Identify® Diagnostics Multi-Drug Rapid Urine Test Dip -CLIA Waived

Package Insert

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BZO/COC/THC/MOP/MET/MTD/PCP/TCA/OXY/MDMA/BUP/FYL.

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. Immunoassay for in vitro diagnostic use only.

Medical and other professional in vitro diagnostic use labeling.

【INTENDED USE】

The Identify Diagnostics Multi-Drug Rapid Urine Test Dip tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150
Methamphetamine (MET)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Fentanyl (FYL)	Fentanyl	1

The Identify Diagnostics Multi-Drug Rapid Urine Test Dip can be a single drug test panel or used for any combination of the above listed analytes. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs 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.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

【SUMMARY】

The Multi-Drug Rapid Urine Test Dip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. 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.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of amphetamines in urine exceeds detective level.

Secobarbital (BAR)

Secobarbital is one of CNS depressants (barbiturates). They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most secobarbital are excreted unaltered in the urine.

The approximate detection time limits for secobarbital are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of secobarbital in urine exceeds detective level.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced secobarbital in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of benzodiazepines in urine exceeds detective level.

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. The plasma half -life of Buprenorphine is 2-4 hours. 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.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the Buprenorphine in urine exceeds detective level.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of Cocaine in urine exceeds detective level.

Marijuana (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of THC-COOH in urine exceeds detective level.

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). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of methadone in urine exceeds detective level.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The Multi-Drug Rapid Urine Test Dip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The Multi-Drug Rapid Urine Test Dip yields a positive result when the Methamphetamine in urine exceeds detective level.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds detective level.

Morphine (MOP/OPI 300)

Opiate refers 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. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of morphine in urine exceeds detective level.

Phencyclidine (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP 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.6 PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of phencyclidine in urine exceeds detective level. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Nortriptyline (TCA)

Nortriptyline is one of the Tricyclic Antidepressants, TCA are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The Multi-Drug Rapid Urine Test Dip yields a positive result when the concentration of tricyclic antidepressants in urine exceeds detective level. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The Multi-Drug Rapid Urine Test Dip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine. The Multi-Drug Rapid Urine Test Dip yields a positive result when Oxycodone in urine exceeds detective level.

Fentanyl(FYL)

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

pain. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

The Multi-Drug Rapid Urine Test Dip is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of fentanyl in urine. The Multi-Drug Rapid Urine Test Dip yields a positive result when fentanyl in urine exceeds detective level.

【PRINCIPLE】

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

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

【PRECAUTIONS】

- Immunoassay for *in vitro* diagnostic use only. The test Panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Panel should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test Panel must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed well before testing.

【MATERIALS】

Materials Provided

- Test Panels
- Package Insert
- Adulteration Color Chart (when applicable)

Materials Required But Not Provided

- Specimen Collection Containers
- Timer

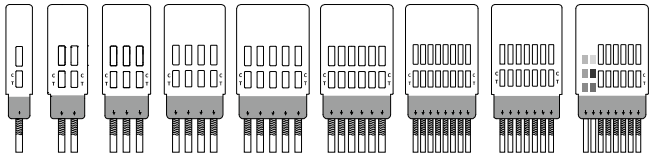
【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature 59-86ºF (15-30ºC) prior to testing.

1. Remove the test panel from the sealed pouch.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. **The adulteration strip(s), if applicable, should be read between 3-5 minutes.** Compare the colors on the adulteration strip to the color chart. **If the results indicate adulteration, do not read the drug test results. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.**
7. If results do not indicate adulteration, **read the drug test result at 5 minutes.** Do not interpret the result after 10 minutes.
8. If preliminary positive results are observed, please send the urine sample to the laboratory for confirmation.

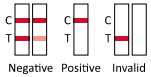
TEST PROCEDURE **Panel**

- Remove the cap.
- Do not immerse pass the max line
- Immerse 10-15 seconds

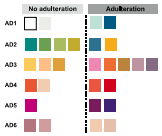


1

Read Drug Result at 5 minutes.



Interpret adulteration strips between 3-5 minutes.
See enclosed color chart for interpretation.



2

【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

***NEGATIVE: A colored line appears in the Control region (C) and a colored line appears in the Test region (T)**. This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test Panel. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF RESULTS (S.V.T ADULTERATION)】

(Please refer to the color chart)

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

No instrumentation is required.

【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 performed in accordance with federal, state, and local regulations.

