

# Multi-Line Rapid Test Cassette (Urine)

#### Package Insert

### Instruction Sheet for testing of combination of the following

### drugs:AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OPI/PCP/PPX/TCA/TM L/KET/OXY/COT/EDDP/FYL

A rapid test for the simultaneous, qualitative detection of multi-line drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

# [INTENDED USE]

The Multi-Line Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of multi-line drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)	
Amphetamine (AMP 1000)	d-Amphetamine	1,000	
Amphetamine (AMP 500)	d-Amphetamine	500	
Amphetamine (AMP 300)	d-Amphetamine	300	
Barbiturates (BAR)	Secobarbital	300	
Benzodiazepines (BZO)	Oxazepam	300	
Benzodiazepines (BZO)	Oxazepam	200	
Benzodiazepines (BZO)	Oxazepam	100	
Buprenorphine (BUP)	Buprenorphine	10	
Cocaine (COC)	Benzoylecgonine	300	
Marijuana (THC)	11-nor-∆9-THC-9 COOH	50	
Marijuana (THC)	11-nor-∆9-THC-9 COOH	150	
Marijuana (THC)	11-nor-∆9-THC-9 COOH	25	
Methadone (MTD)	Methadone	300	
Methamphetamine (MET 1,000)	hamphetamine (MET 1,000) d-Methamphetamine		
Methamphetamine (MET 500)	d-Methamphetamine	500	
Methamphetamine (MET 300)	d-Methamphetamine	300	
Methylenedioxymethamphetamine (MDMA)	d,I-Methylenedioxymethamphetami ne	500	
Morphine (MOP)	Morphine	300	
Morphine (MOP)	Morphine	100	
Methaqualone(MQL)	Methaqualone	300	
Opiate (OPI)	Morphine	2,000	
Phencyclidine (PCP)	Phencyclidine	25	
Propoxyphene (PPX)	Propoxyphene	300	
Tricyclic Antidepressants (TCA)	cyclic Antidepressants (TCA) Nortriptyline		
Tramadol (TML)	Tramadol	100	
Ketamine (KET)	Ketamine	1,000	
Oxycodone (OXY)	Oxycodone	100	
Cotinine(COT)	Cotinine	200	
2-ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolidine	300	
2-ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolidine	100	
Fentanyl(FYL20)	Norfentanyl	20	

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical 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.

# [SUMMÁRY]

The Multi-line Rapid Test Cassette 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 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine<sup>®</sup>) 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-line Rapid Test Cassette yields a positive result when the concentration of

amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

# Amphetamine (AMP 500)

The Multi-line Rapid Test Cassette yields a positive result when amphetamines in urine exceed 500 ng/mL. See Amphetamine (AMP 1,000) for the summary.

## Amphetamine (AMP 300)

The Multi-line Rapid Test Cassette yields a positive result when amphetamines in urine exceed 300 ng/mL. See Amphetamine (AMP 1,000) for the summary.

## Barbiturates (BAR 300)

Barbiturates are CNS depressants. 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 barbiturates are excreted unaltered in the urine. The approximate detection time limits for barbiturates are: Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days2

The Multi-line Rapid Test Cassette yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

#### Benzodiazepines (BZO 300)

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Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific reptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some sucical 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-line Rapid Test Cassette yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

#### Benzodiazepines (BZO 200)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Benzodiazepines in urine exceeds 200ng/mL. See Benzodiazepines (BZO 300) for the summary. Benzodiazepines (BZO 100)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Benzodiazepines in urine exceeds 100ng/mL. See Benzodiazepines (BZO 300) for the summary. Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex<sup>™</sup>, Buprenex<sup>™</sup>, Temgesic<sup>™</sup> and Suboxone<sup>™</sup>, which contain Buprenorphine HCI alone or in combination with Naloxone HCI. Theraputically, 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/m after therapeutic administration, but can range up to 20 ng/m in abuse situations.10 The plasma half life of Buprenorphine is 2-4 hours.10 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, intravasal and inhalation routes.

The Multi-line Rapid Test Cassette yields a positive result when the Buprenorphine in urine exceeds 10 ng/mL.

