Rapid Single/multi-drug Test Cup
Catalogue No.: DOA12CUP01

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

AMP1000/BAR300/BZO300/COC300/KET1000/ MDMA500

MET1000/MOP300/ MQL300/MTD300/THC50/TRA200

Include Specimen Validity Tests (S.V.T.): OX/pH/SG

Rapid Single/multi-drug Test Cup is a rapid, screening test for the qualitative detection of single/multiple drugs and drug metabolites in human urine at specified cut off levels.

For professional use only. For in vitro diagnostic use only.

INTENDED USE

Rapid Single/multi-drug Test Cup is an immuno-chromatographic assay for the qualitative determination of the presence of drugs listed in the table below.

Drug(Identifier)	Calibrator	Cut-off level
Amphetamine (AMP)	d-Amphetamine	1000ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Ketamine (KET)	Ketamine	1000ng/mL
Methylenedioxymethamphetamine - ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000ng/mL
Morphine(MOP300)	Morphine	300ng/mL
Methaqualone (MQL)	Methaqualone	300ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL
Tramadol (TRA)	Tramadol	200 ng/mL

The test you purchased may test for any combination of drugs listed in the table above. This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Amphetamine (AMP)

Amphetamine and the structurally related “designer” drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthemic , and cardiovascular properties. They are usually taken orally, intraveneously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine . Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structural in the brain. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. It can be detected in the urine for 1 to 2 days after use.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse.

BENZODIAZEPINES (BZO)

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse.

Cocaine (COC)

Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time.

Ketamine (KET)

Ketamine is a short-acting “dissociative” anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP (‘Angel Dust’). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets’ offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately an 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

Methylenedioxymethamphetamine - ecstasy (MDMA)

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2 – 3 hours.

Methamphetamine (MET)

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine(MOP300)

Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake.

Methaqualone (MQL)

Methaqualone is a sedative and hypnotic medication. Methaqualone is a depressant that increases the activity of the GABA receptors in the brain and nervous system. When GABA activity is increased, blood pressure drops and the breathing and pulse rates slow, leading to a state of deep relaxation. Methaqualone peaks in the bloodstream within several hours, its effects generally lasting four to eight hours. Regular users build up a physical tolerance, requiring larger doses for the same effect. Overdose can lead to nervous system shut down, coma and death.

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). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12 – 24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylprryolidine), and EMDP (2- ethyl-5-methy -3, 3-diphenylpyrrolidine).

Opiate(OPI2000)

See Morphine(MOP300) for the summary.

Marijuana (THC)

Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

Tramadol (TRA)

Tramadol [2-(dimethylaminomethyl)-1-(3-methoxyphenyl) cyclohexanol] is used similarly to codeine, to treat moderate to moderately severe pain. It is a synthetic analog of the phenanthrene alkaloid codeine and, as such, is an opioid and also a prodrug (codeine is metabolized to morphine, tramadol is converted to Odesmethyltramadol). Tramadol and its metabolites are excreted primarily in the urine with observed plasma half-lives of 6.3 and 7.4 hours for tramadol and O-desmethyltramadol (denoted M1), respectively. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

Specimen Validity Tests (S.V.T.)

The strip contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample

Oxidants (OX) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant. Normal human urine should not contain oxidants or PCC.

Specific gravity(SG) tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

PRINCIPLE

Rapid Single/multi-drug Test Cup is a competitive immunoassay that is used to screen for the presence of various drugs *and drug metabolites* in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each strip, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Immunoassay for *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test cup should remain in the sealed pouch until use.
- The used test cup should be discarded according to local regulations.

CONTENTS OF THE KITS

- Drug Test Cup.
- Desiccant .
- Leaflet with instruction for use.

