

## Rapid Response™

### Drug Screen Cup (Urine)

Product 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.

CLIA WAIVED.

Immunoassay for *in vitro* diagnostic use only.

Medical and other professional *in vitro* diagnostic use labeling.

### Intended Use

Rapid Response™ Drug Screen Cup is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of one or more combination of following drugs in human urine specimen at the cut-off 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)	Benzoyllecgonine	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	1000
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9 COOH	50
Fentanyl (FYL)	Fentanyl	1

Rapid Response™ Drug Screen Cup can be a single drug test cup 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 misuse of these drugs. Clinical consideration and professional judgment should be applied to any drug 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 people who use opioids. Substitution treatment is a form of medical care offered to people who use opiates (primarily people who use heroin) 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 misuse 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 misuse 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 misused via intravenous, sublingual, intranasal and inhalation routes.

The Rapid Response™ Drug Screen Cup 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 benzoyllecgonine. Benzoyllecgonine, 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 Rapid Response™ Drug Screen Cup yields a positive result when the concentration of Cocaine in urine exceeds detective level.

#### Marijuana (THC)

THC ( $\Delta^9$ -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- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid (THC-COOH). The Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 misuse 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 has 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Oberlander, 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 Rapid Response™ Drug Screen Cup 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 misuse. 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 Rapid Response™ Drug Screen Cup 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.<sup>6</sup> PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

The Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup yields a positive result when Oxycodone in urine exceeds detective level.

#### Fentanyl (FYL)

Fentanyl, belongs to powerful narcotics analgesics, and is a  $\mu$  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 people who use amphetamine, people who take fentanyl mainly have the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

The Rapid Response™ Drug Screen Cup 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 Rapid Response™ Drug Screen Cup 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 Cup 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 Cup should be discarded according to federal, state and local regulations.

### Materials

#### Materials provided

- Test Cups
- Adulteration Color Chart (when applicable)
- Product Insert

#### Materials required but not provided

- Specimen Collection Containers
- Timer

### 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 Cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### Specimen Collection and Preparation

#### Urine Assay

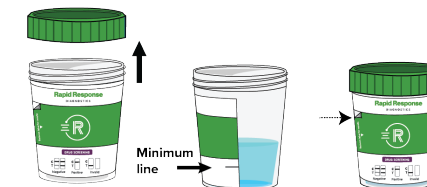
The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### 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.

### Test Procedure

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

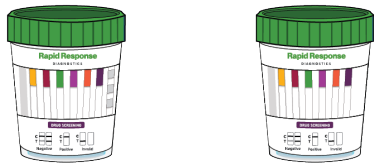


- Open the cap and add specimen.
- Specimen volume must exceed the minimum line.
- Peel off the label to view results.

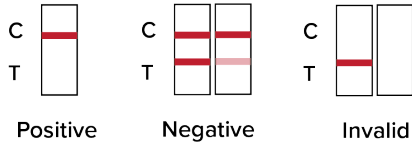
1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off label to reveal adulteration strip(s), if applicable.
7. Technician peels off the label on the test cup to view results.
8. 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. Do 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.

- If results do not indicate adulteration, read the drug test result at **5 minutes**. Do not interpret the result after 10 minutes.
- If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

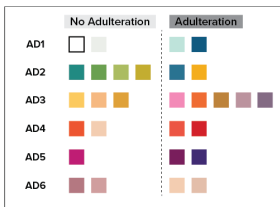
### Results Interpretation



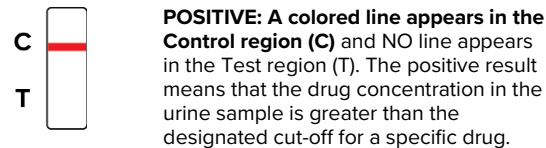
Cup with adulteration      Cup without adulteration



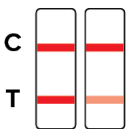
Read drug results at 5 minutes.



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

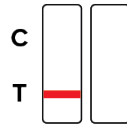


**POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T).** The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.



**\*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

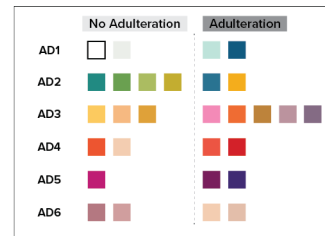
should be considered negative whenever there is even a faint line.



**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 cup. 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

- The Rapid Response™ Drug Screen Cup 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.
- There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.