## Cocaine (COC 300)

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. <sup>34</sup> 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.<sup>4</sup> The Multi-line Rapid Test Cassette yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

# Marijuana (THC50)

THC (A9-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 Multi-line Rapid Test Cassette yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>1</sup> Mariluana (THC150)

# The Multi-line Rapid Test Cassette yields a positive result when the concentration of THC-COOH

in urine exceeds 150ng/mL. See Marijuana (THC 50) for the summary. Marijuana (THC25)

#### The Multi-line Rapid Test Cassette yields a positive result when the concentration of THC-COOH in urine exceeds 25ng/mL. See Marijuana (THC 50) for the summary. 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.<sup>7</sup>

The Multi-line Rapid Test Cassette yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

## Methamphetamine (MET 1,000)

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 dearninated 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-line Rapid Test Cassette 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-line Rapid Test Cassette yields a positive result when the Methamphetamine in urine exceeds 1,000ng/mL

### Methamphetamine (MET 500)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL. See Methamphetamine (MET1000) for the summary.

#### Methamphetamine (MET 300)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Methamphetamine in urine exceeds 300 ng/mL. See Methamphetamine (MET1000) for the summary.

#### Methylenedioxymethamphetamine (MDMA500)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. 5 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.

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Methylenedioxy- methamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxy- methamphetamine positive specimens.

# Morphine/Opiate (MOP 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.<sup>2</sup>

The Multi-line Rapid Test Cassette yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

### Morphine/Opiate (MOP 100)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of morphine in urine exceeds 100ng/mL. See Morphine/Opiate (MOP 300) for the summary.

# Morphine/Opiate (OPI 2.000)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>1</sup> See morphine (MOP 300) for summary

# Methagualone (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956.<sup>2</sup> It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methagualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Methaqualone in urine exceeds 300 ng/mL.

# 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-line Rapid Test Cassette yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, ÚSA).

# Propoxyphene (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet<sup>™</sup>, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

### Tricyclic Antidepressants (TCA)

TCA (Tricyclic Antidepressants) 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-line Rapid Test Cassette yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

# Tramadol (TMI)

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

The Multi-line Rapid Test Cassette 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 Tramadol in urine. The The Multi-line Rapid Test Cassette vields a positive result when Tramadol in urine exceed 100 ng/mL.

# Ketamine(KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use. Ketamine is excreted in the urine as unchanged drug (2.3%) and metabolites (96.8%)

The Multi-line Rapid Test Cassette 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 Ketamine in urine. The Multi-line Rapid Test Cassette yields a positive result when Ketamine in urine

### exceeds 1,000ng/mL. 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<sup>®</sup>, Tylox<sup>®</sup>, Percodan<sup>®</sup> and Percocet<sup>®</sup>. While Tylox<sup>®</sup>, Percodan<sup>®</sup> and Percocet<sup>®</sup> 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-line Rapid Test Cassette 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-line Rapid Test Cassette yields a positive result when Oxycodone in urine exceeds 100ng/ml

### Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum. transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%." While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.<sup>2</sup> Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The Multi-line Rapid Test Cassette yields a positive result when the concentration of Cotinine in urine exceeds 200 ng/ml

#### 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 300)

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.<sup>1</sup> Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better urine marker for methadone maintenance than unmetabolized methadone.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of EDDP in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHŠA) does not have a recommended screening cut-off for EDDP positive specimens.

# 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)

The Multi-line Rapid Test Cassette yields a positive result when the concentration of EDDP in urine exceeds 100ng/mL. See 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine(EDDP300)for the summarv

#### Fentanyl (FYL20)

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<sup>1</sup>. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc<sup>2,3</sup>, 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 4

The Multi-line Rapid Test Cassette 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 FYL in urine. The FYL Rapid Test Cassette (Urine) yields a positive result when FYL in urine exceeds 20 ng/mL.

#### [PRINCIPLE]

The Multi-Line Rapid Test Cassette is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

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 strip. 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 strip 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]

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for in vitro diagnostic use only. The test card 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 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test panels 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 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing Materials Provided

# [MATERIALS]

- Test Cassettes Droppers
- Package insert

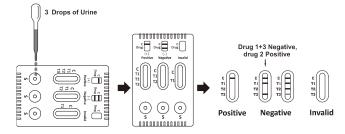
# Materials Required But Not Provided

timer

- Specimen collection container
- [DIRECTIONS FOR USE]

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

- 1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- 2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below
- 3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



#### [INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

NEGATIVE:\* A colored line appears in the Control region (C) and colored lines 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 lines(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 card. If the result is still invalid, contact vour manufacturer.

# 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.

## LIMITATIONS

- 1. The Multi-line Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) 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.

This test does not distinguish between drugs of abuse and certain medications.
 A positive test result may be obtained from certain foods or food supplements.