ADDITIONAL REQUIREMENTS

- Timer (watch or clock)
- External controls

STORAGE AND STABILITY

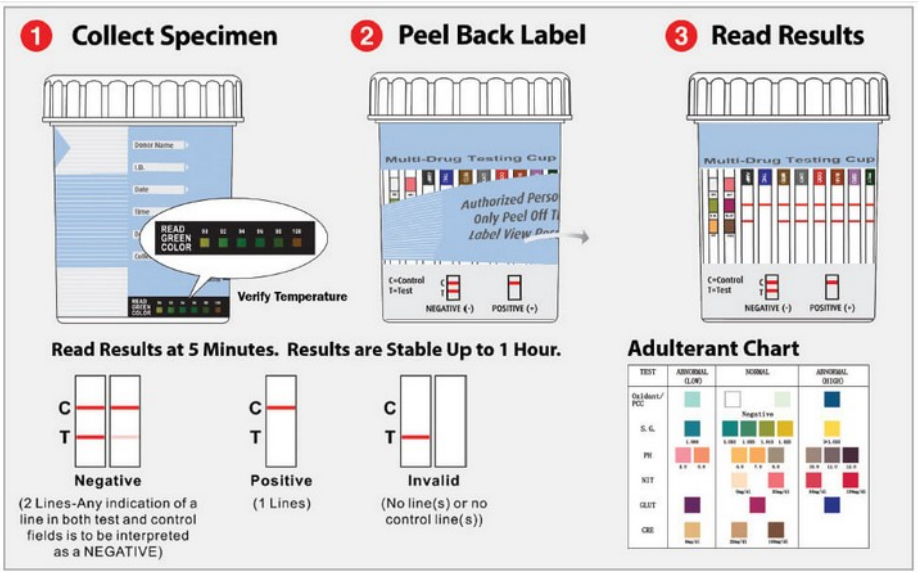
- Store at 39 ~ 86 ºF (4 ~ 30 ºC) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND PREPARATION

- Urine collected at any time of the day may be used.
- For best results, test specimens immediately following collection.
- Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours.

For longer storage, freeze the samples (-20°C or below).

- Bring frozen or refrigerated samples to room temperature before testing.



HOW TO PERFORM THE TEST?

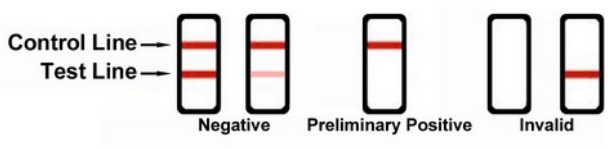
Test must be in room temperature (15ºC to 30ºC)

1. After the urine has been collected, tighten lid to the indicator, and place the test cup on a flat surface.
2. Read temperature immediately to verify that urine temperature is within the acceptable range. 90 – 100°F (32 – 38°C)
3. Peel off label and read the results. The drug test results should be read at 5 minutes. **The drug test results remain stable for up to thirty minutes.**

READING THE RESULTS

Preliminary positive (+)

A rose-pink band is visible in each control region. If no color band appears in appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.



the

Negative (-)

If a rose-pink band is visible in each control region and the appropriate test "T" region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid. Another test should opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.

Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.

Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST "T" REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEAGATIVE RESULT.

***IMPORTANT*:** This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Rapid Single/multi-drug Test Cup. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by Rapid Single/multi-drug Test Cup. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

QUALITY CONTROL

A procedural control is included in the test. A 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.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control should be run with each new lot, and every 30 days to check storage stability. Positive and negative

control should give the expected results.

Users can commercially obtain control materials (For example from Sigma-Aldrich Corporation).The concentration of drug(s) in positive and negative controls are approximately 50% above and below the cutoff concentration of the assay.

PERFORMANCE CHARACTERISTICS

Accuracy

The comparison studies were conducted using Rapid Single/multi-drug Test Cup and commercially available rapid drugs of abuse tests. The studies were performed on approximately 600 clinical specimens per drug type previous collected from the clinical settings. Results were as follows:

Format	% Agreement with Predicate Test		Format	% Agreement with Predicate Test		Format	% Agreement with Predicate Test	
AMP	Positive	100.00%	K2	Positive	100.00%	OPI2000	Positive	98.53%
	Negative	99.31%		Negative	99.65%		Negative	99.25%
BAR	Positive	100%	KET	Positive	98.65%	OXY	Positive	100%
	Negative	99.30%		Negative	99.05%		Negative	99.10%
BUP	Positive	100.00%	MAM	Positive	97.62%	PCP	Positive	100%
	Negative	98.78%		Negative	99.28%		Negative	99.30%
BZO	Positive	100%	MDMA	Positive	100%	PPX	Positive	100.00%
	Negative	99.20%		Negative	99.50%		Negative	98.09%
COC	Positive	100.00%	MET	Positive	98.15%	TCA	Positive	100.00%
	Negative	99.66%		Negative	99.08%		Negative	98.74%
COT	Positive	98.55%	MOP300	Positive	100.00%	THC	Positive	100.00%
	Negative	99.44%		Negative	99.29%		Negative	99.48%
ETG	Positive	97.83%	MQL	Positive	98.41%	TRA	Positive	98.28%
	Negative	99.46%		Negative	99.44%		Negative	99.45%
FYL	Positive	100.00%	MTD	Positive	100%			
	Negative	99.64%		Negative	99.40%			

TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.

Specificity and cross reactivity

To test the specificity and cross reactivity of the test, 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.

