repeatability of the test results is not less than 90%.

4. Cross reaction

Reducing agent: such as ascorbic acid, can cause nitrite pseudyin.When urine contains protein (1g/L-7.5g/L), the specific gravity reading can be high.

Diluted urine from polyuria, excessive drinking of water, or other conditions typically results in urine with low creatinine concentrations.

Alcohol tests react with methanol, ethanol, etc.

MANUFACTURER/POST-SALE SERVICE UNIT

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INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
	Temperature limit	LOT	Batch code
	Do not re-use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date		Contains sufficient for <n> tests
EC REP	Authorized representative in the European		Keep away from sunlight

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