# [EXPECTED VALUES]

This 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

A side-by-side comparison was conducted using the Multi-line Rapid Test Cassette and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated from these clinical studies:

Method			:/MS	% Agreement	Overall	
Multi-Drug Rapid Tes	st Cassette	Pos.	Neg.	with GC/MS	agreemer	
Methamphetamine	Positive	92	8	97.9%	96.0%	
(MET 1,000ng/ml)	Negative	2	148	94.9%	90.0%	
Methamphetamine	Positive	103	7	97.2%	96.0%	
(MET 500ng/ml)	Negative	3	137	95.1%	96.0%	
Methamphetamine	Positive	107	5	98.2%	07.00/	
(MET 300ng/ml)	Negative	2	136	96.5%	97.2%	
Cocaine	Positive	103	5	97.1%		
(COC 300ng/ml)	Negative	3	139	96.5%	96.8%	
Marijuana	Positive	115	3	>99.9%		
		0	132	97.8%	98.8%	
(THC50ng/ml)	Negative	127				
Marijuana	Positive		5	97.6%	97.5%	
(THC150ng/ml)	Negative	3	185	97.3%	_	
Marijuana	Positive	117	9	99.2%	96.9%	
(THC25ng/ml)	Negative	1	193	95.5%		
Amphetamine	Positive	95	9	97.9%	95.6%	
(AMP 1,000ng/ml)	Negative	2	144	94.1%	95.078	
Amphetamine	Positive	101	11	99.0%	05.00/	
(AMP 500ng/ml)	Negative	1	137	92.6%	95.2%	
Amphetamine	Positive	105	7	98.1%	1	
(AMP 300ng/ml)	Negative	2	136	95.1%	97.2%	
Benzodiazepines	Positive	118	4	97.5%	-	
					97.2%	
(BZO 300ng/ml)	Negative	3	125	96.9%		
Benzodiazepines	Positive	137	2	97.2%	98.0%	
(BZO 200ng/ml)	Negative	4	157	98.7%	00.070	
Benzodiazepines	Positive	138	2	97.9%	98.3%	
(BZO 100ng/ml)	Negative	3	157	98.7%	90.376	
Methadone	Positive	107	5	96.4%	00.40/	
(MTD 300ng/ml)	Negative	4	134	96.4%	96.4%	
Barbiturates	Positive	111	7	95.7%	1	
(BAR 300ng/ml)	Negative	5	127	94.8%	95.2%	
Tricyclic	Positive	109	11	94.0%	-	
	Positive	109	11	94.0%	92.8%	
Antidepressants	Negative	7	123	91.8%	92.8%	
(TCA 1000ng/ml)		405	1 5	00.00/		
Methylenedioxy	Positive	125	5	96.9%	00.40/	
methamphetamine	Negative	4	116	95.9%	96.4%	
(MDMA 500ng/ml)	•					
Morphine	Positive	103	11	95.4%	93.6%	
(MOP 300ng/ml)	Negative	5	119	91.5%	00.070	
Morphine	Positive	142	5	>99.9%	98.4%	
(MOP 100ng/ml)	Negative	0	163	97.0%	30.470	
Phencyclidine	Positive	108	4	95.6%	00.40/	
(PCP 25ng/ml)	Negative	5	133	97.1%	96.4%	
Propoxyphene	Positive	115	11	96.6%	1	
(PPX 300ng/ml)	Negative	4	120	91.6%	94.0%	
	Positive	116	120	94.3%	+	
Opiate (OPI 2000ng/ml)					92.8%	
(OPI 2000ng/ml)	Negative	7	116	91.3%		
Methaqualone	Positive	107	11	91.5%	91.6%	
(MQL 300ng/ml)	Negative	10	122	91.7%	2	
Tramadol	Positive	120	8	97.6%	95.6%	
(TML 100ng/ml)	Negative	3	119	93.7%	33.0 %	
Buprenorphine	Positive	123	1	98.4%	00.007	
(BUP 10ng/ml)	Negative	2	124	99.2%	98.8%	
Ketamine	Positive	100	8	95.2%	1	
(KET 1000ng/ml)	Negative	5	137	94.5%	94.8%	
Oxycodone	Positive	104	2	98.1%	+	
		104	142		98.4%	
(OXY 100ng/ml)	Negative			98.6%	96.4%	
COT	Positive	87	4	94.6%		
		5	154	97.4%		
200	Negative			98.8%		
200 EDDP	Positive	82	5		07 00/	
200			5 112	95.7%	97.0%	
200 EDDP	Positive	82				
200 EDDP 300	Positive Negative Positive	82 1 87	112 6	95.7% 96.7%	97.0% 95.5%	
200 EDDP 300 EDDP	Positive Negative	82 1	112	95.7%		

