Rapid Single/Multi-drug Test Cup

Instruction of use for testing of any combination of the following drugs:
AMP/BAR/BZO/BUP/COC/THC/MET/MTD/EDDP/MDMA/MOP300/OPI2000/OXY/PCP/PPX/TCA

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. 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
Buprenorphine(BUP)	Buprenorphine	10 ng/mL
Cocaine /COC	Benzoylecgonine	300 ng/mL
marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methadone Metabolite(EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP)	300 ng/mL
Methylenedioxymethamphetamine - ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500 ng/mL
Morphine*(MOP300)*	Morphine	300ng/mL
Opiate 2000 (OPI)	Morphine	2000ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene(PPX)	Propoxyphene	300 ng/mL
Tri-cyclic Antidepressants (TCA)	Notriptyline	1000ng/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.

Buprenorphine(BUP)
Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts.Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.3 The plasma half life of Buprenorphine is 2-4 hours.3 While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. 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.

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.

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-tetrahydro cannabinol-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.

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.

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).

Methadone Metabolite(EDDP)
EDDP(2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine) is the primary metabolite of methadone. Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. The detection of EDDP is more beneficial than traditional methadone screening since EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

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.

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. One Step Multi-drug Test Cup yields a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

Opiate(OPI2000)
Rapid Single/Multi-drug Test Cup yields a positive result when the concentration of Opiates in urine exceeds 2000ng/mL.See Morphine (MOP300) for the summary.

Oxycodone (OXY)
Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy.

Phencyclidine (PCP)
Phencyclidine, commonly known as PCP or “angel dust” is used primarily as recreational drug due to its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of Phencyclidines (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heat rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

Propoxyphene(PPX)
Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration.

Tri-cyclic Antidepressants (TCA)
Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs.

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

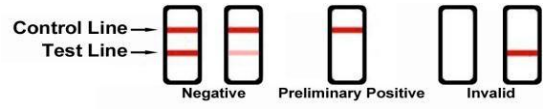
STORAGE AND STABILITY
• Store at 39 ~ 86 ºF (4 ~ 30 ºC) in the sealed pouch up to the expiration date.

SPECIMEN COLLECTION AND PREPARATION
• Collect urine sample with a clean, dry container. Urine collected at any time of the day may be used.
• DO NOT FREEZE.
• Keep away from direct sunlight, moisture and heat.
• 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 – 100ºF (32 – 38ºC)
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 the appropriate test “T” region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.
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.

INDEX OF SYMBOLS

	Consult instructions f or use		Keep away f rom sunlight
IVD	In v itro diagnostic medical dev ice		Keep dry
4°c 30°c	Store between 4 ~ 30 ºC		Do not reuse

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%	MDMA	Positive	100%	PCP	Positive	100%
	Negative	99.20%		Negative	99.50%		Negative	99.30%
BAR	Positive	100%	MET	Positive	98.10%	PPX	Positive	100.00%
	Negative	99.30%		Negative	99.10%		Negative	98.10%
BUP	Positive	100.00%	MOP300	Positive	100.00%	TCA	Positive	100.00%
	Negative	98.80%		Negative	99.30%		Negative	98.70%
BZO	Positive	100%	MTD	Positive	100%	THC	Positive	100.00%
	Negative	99.20%		Negative	99.40%		Negative	99.50%
COC	Positive	100.00%	OPI2000	Positive	98.50%			
	Negative	99.70%		Negative	99.20%			
EDDP	Positive	100.00%	OXY	Positive	100%			
	Negative	99.40%		Negative	99.10%			

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
AMP		**MDMA**	
d-Amphetamin	1,000	D-Amphetamine	>100000
d.l-Amphetamine	2,500	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500
1-Amphetamine	50,000	3,4-methylenedioxyamphetamine (MDA)	2200
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,000	3,4-Methylenedioxyethylamphetamine (MDEA)	240
BAR		**MOP300**	
Secobarbital	300	Morphine	300
Amobarbital	500	Codeine	300
Alphenol	150	Hydrocodone	2000
Aprobarbital	200	Hydromorphine	1500
Butabarbital	75	6-Monoacetylmorphine（6-MAN）	750
Butalbital	1,500	Morphine 3-b-D-glucuronide	300
Butethal	100	**MTD**	
Cyclopentobarbital	600	Methadone	300
Pentobarbital	700	(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000
Phenobarbital	300	Doxylamine	50000
BUP		**OPI 2000**	
Buprenorphine	10	Morphine	2,000
Norbuprenorphine	20	Codeine	2,000
Buprenorphine 3-D-glucuronide	15	Hydrocodone	15,000
Norbuprenorphine 3-D-glucuronide	200	Hydromorphine	10,000
BZO		6-Monoacetylmorphine	5,000
Oxazepam	300	Morphine 3-b-D-glucuronide	2,000
Alprazolam	200	**OXY**	
α-Hydroxyalprazolam	1100	Oxycodone	100
Bromazepam	1000	Naloxone	50000
Chlordiazepoxide	2000	Naltrexone	50000
Clobazam	100	Morphine 3-β-D-glucuronide	50000
Clonazepam	800	Hydrocodone	3000
Clorazepate	200	Hydromorphone	75000
Delorazepam	1600	Oxymorphone	1000
Diazepam	200	**PCP**	
Estazolam	1000	Phencyclidine	25
Flunitrazepam	350	4-Hydroxyphencyclidine	15000
Lorazepam	1200	**PPX**	
Midazolam	2500	d-Propoxyphene	300
Nitrazepam	100	d-Norpropoxyphene	300
Nordiazepam	400	**TCA**	
Temazepam	120	Notriptyline	1000
Triazolam	1000	Nordoxepin	1000
COC		Trimipramine	5000
Benzoylecgonine	300	Promazine	3000
Cocaine	800	Desipramine	1000
Cocaethylene	12,500	Imipramine	1000
Ecgonine HCl	35,000	Chomipramine	12500
EDDP		Doxepin	2000
EDDP	300	Maprotiline	2000
Methadone	3,000,000	Amitriptyline	1000
MET		**THC**	

D(+)-Methamphetamine	1,000	11-nor-Δ9-THC-9-COOH	50
L(-)-Methamphetamine	8,000	11-nor-Δ8-THC-9-COOH	50
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000	Δ8- Tetrahydrocannabinol	10,000
p-hydroxymethamphetamine	30,000	Δ9- Tetrahydrocannabinol	15,000
3,4-Methylenedioxyethylamphetamine(MDEA)	10,000	Cannabinol	20,000
		Cannabidiol	＞100,000

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

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.

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.

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.