【LIMITATIONS】

1. The Multi-Drug Rapid Urine Test Dip provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry or Liquid Chromatography/mass spectrometry is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests. Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.

【EXPECTED VALUES】

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

【PERFORMANCE CHARACTERSTICS】

Accuracy

About 80 clinical urine specimens with known LC/MS values and tested by Multi-Drug Rapid Urine Test Dip. Each test was performed by three operators. Results were as follows:

Amphetamine(AMP500)

Result		Candidate Device Result		The Agreement Rate
Operator	**LC/MS Result**	**Positive**	**Negative**	
Operator A	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Secobarbital(BAR300)

Result		Candidate Device Result		The Agreement Rate
Operator	**LC/MS Result**	**Positive**	**Negative**	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Oxazepam (BZO300)

Result		Candidate Device Result		The Agreement Rate
Operator	**LC/MS Result**	**Positive**	**Negative**	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Cocaine(COC150)

Result		Candidate Device Result		The Agreement Rate
Operator	**LC/MS Result**	**Positive**	**Negative**	
Operator A	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 150ng/mL (+)	40	0	40/40=100%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		

Marijuana(THC50)

Result		Candidate Device Result		The Agreement Rate
Operator	**LC/MS Result**	**Positive**	**Negative**	
Operator A	Above 50ng/mL (+)	40	0	40/40=100%
	Lower 50ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 50ng/mL (+)	39	1	39/40=97.5%
	Lower 50ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 50ng/mL (+)	40	0	40/40=100%
	Lower 50ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		

Morphine(MOP/OPI 300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Methamphetamine(MET500)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Methadone(MTD300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Phencyclidine(PCP25)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Nortriptyline(TCA1000)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1000ng/mL (+)	39	1	39/40=97.5%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 1000ng/mL (+)	39	1	39/40=97.5%
	Lower 1000ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 1000ng/mL (+)	40	0	40/40=100%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Oxycodone(OXY100)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 100ng/mL (+)	40	0	40/40=100%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		
Operator B	Above 100ng/mL (+)	39	1	39/40=97.5%
	Lower 100ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 100ng/mL (+)	39	1	39/40=97.5%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Ecstasy(MDMA500)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Buprenorphine(BUP10)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 10ng/mL (+)	39	1	39/40=97.5%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 10ng/mL (+)	39	1	39/40=97.5%
	Lower 10ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 10ng/mL (+)	40	0	40/40=100%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Fentanyl(FYL1)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		
Operator B	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	3	37	37/40=92.5%
	Accuracy	(38+37)/80=93.75%		
Operator C	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		

Analytical Specificity

The following table lists compounds that are positively detected in urine by Multi-Drug Rapid Urine Test Dip at 5 minutes.

Drug	Concentration (ng/ml)	Cross- Reactivity (%)
Amphetamine(AMP500)		
Hydroxyamphetamine	5000	10%
(+/-)-Methylenedioxyamphetamine(MDA)	25	2000%
D,L-Amphetamine	500	100%
D-Amphetamine	500	100%
Diethylstilbestrol	>100000	<0.5%
L-Amphetamine	500	100%
Phentermine	500	100%
β-Phenylethylamine	>100000	<0.5%
Tyramine	>100000	<0.5%
p-Hydroxynorephedrine	>100000	<0.5%
D,L-Norephedrine	>100000	<0.5%
p-Hydroxyamphetamine	5000	10%
D-Methamphetamine	>100000	<0.5%
L-Methamphetamine	>100000	<0.5%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	100000	0.5%
Phenylpropanolamine	>100000	<0.5%
Benzphetamine	>100000	<0.5%
L-Ephedrine	>100000	<0.5%
L-Epinephrine	>100000	<0.5%
D,L-Epinephrine	>100000	<0.5%
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100000	0.5%
Secobarbital(BAR300)		
Alphenal	300	100%
Amobarbital	300	100%
Aprobarbital	300	100%
Butabarbital	500	60%
Butethal	200	150%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	200	150%
Secobarbital	300	100%
Butalbital	2000	15%
Barbital	300	100%
Oxazepam (BZO300)		
a-Hydroxyalprazolam	10000	3%
Alprazolam	200	150%
Bromazepam	1000	30%
Chlordiazepoxide	300	100%
Clobazam	200	150%
Clonazepam	200	150%
Clorazepate Dipotassium	300	100%
Desalkylflurazepam	>100000	<0.3%
Diazepam	300	100%
Estazolam	100	300%
Flunitrazepam	300	100%
D,L-Lorazepam	1000	30%
Midazolam	1000	30%
Nitrazepam	200	150%
Norchlordiazepoxide	200	150%
Nordiazepam	200	150%
Oxazepam	300	100%
R,S-Lorazepam glucuronide	1000	30%
Temazepam	100	300%
Triazolam	300	100%
Demoxepam	2000	15%
Flurazepam	300	100%
Delorazepam	2000	15%
Lormetazepam	100	300%
Buprenorphine(BUP10)		
Buprenorphine	10	100%
Buprenorphine-3-D-Glucuronide	20	50%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Hydromorphone	>100000	<0.01%
Codeine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Cocaine(COC150)		
Benzoylecogonine	150	100%
Cocaethylene	250	60%
Cocaine hydrochloride	125	120%
Ecgonine	>100000	<0.2%
Norcocaine	>100000	<0.2%
Ecgonine methyl ester	>100000	<0.2%