Compound	Response equivalent to cutoff in ng/mL	Compound	Response equivalent to cutoff in ng/mL
Amphetamine (AMP)		**6-Acetylmorphine (MAM)**	
d-Amphetamin	1,000	6-Monoacetylmorphine(6-MAN)	10
d.l-Amphetamine	2,500	Morphine	100
1-Amphetamine	50,000	Codeine	100
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,000	Hydrocodone	1000
Barbiturates (BAR)		Hydromorphine	1000
Secobarbital	300	Morphine 3-b-D-glucuronide	50
Amobarbital	500	**Methylenedioxymethamphetamine -**	

		ecstasy (MDMA)	
Alphenol	150	D-Amphetamine	>100000
Aprobarbital	200	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500
Butabarbital	75	3,4-methylenedioxyamphetamine (MDA)	2200
Butalbital	1,500	3,4-Methylenedioxyethylamphetamine (MDEA)	240
Butethal	100	**Methamphetamine (MET)**	
Cyclopentobarbital	600	D(+)-Methamphetamine	1,000
Pentobarbital	700	L(-)-Methamphetamine	8,000
Phenobarbital	300	(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
Buprenorphine(BUP)		p-hydroxymethamphetamine	30,000
Buprenorphine	10	3,4-Methylenedioxyethylamphetamine(MDEA)	10,000
Norbuprenorphine	20	**Morphine(MOP300)**	
Buprenorphine 3-D-glucuronide	15	Morphine	300
Norbuprenorphine 3-D-glucuronide	200	Codeine	300
Benzodiazepines (BZO)		Hydrocodone	2000
Oxazepam	300	Hydromorphine	1500
Alprazolam	200	6-Monoacetylmorphine(6-MAN)	750
α-Hydroxyalprazolam	1100	Morphine 3-b-D-glucuronide	300
Bromazepam	1000	**Methaqualone (MQL)**	
Chlordiazepoxide	2000	Methaqualone	300
Clobazam	100	**Methadone (MTD)**	
Clonazepam	800	Methadone	300
Clorazepate	200	(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000
Delorazepam	1600	Doxylamine	50000
Diazepam	200	**Opiate 2000 (OPI)**	
Estazolam	1000	Morphine	2,000
Flunitrazepam	350	Codeine	2,000
Lorazepam	1200	Hydrocodone	15,000
Midazolam	2500	Hydromorphine	10,000
Nitrazepam	100	6-Monoacetylmorphine	5,000
Nordiazepam	400	Morphine 3-b-D-glucuronide	2,000
Temazepam	120	**Oxycodone (OXY)**	
Triazolam	1000	Oxycodone	100
Cocaine (COC)		Naloxone	50000
Benzoylecgonine	300	Naltrexone	50000
Cocaine	800	Morphine 3-β-D-glucuronide	50000
Cocaethylene	12,500	Hydrocodone	3000
Ecgonine HCl	35,000	Hydromorphone	75000
Cotinine (COT)		Oxymorphone	1000
(-)-Cotinine	200	**Phencyclidine (PCP)**	
(-)-Nicotine	6,250	Phencyclidine	25
Ethylglucuronide (ETG)		4-Hydroxyphencyclidine	15000
Ethyl-β-D-glucuronide	500	**Propoxyphene(PPX)**	
Ethyl-β-D-glucuronide-D5	500	d-Propoxyphene	300
Fentanyl (FYL)		d-Norpropoxyphene	300
Fentanyl	200	**Tri-cyclic Antidepressants (TCA)**	

Synthetic Cannabinoid (K2)		Notriptyline	1000
JWH-018 Pentanoic Acid metabolite	50	Nordoxepin	1000
JWH-073 Butanoic Acid metabolite	50	Trimipramine	5000
JWH-018 N-4-hydroxypentyl	16,000	Promazine	3000
JAM2201 N-Pentanoic Acid metabolite	400	Desipramine	1000
JWH398 N-Pentanoic Acid metabolite	800	Imipramine	1000
JWH-210 N-(5-carboxypentyl) metabolite	5,000	Chomipramine	12500
JWH-073 3-hydroxypentyl metabolite	5,000	Doxepin	2000
JWH-019 5-hydroxypentyl metabolite	80,000	Maprotiline	2000
JWH-018 5-hydroxypentyl metabolite	90,000	Amitriptyline	1000
JWH-073 4-hydroxypentyl metabolite	80,000	**Marijuana (THC)**	
Ketamine (KET)		11-nor-Δ9-THC-9-COOH	50
Ketamine	1,000	11-nor-Δ8-THC-9-COOH	50
Norketamine	3,000	Δ8- Tetrahydrocannabinol	10,000
Methoxy-amphetamine	12,500	Δ9- Tetrahydrocannabinol	15,000
Promethazine	25,000	Cannabinol	20,000
4 - hydroxyphenyl cyclohexyl piperidine	50,000	Cannabidiol	>100,000
		Tramadol (TRA)	
		Tramadol	200

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine urine with the concentration 50% below and above the cutoff, respectively. All potential interfering substances were added at a concentration of 100μg/mL. The urine specimens were tested with the test device. None of the urine samples showed any deviation from the expected results.