\* Clinical samples for each drug were run using each of the Multi-line Rapid Test Cassette by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

# Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of code specimens, containing drugs at concentrations of  $\pm$  50% and  $\pm$  55% cut-off level, was labeled, blinded and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval). Analytical Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations. >99% agreement with expected results was found at  $\pm$  50% cut-off for each drug tested (with a 95% confidence interval).

# Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-line Rapid Test Cassette at 5 minutes.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
	AMPHETAMIN		
D,L-Amphetamine sulfate	200	Phentermine	800
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy	400	Methoxyphenamine	6,000
amphetamine		D-Amphetamine	1,000
	AMPHETAMI		
D,L-Amphetamine sulfate	100	Phentermine	400
L-Amphetamine	12,500	Maprotiline	25,000
(±) 3,4-Methylenedioxy	200	Methoxyphenamine	3,000
amphetamine		D-Amphetamine	500
	AMPHETAMI		
D,L-Amphetamine sulfate	70	Phentermine	300
L-Amphetamine	10,000	Maprotiline	12,500
(±) 3,4-Methylenedioxy	150	Methoxyphenamine	2,000
amphetamine		D-Amphetamine	300
	BARBITURAT		
Amobarbital	3,000	Alphenol	300
5,5-Diphenylhydantoin	6,000	Aprobarbital	450
Allobarbital	450	Butabarbital	150
Barbital	6,000	Butalbital	6,000
Talbutal	30	Butethal	450
Cyclopentobarbital	25,000	Phenobarbital	300
Pentobarbital	6,000	Secobarbital	300
	BENZODIAZEPI		
Alprazolam	100	Bromazepam	780
a-hydroxyalprazolam	1,500	Chlordiazepoxide	780
Clobazam	200	Nitrazepam	200
Clonazepam	390	Norchlordiazepoxide	100
Clorazepate dipotassium	390	Nordiazepam	780
Delorazepam	780	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	1,500
(±) Lorazepam	3,100	Estazolam	6,250
RS-Lorazepam glucuronide	200	Triazolam	3,100
Midazolam	6,250		
	BENZODIAZEPI	NES (BZO 200)	
Alprazolam	70	Bromazepam	520
a-hydroxyalprazolam	1,000	Chlordiazepoxide	520
Clobazam	120	Nitrazepam	120
Clonazepam	260	Norchlordiazepoxide	70
Clorazepate dipotassium	260	Nordiazepam	520
Delorazepam	520	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	1,000
(±) Lorazepam	2,000	Estazolam	4,200
RS-Lorazepam glucuronide	120	Triazolam	2,000
Midazolam	4,200		
	BENZODIAZEP		
Alprazolam	40	Bromazepam	260
a-hydroxyalprazolam	500	Chlordiazepoxide	260
Clobazam	60	Nitrazepam	60 40
Clonazepam	130		
Clorazepate dipotassium	130	Nordiazepam	260
Delorazepam	260	Oxazepam	100
Desalkylflurazepam	60	Temazepam	400
Flunitrazepam	60	Diazepam	500
(±) Lorazepam	1,000	Estazolam	2,100
RS-Lorazepam glucuronide	60	Triazolam	1,000
Midazolam	2,100		
	BUPRENORF		

Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
	COCAINE (		
Benzoylecgonine	300	Cocaethylene	12,500
Cocaine HCI	200	Ecgonine	30,000
Oranakiaal	MARIJUAN		45.000
Cannabinol	20,000	△8-THC	15,000
11-nor-△8- THC-9 COOH	30 50	∆9-THC	15,000
11-nor-△9-THC-9 COOH	MARIJUANA	(THC150)	
Cannabinol	60,000	∆8-THC	45,000
11-nor-△8- THC-9 COOH	180	∆9-THC	45,000
11-nor-△9-THC-9 COOH	150		43,000
11-1101-23-1110-3 00011	MARIJUAN	A (THC25)	
Cannabinol	10,000	∆8-THC	7,500
11-nor-△8- THC-9 COOH	15	∆9-THC	7,500
11-nor-△9-THC-9 COOH	25		. 1000
	METHADONE	E (MTD300)	
Methadone	300	Doxylamine	100,000
	METHAMPHETAN		
ρ-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-	6,250
D-Methamphetamine	1,000	methamphetamine	
L-Methamphetamine	12,500	Mephentermine	50,000
	METHAMPHETA		
ρ-Hydroxymethamphetamine		(±)-3,4-Methylenedioxy-	3,000
D-Methamphetamine	500	methamphetamine	
L-Methamphetamine	9,000	Mephentermine	25,000
	METHAMPHETA		
ρ-Hydroxymethamphetamine		(±)-3,4-Methylenedioxy-	1,800
D-Methamphetamine	300	methamphetamine	-
L-Methamphetamine	3,750	Mephentermine	15,000
	OXYMETHAMPH	ETAMINE (MDMA500) Ecsta	isy
(±) 3,4-Methylenedioxy methamphetamine HCI	500	3,4-Methylenedioxyethyl-am phetamine	300
(±) 3,4-Methylenedioxyampheta	3,000		
mine HCI	MODDUINE	(1400 000)	
O a da in a	MORPHINE		0.000
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide Ethylmorphine		Oxycodone Oxymorphone	30,000 50,000
Hydrocodone	6,000 50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	400	Morphine	300
e monouceurymorphine	MORPHINE		000
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3-β-D-Glucuronide		Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000
Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacethylmorphine	100	Morphine	100
	Methaqualon		
Methaqualone	300		
	OPIATE (C		
Codeine			
Ethylmorphine	2,000	Morphine	2,000
Hydrocodone	3,000	Norcodeine	25,000
	3,000 50,000	Norcodeine Normorphone	25,000 50,000
Hydromorphone	3,000 50,000 12,500	Norcodeine Normorphone Oxycodone	25,000 50,000 25,000
Hydromorphone Levorphanol	3,000 50,000 12,500 25,000	Norcodeine Normorphone Oxycodone Oxymorphone	25,000 50,000 25,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine	3,000 50,000 12,500 25,000 3,000	Norcodeine Normorphone Oxycodone Oxymorphone Procaine	25,000 50,000 25,000 25,000 50,000
Hydromorphone Levorphanol	3,000 50,000 12,500 25,000 3,000 2,000	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine	25,000 50,000 25,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide	3,000 50,000 12,500 25,000 3,000 2,000 PHENCYCLI	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP)	25,000 50,000 25,000 25,000 50,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine	3,000 50,000 12,500 25,000 3,000 2,000 PHENCYCLII 25 PROPOXYPH	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine ENE (PPX)	25,000 50,000 25,000 25,000 50,000 25,000 6,250
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene	3,000 50,000 12,500 25,000 2,000 2,000 PHENCYCLI 25 PROPOXYPH 300	Norcodeine Normorphone Oxycodone Oxycodone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine IENE (PPX) D-Norpropoxyphene	25,000 50,000 25,000 25,000 50,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene	3,000 50,000 12,500 25,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA)	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline	3,000 50,000 12,500 25,000 2,000 PHENCYCLI 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine	25,000 50,000 25,000 25,000 50,000 25,000 6,250 300 400
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordoxepine	3,000 50,000 12,500 25,000 3,000 PHENCYCLI 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000	Norcodeine Normorphone Oxycodone Oxycodone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine <b>IENE (PPX)</b> D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordxepine Trimipramine	3,000 50,000 12,500 25,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordoxepine Trimipramine Amitriptyline	3,000 50,000 12,500 25,000 2,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine ENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline	25,000 50,000 25,000 25,000 25,000 6,250 6,250 300 400 50,000 1,500
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordoxepine Trimipramine Amitriptyline Promazine	3,000 50,000 12,500 25,000 3,000 PHENCYCLI 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 3,000	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline Promethazine	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500 1,500 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordoxepine Trimipramine Amitriptyline Promazine Desipramine	3,000 50,000 12,500 2,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 3,000 200	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine ENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline	25,000 50,000 25,000 25,000 25,000 6,250 6,250 300 400 50,000 1,500
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene TRI Nortriptyline Nordoxepine Trimipramine Amitriptyline Promazine	3,000 50,000 12,500 25,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 200 1,500	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine ENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline Promethazine Perphenazine	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500 1,500 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene Trin Nortriptyline Nordoxepine Trimipramine Amitriptyline Promazine Desipramine Cyclobenzaprine	3,000 50,000 12,500 25,000 2,000 PHENCYCLI 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 3,000 1,500 TRAMADO	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline Perphenazine Perphenazine DL (TML)	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500 1,500 25,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene Trimpramine Amitriptyline Promazine Desipramine Cyclobenzaprine n-Desmethyl-cis-tramadol	3,000 50,000 12,500 22,000 2,000 PHENCYCLII 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 200 TRAMADO 200	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine IENE (PPX) DI-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline Promethazine Perphenazine DoL (TML) o-Desmethyl-cis-tramadol	25,000 50,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500 1,500 25,000 25,000 25,000 25,000 25,000
Hydromorphone Levorphanol 6-Monoacetylmorphine Morphine 3-β-D-glucuronide Phencyclidine D-Propoxyphene Trin Nortriptyline Nordoxepine Trimipramine Amitriptyline Promazine Desipramine Cyclobenzaprine	3,000 50,000 12,500 25,000 2,000 PHENCYCLI 25 PROPOXYPH 300 CYCLIC ANTIDEI 1,000 400 3,000 1,500 3,000 1,500 TRAMADO	Norcodeine Normorphone Oxycodone Oxymorphone Procaine Thebaine DINE (PCP) 4-Hydroxyphencyclidine EENE (PPX) D-Norpropoxyphene PRESSANTS (TCA) Imipramine Clomipramine Doxepine Maprotiline Perphenazine Perphenazine DL (TML)	25,000 50,000 25,000 25,000 25,000 25,000 6,250 300 400 50,000 1,500 1,500 25,000 25,000