Methamphetamine(MET500)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	6000	8.3%
(±)-MDMA	1000	50%
D-Methamphetamine	500	100%
L-Methamphetamine	10000	5%
Fenfluramine	50000	1%
p-Hydroxymethamphetamine	250	200%
D,L-Methamphetamine	250	200%
β-Phenylethylamine	>100000	<0.5%
Mephetermine	25000	2%
Methoxyphenamine hydrochloride	75000	0.7%
L-Amphetamine	100000	0.5%
D-Amphetamine	100000	0.5%
D,L-Amphetamine	250	200%
Chloroquine	25000	2.0%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
Trimethobenzamide	>100000	<0.5%
l-phenylephrine	>100000	<0.5%
(1R,2S)-(-)-Ephedrine	>100000	<0.5%
Procaine hydrochloride	>100000	<0.5%
Phentermine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Morphine(MOP/OPI 300)		
6-acetylmorphine	300	100%
Codeine	250	120%
Dihydrocodeine	5000	6%
EthylMorphine	200	150%
Heroin	500	60%
Hydrocodone	1000	30%
Hydromorphone	10000	3%
Levorphanol tartrate	1500	20%
Morphine	300	100%
Nalorphine hydrochloride	300	100%
Thebaine	20000	1.5%
s-Monoacetylmorphine	300	100%
Morphine-3-β-d-glucuronide	1000	30%
6-Monoacetylmorphine (6-MAM)	300	100%
Codeine-6-β-D-glucuronide	25000	1.2%
Morphine-6-β-D-glucuronide	1000	30%
6-Acetylcodeine	25000	1.2%
Normorphine	50000	0.6%
Oxycodone	>100000	<0.3%
Oxymorphone	>100000	<0.3%
Norcodeine	25000	1.2%
Procaine hydrochloride	>100000	<0.3%
Norpropoxyphene	>100000	<0.3%
Phencyclidine(PCP25)		
PCP (Phencyclidine)	25	100%
4-Hydroxyphencyclidine	15	167%
Pheniramine	50000	0.05%
Methadone(MTD300)		
(±)-Methadone	300	100%
EDDP	>100000	<0.3%
EMDP	>100000	<0.3%
LAAM	>100000	<0.3%
Alpha Methadol	>100000	<0.3%
Doxylamine	>100000	<0.3%
Disopyramide	6000	5.0%
Esomeprazole	10000	3.0%
Pheniramine	100000	0.3%
Oxycodone(OXY100)		
Ethyl Oxycodone	100	100%
Hydrocodone	50000	0.2%
Hydromorphone	25000	0.4%
Levorphanol tartrate	50000	0.2%
Naloxone hydrochloride	50000	0.2%
Naltrexone hydrochloride	>100000	<0.1%
Oxycodone	100	100%
Oxymorphone	100	100%
Oxymorphone-3β-D-glucuronide	>100000	<0.1%
Noroxycodone	1000	10%
Noroxymorphone	25000	0.4%
Dihydrocodeine	12500	0.8%
Codeine	100000	0.1%
Morphine	>100000	<0.1%
Acetylmorphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Thebaine	>100000	<0.1%
6-acetylmorphine	>100000	<0.1%
Marijuana (THC50)		
11-nor-Δ^8-THC-9-COOH	20000	0.25%
(-)-11-nor-9-carboxy-Δ^9-THC	50	100%
(±)-11-nor-9-Carboxy-Δ^9-THC	50	100%
11-nor-Δ^9-THC -carboxy glucuronide	50	100%
11-hydroxy-Δ^9-Tetrahydrocannabinol	5000	1.0%
Δ^8- Tetrahydrocannabinol	100000	0.05%