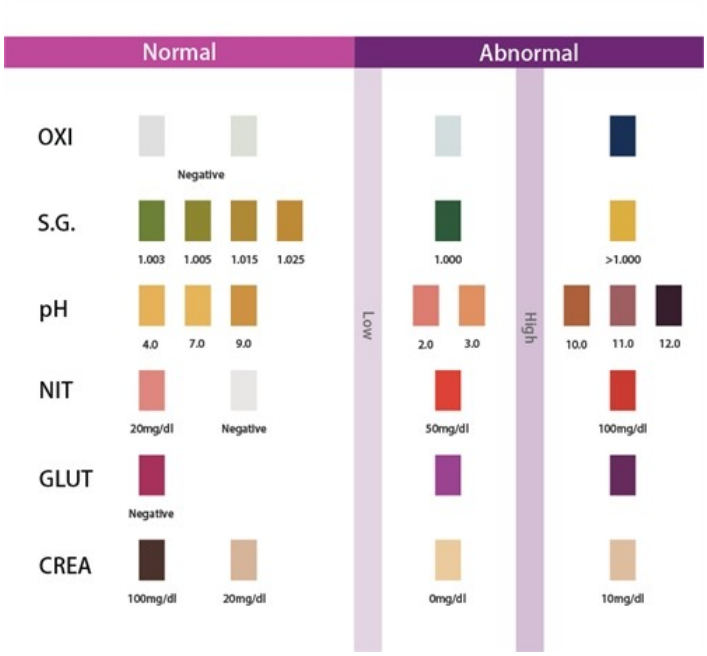
Acetaminophen	Chlorothiazide	Estrone-3-sulfate	Isoxsuprine	Oxymetazoline	Sulindac
Acetophenetidin	Chlorpheniramine	Ethyl-p-aminobenzoate	Ketoprofen	Oxytetracycline	Tetracycline
Amoxicillin	d,l-Chlorpromazine	Erythromycin	Labetalol	Papaverine	Tetrahydrozoline
Ampicillin	Cholesterol	Fenoprofen	Lisinopril	Penicillin-G	Thiamine
Aspirin	Clonidine	Flucloxacillin	Loperamide	Pentazocine	Thioridazine
Atenolol	Cimetidine	Fluoxetine	Meperidine	Perphenazine	d, l-Thyroxine
Atorvastatin	Citalopram	Furosemide	Meprobamate	Phenelzine	Tolbutamine
Azlocillin	Cortisone	Gentisic acid	Methoxyphenamine	Prednisolone	Tolbutamide
Benzilic acid	Creatinine	Hemoglobin	Methylphenidate	Prednisone	Trifluoperazine
Benzylpenicillin	Deoxycorticosterone	Hydralazine	Nadolol	d,l-Propanolol	Tryptamine
Benzoic acid	Dexamethasone	Hydrochlorothiazide	Nalidixic acid	d-Pseudoephedrine	Uric acid
Bilirubin	Dextromethorphan	Hydrocortisone	Naproxen	Quinacrine	Verapamil
Benzydamine	Diclofenac	o-Hydroxyhippuric acid	Niacinamide	Quinine	Zomepirac
Caffeine	Diflunisal	p-Hydroxytyramine	Nifedipine	Quindine	
Carbamazepine	Digoxin	Ibuprofen	Norethindrone	Ranitidine	
Cephalexin	Diphenhydramine	Indomethacin	d,l-Octopamine	Salicylic acid	
Chloralhydrate	Ephedrine	Iproniazid	Oxalic acid	Serotonin	
Chloramphenicol	β-Estradiol	d,l-Isoproterenol	Oxolinic acid	Sulfamethazine	

Effect of Urinary Specific Gravity

The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine or drug positive urine with the concentration at 50% below and 50% above cutoff level. Each sample was tested by the test device. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with each drug at 50% below and 50% above cutoff levels. Each sample was tested by the ctest device. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.



BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.

Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988

Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.

Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.

Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986

Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.

McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

APPLICABLE STANDARDS

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests

EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 13640:2002.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Sufficient for		Date of manufacture
IVD	In vitro diagnostic medical device		Use by		Do not reuse
4°C 30°C	Store between 4 ~ 30 ℃	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight		Keep dry	EC REP	Authorised Representative in the EU

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