		venlafaxine				
		NE (KET1, 000)				
Ketamine	1,000	Benzphetamine	25,000			
Dextromethorphan	1,500	(+) Chlorpheniramine	25,000			
Methoxyphenamine 12,500 Clonidine 100,000						
d-Norpropoxyphene						
Promazine	25,000	4-Hydroxyphencyclidine	50,000			
Promethazine	25,000	Levorphanol	50,000			
Pentazocine	25,000	MDE	50,000			
Phencyclidine	12,500	Meperidine	25,000			
Tetrahydrozoline	400	d-Methamphetamine	25,000			
Mephentermine	25,000	I-Methamphetamine	50,000			
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylendioxymethamp hetamine	100,000			
Disopyramide	12,500	Thioridazine	50,000			
		DONE (OXY100)				
Oxycodone	100 Hydromorphone		50,000			
Oxymorphone	200	Naloxone	25,000			
Levorphanol	50,000	Naltrexone	25,000			
Hydrocodone	6,250					
	COT	ININE (COT)				
(-)-Cotinine 200 (-)-Nicotine		3,000				
		3,3-diphenylpyrrolidine (EDDP3)	00)			
2-Ethylidene-1,5-dimethyl-3			300			
		3,3-diphenylpyrrolidine (EDDP1)	00)			
2-Ethylidene-1,5-dimethyl-3			100			
	FENTA	ANYL (FYL20)				
Norfentanyl	20	Noscapine	25,000			
Perphenazine	5,000	Chlorpromazine	25,000			
Quinacrine	25,000					
	Effect of Urin	ary Specific Gravity				

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-line Rapid Test Cassette was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

## Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-line Rapid Test Cassette. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine. Methaqualone, Tramadol Ketamine, Phencyclidine, Propoxyphene, Tricyclic Antidepressants. Oxycodone,Cotinine,2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine or Fentanyl. The following compounds show no cross-reactivity when tested with the Multi-line Rapid Test Cassette at a concentration of 100 µg/mL.

	Non Cross-React	ting Compounds	
Acetophenetidin	I-Cotinine	Ketamine	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
I-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,I-Brompheniramine	Furosemide	d,I-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,I-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,I-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,I-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,I-Isoproterenol	Prednisone	Verapamil
Clonidine	Isoxsuprine	d,I-Propanolol	Zomepirac
Cortisone			

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	Index of Symbols						
ĺ	Consult instructions for use		∑∑	Tests per kit		1	Manufacturer
IVD	For <i>in vitro</i> diagnostic use only		$\square$	Use by		2	Do not reuse
2°C	Store between 2-30°C		LOT	Lot Number		REF	Catalog #

SureScreen Diagnostics Ltd 1 Prime Parkway Prime Enterprise Park Manufacturer Derby. DE1 3QB

United Kingdom

Number: Effective date:

CE