Δ^9- Tetrahydrocannabinol	100000	0.05%
Cannabinol	>100000	<0.05%
Cannabidiol	>100000	<0.05%
Estasy(MDMA500)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	250	200%
(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
(±)-MDMA	500	100%
L-Methamphetamine	>100000	<0.5%
d-methamphetamine	>100000	<0.5%
d-amphetamine	>100000	<0.5%
l-amphetamine	>100000	<0.5%
d,l-Amphetamine	>100000	<0.5%
d,l-Methamphetamine	>100000	<0.5%
Phentermine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Nortriptyline (TCA1000)		
Amitriptyline	1500	66.7%
Chlorpheniramine	>100000	<1%
Clomipramine	1000	100%
Cyclobenzaprine Hydrochloride	>100000	<1%
Desipramine	300	333.3%
Doxepine	10000	10%
Duloxetine	>100000	<1%
Imipramine	500	200%
Norclomipramine	250	400%
Nordoxepine	>100000	<1%
Nortriptyline hydrochloride	1000	100%
Promazine	500	200%
Trimipramine	1500	66.7%
Maprotiline	>100000	<1%
Promethazine hydrochloride	50000	2%
Fentanyl(FYL1)		
Fentanyl	1	100%
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20000	0.005%
Isobutyryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%
Sufentanil	10	10%
Alfentanil	5000	0.02%
Despropionyl fentanyl (4-ANPP)	2500	0.04%
Cyclopropylfentanyl	3	33.3%
Remifentanil	>100000	<0.001%
Norfentanyl	>100000	<0.001%
Acetyl norfentanyl	>100000	<0.001%
Norcarfentanil	>100000	<0.001%
6-Acetyl morphine	>100000	<0.001%
Amphetamine	>100000	<0.001%
Buprenorphine	>100000	<0.001%
Buprenorphineglucuronide	>100000	<0.001%
Codeine	>100000	<0.001%
Dextromethorphan	>100000	<0.001%
Dihydrocodeine	>100000	<0.001%
EDDP	>100000	<0.001%
EMDP	>100000	<0.001%
Fluoxetine	>100000	<0.001%
Heroin	>100000	<0.001%
Hydrocodone	>100000	<0.001%
Hydromorphone	>100000	<0.001%
Ketamine	>100000	<0.001%
Levorphanol	>100000	<0.001%
Meperidine	>100000	<0.001%
Methadone	>100000	<0.001%
Morphine	>100000	<0.001%
Morphine-3-glucuronide	>100000	<0.001%
Naloxone	>100000	<0.001%
Naltrexone	>100000	<0.001%
Norbuprenorphine	>100000	<0.001%
Norcodeine	>100000	<0.001%
Norketamine	>100000	<0.001%
Normeperidine	>100000	<0.001%
Normorphine	>100000	<0.001%
Noroxycodone	>100000	<0.001%
Oxycodone	>100000	<0.001%
Oxymorphone	>100000	<0.001%
Pentazocine (Talwin)	>100000	<0.001%
Pipamperone	>100000	<0.001%
Risperidone	>100000	<0.001%
Tapentadol	>100000	<0.001%
Thioridazine	>100000	<0.001%
Tilidine	>100000	<0.001%
Tramadol	>100000	<0.001%
Tramadol-O-Desmethyl	>100000	<0.001%
Tramadol-N-Desmethyl	>100000	<0.001%
Isotonitaze	>100000	<0.001%