- 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.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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.
- This test does not distinguish between illicit drugs and certain medications.
- 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 Characteristics

#### Accuracy

About 80 clinical urine specimens with known LC/MS values and tested by Rapid Response™ Drug Screen Cup. Each test was performed by three operators. Results were as follows:

#### Amphetamine (AMP500)

Operator	Result LC/MS Result	Candidate Device Result		The Agreement Rate
		Positive	Negative	
Operator A	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 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 (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

#### Secobarbital (BAR300)

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

#### Oxazepam (BZO300)

Operator	Result LC/MS Result	Candidate Device Result		The Agreement Rate
		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	(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%		

#### Cocaine (COC150)

Operator	Result LC/MS Result	Candidate Device Result		The Agreement Rate
		Positive	Negative	
Operator A	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 150ng/mL (+)	40	0	40/40=100%
	Lower 150ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

#### Marijuana (THC50)

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

#### Morphine (MOP/OPI 300)

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

#### Methamphetamine (MET500)

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

#### Methadone (MTD300)

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

#### Phencyclidine (PCP25)

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















DL-Tyrosine	Dopamine HCl
Doxepin (except TCA test)	Doxylamine
Duloxetine	Ecgonine methyl ester
EMDP	Ephedrine
Erythromycin	Esomeprazole Magnesium (except MTD test)
Fenoprofen	Ethanol(1%)
Fluphenazine	Fluoxetine Hydrochloride
Gabapentin	Furosemide
Gamma Globulin (500mg/dL)	Galactose (10mg/dL)
Gentisic acid	Gatifloxacin
Hemoglobin	Glucose (3000mg/dL)
Hydrochlorothiazide	Hydralazine
Hydroxytyramine	Hydrocortisone
Isoproterenol	Ibuprofen
Ketamine	Isoxsuprine
L-Ephedrine	Ketoprofen
L-phenylephrine	L-Epinephrine
Labetalol	LAAM HCl
Levonorgestrel	Levofloxacin Hydrochloride
Lidocaine Hydrochloride	Levothyroxine Sodium
Loperamide	Lisinopril
Magnesium	Loratadine
Meperidine	Maprotiline
Methapyrilene	Meprobamate
Methoxyphenamine (except AMP/MET test)	Methaqualone
Metronidazole (300ug/ml)	Metoprolol Tartrate
N-Acetylprocainamide	Mifepristone
Nalidixic acid	NaCl (4000mg/dL)
Naproxen	Naloxone hydrochloride (except OXY test)
Nicotine	Naltrexone hydrochloride
Nitroglycerin	Niacinamide
Norethindrone	Nifedipine
Noscapine	Nordoxepin
Octopamine	Norfentanyl
Omeprazole	O-Hydroxyhippuric acid
Oxolinic acid	Olanzapine
Paliperidone	Oxalic acid (100 mg/dL)
Penicillin-G	Oxymetazoline
Perphenazine	Papaverine
Phenelzine	PenicillinV Potassium
Phenylpropanolamine	Phenacetin
Pregablin	Phenethylamine
Promethazine(except TCA test)	Prednisone
Propranolol	Procaine
Quetiapine	Propoxyphene
Ranitidine	Pseudoephedrine
Rifampicin	Quinine
Salicylic acid	Riboflavin (10mg/dL)
Sertraline	Risperidone
Simvastatin	Serotonin (5- Hydroxytyramine)
Sulindac	Sildenafil Citrate
Tetrahydrocortisone 3-(β-Dglucuronide)	Sulfamethazine
Tetrahydrozoline	Telmisartan
Thiamine	Tetrahydrocortisone, 3-acetate
Tramadol Hydrochloride	Theophylline
Trifluoperazine	Thioridazine
Trimethoprim	Triamterene
Urea (2000mg/dL)	Trimethobenzamide

Valproic acid (250ug/ml)	Tyramine
Verapamil	Uric acid
Vitamin C	Venlafaxine HCl
Zomepirac	Vitamin B2
Zaleplon	β-Estradiol

### Bibliography

1. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
4. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
5. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
6. Brunton L. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

### Glossary of Symbols

	Consult instructions for use	 Test per Kit	 Do Not Reuse
	Store between 35.6°F to 86°F (2-30°C)	 Use by	 Catalogue #
	Lot Number	 For <i>in vitro</i> diagnostic use only	 Manufacturer
	Do not use if package is damaged		

 **BTNX Inc.**  
 722 Rosebank Road,  
 Pickering, ON L1W 4B2  
 Canada



**Technical Support: 1-888-339-9964**