Precision

This study is performed by three personnel who don't know the sample number system participate in the study. Three lots were run in consecutive business days at each

concentration for each lot per day. The results as follows:

Drugs	Concentration	n	Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
MOP /OPI 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	0	50	0	50	0	50	0
	300ng/ml	27	23	28	22	26	24	27
	375ng/ml	50	0	50	0	50	0	50
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
MDMA 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	0	50	0	50	0	50	0
	500ng/ml	28	22	25	25	28	22	28
	625ng/ml	50	0	49	1	50	0	50
	750ng/ml	50	50	0	50	0	50	0
	875	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
OXY 100	0ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	0	50	0	50	0	50
	50ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	1	49	0	50	0	50
	100ng/ml	50	27	23	29	21	27	23
	125ng/ml	50	50	0	50	0	50	0
	150ng/ml	50	50	0	50	0	50	0
	175ng/ml	50	50	0	50	0	50	0
	200ng/ml	50	50	0	50	0	50	0
PCP 25	0ng/ml	50	0	50	0	50	0	50
	6.25ng/ml	50	0	50	0	50	0	50
	12.5ng/ml	50	0	50	0	50	0	50
	18.75ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	25	25	27	23	26	24
	31.25ng/ml	50	49	1	50	0	50	0
	37.5ng/ml	50	50	0	50	0	50	0
	43.75ng/ml	50	50	0	50	0	50	0
	50ng/ml	50	50	0	50	0	50	0
COC 150	0ng/ml	50	0	50	0	50	0	50
	37.5ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	112.5ng/ml	50	0	50	1	49	0	50
	150ng/ml	50	28	22	29	21	26	24
	187.5ng/ml	50	50	0	50	0	49	1
	225ng/ml	50	50	0	50	0	50	0
	262.5ng/ml	50	50	0	50	0	50	0
	300ng/ml	50	50	0	50	0	50	0
MTD 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	28	22	26	24	25	25
	375ng/ml	50	50	0	49	1	50	0
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
BAR 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	27	23	27	23	29	21
	375ng/ml	50	49	1	50	0	50	0
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
BZO 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	26	24	26	24	26	24
	375ng/ml	50	50	0	49	1	50	0
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
AMP 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	50	0	50	0	50	1	49
	500ng/ml	50	28	22	26	24	29	21
	625ng/ml	50	49	1	49	1	0	50
	750ng/ml	50	50	0	50	0	50	0
	875ng/ml	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
MET 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	50	1	49	0	50	0	50
	500ng/ml	50	28	22	27	23	25	25
	625ng/ml	50	0	50	49	1	0	50
	750ng/ml	50	50	0	50	0	50	0
	875ng/ml	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
TCA 1000	0ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	500ng/ml	50	0	50	0	50	0	50
	750ng/ml	50	0	50	0	50	0	50
	1000ng/ml	50	26	24	28	22	26	24
	1250ng/ml	50	0	50	0	50	49	1
	1500ng/ml	50	50	0	50	0	50	0
	1750ng/ml	50	50	0	50	0	50	0
	2000ng/ml	50	50	0	50	0	50	0
THC 50	0ng/ml	50	0	50	0	50	0	50
	12.5ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	0	50	0	50	0	50
	37.5ng/ml	50	1	49	0	50	0	50
	50ng/ml	50	25	25	27	23	25	25
	62.5ng/ml	50	0	50	0	50	49	1
	75ng/ml	50	50	0	50	0	50	0
	87.5ng/ml	50	50	0	50	0	50	0
	100ng/ml	50	50	0	50	0	50	0
BUP 10	0ng/ml	50	0	50	0	50	0	50
	2.5ng/ml	50	0	50	0	50	0	50
	5ng/ml	50	0	50	0	50	0	50
	7.5ng/ml	50	0	50	1	49	1	49
	10ng/ml	50	26	24	25	25	26	24
	12.5ng/ml	50	49	1	0	50	0	50
	15ng/ml	50	50	0	50	0	50	0
	17.5ng/ml	50	50	0	50	0	50	0
	20ng/ml	50	50	0	50	0	50	0
FYL1	0ng/ml	50	0	50	0	50	0	50
	0.25ng/ml	50	0	50	0	50	0	50
	0.5ng/ml	50	0	50	0	50	0	50
	0.75ng/ml	50	1	49	1	49	2	48
	1ng/ml	50	28	22	30	20	27	23
	1.25ng/ml	50	0	50	0	50	0	50
	1.5ng/ml	50	50	0	50	0	50	0
	1.75ng/ml	50	50	0	50	0	50	0
	2ng/ml	50	50	0	50	0	50	0

Effect of Urinary Specific Gravity

Total 12 urine samples of specific gravities (SG) ranging from 1.000-1.035 were collected. Values of SG levels were determined by a refractometer. Target drugs were spiked to these urine samples at +50% cut-off and -50% cut-off concentrations. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked pH-adjusted urine was tested with the Multi-Drug Rapid Urine Test Dip. The results demonstrate the varying ranges of urinary pH do not affect the test results.

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine target drugs urine with concentrations at 50% below and 50% above Cut-Off levels. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Urine Test Dip at a concentration of 100µg/ml or specified concentrations.

Non Interference Compounds

3-Hydroxytyramine	Digoxin	Nitroglycerin
Acetaminophen	Diphenhydramine HCl	Nordoxepin
Acetone(1000mg/dL)	Disopyramide(except MTD test)	Norethindrone
Acetophenetidin	DL-Tryptophan	Norfentanyl
Acetylsalicylic acid	DL-Tyrosine	Noscapine
Acyclovir	Dopamine HCl	O-Hydroxyhippuric acid
Albumin(100mg/dL)	Doxepin(except TCA test)	Octopamine
Albuterol sulfate(Proair HFA)	Doxylamine	Olanzapine
Alpha Methadol	Duloxetine	Omeprazole
Aminophylline	Ecgonine methyl ester	Oxalic acid (100 mg/dL)
Aminopyrine	EMDP	Oxolinic acid
Amoxicillin	Ephedrine	Oxymetazoline
Ampicillin	Erythromycin	Paliperidone
Apomorphine	Esomeprazole Magnesium(except MTD test)	Papaverine
Aripiprazole	Ethanol(1%)	Penicillin-G
Ascorbic acid	Fenoprofen	PenicillinV Potassium
Aspartame	Fluoxetine Hydrochloride	Perphenazine
Aspirin	Fluphenazine	Phenacetin
Atomoxetine	Furosemide	Phenelzine
Atorvastatin Calcium	Gabapentin	Phenethylamine
Atropine	Galactose (10mg/dL)	Phenylpropanolamine
Azithromycin	Gamma Globulin (500mg/dL)	Prednisone
Benzilic acid	Gatifloxacin	Pregablin
Benzocaine	Gentisic acid	Procaine
Benzoic acid	Glucose (3000mg/dL)	Promethazine(except TCA test)
Benzphetamine	Hemoglobin	Propoxyphene
Bilirubin	Hydralazine	Propranolol
Boric Acid (1%)	Hydrochlorothiazide	Pseudoephedrine
Bupropion	Hydrocortisone	Quetiapine
Caffeine	Hydroxytyramine	Quinine
Cannabidiol	Ibuprofen	Ranitidine
Captopril	Isoproterenol	Riboflavin (10mg/dL)
Carbamazepine	Isoxsuprine	Rifampicin
Carfentanil(except FYL test)	Ketamine	Risperidone
Cefradine	Ketoprofen	Salicylic acid
Cephalexin	L-Ephedrine	Serotonin (5- Hydroxytyramine)
Chloralhydrate	L-Epinephrine	Sertraline
Chloramphenicol	L-phenylephrine	Sildenafil Citrate
Chloroquine(except MET test)	LAAM HCl	Simvastatin
Chlorothiazide	Labetalol	Sulfamethazine
Chlorpheniramine	Levofloxacin Hydrochloride	Sulindac
Chlorpromazine	Levonorgestrel	Telmisartan
Cholesterol	Levothyroxine Sodium	Tetrahydrocortisone 3-(β-Dglucuronide)
Ciprofloxacin Hydrochloride	Lidocaine Hydrochloride	Tetrahydrocortisone, 3-acetate
Citalopram	Lisinopril	Tetrahydrozoline
Clarithromycin	Loperamide	Theophylline
Clonidine	Loratadine	Thiamine
Clozapine	Magnesium	Thioridazine
Conjugated Estrogens	Maprotiline	Tramadol Hydrochloride
Cortisone	Meperidine	Triamterene
Cotinine	Meprobamate	Trifluoperazine
Creatinine	Methapyrilene	Trimethobenzamide
Cyclobenzaprine	Methaqualone	Trimethoprim
D-Pseudoephedrine	Methoxyphenamine (except AMP/MET test)	Tyramine
D,L-Epinephrine	Metoprolol Tartrate	Urea (2000mg/dL)

D,L-Isoproterenol	Metronidazole (300ug/ml)	Uric acid
D,L-Octopamine	Mifepristone	Valproic acid (250ug/ml)
D,L-Propranolol	N-Acetylprocainamide	Venlafaxine HCl
D,L-Tryptophan	NaCl (4000mg/dL)	Verapamil
D,L-Tyrosine	Nalidixic acid	Vitamin B2
Delorazepam(except BZO test)	Naloxone hydrochloride(except OXY test)	Vitamin C
Deoxycorticosterone	Naltrexone hydrochloride	Zaleplon
Desloratadine	Naproxen	Zomepirac
Dextromethorphan	Niacinamide	β-Estradiol
Diclofenac sodium	Nicotine	
Diflunisal	Nifedipine	

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【GLOSSARY OF SYMBOLS】

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
UDI	Unique device identifier		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use				

Manufactured for:

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