Accurate

One Step Urine Dip Scan From LaneWorkSafe

Package Insert

Instruction Sheet for testing of any combination of the following drugs: AMP/BZO/COC/THC/MET/MOP/FYL/BUP/PGB/OXY/MTD/TML

These devices are intended for Workplace Testing for substances of abuse.

All detectable substances as listed in Table 1 show a positive result when the level specimen exceeds cut off level.

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

INTENDED USE

The ***Accurate*** Test Scan is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

TABLE 1

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 300)	d-Amphetamine	300
Benzodiazepines (BZO 200)	Oxazepam	200
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylecgonine	300
Fentanyl (FYL20)	Fentanyl	20
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Methadone (MTD 300)	Methadone	300
Methamphetamine (MET 300)	d-Methamphetamine	300
Morphine (MOP 300)	Morphine	300
Oxycodone (OXY)	Oxycodone	100
Pregabalin (PGB or LYRICA)	Pregabalin	50000
Tramadol (TML 200)	Cis-Tramadol	200

Configurations of the Accurate One Step Urine Dip Scan come with any combination of the above listed drug analytes. 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.

SUMMARY AND EXPLANATION OF THE TEST

AMPHETAMINE (AMP)

Amphetamine is a 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 behaviour. 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.

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 barbiturates 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.

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.[7] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

COCAINE (COC)

Cocaine is a potent central nervous system stimulant and a local anaesthetic. 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.3,4Benzoylecgonine, 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.[4]

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[1]. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc[2,3], 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 behaviour and more lifelong medication overdose[4].

The FYL Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilises a monoclonal antibody to selectively detect elevated levels of FYL in urine. The FYL Rapid Test Dipstick (Urine) yields a positive result when FYL in urine exceeds detective level.

MARIJUANA (THC)

THC (Δ9-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 behavioural 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-Δ9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

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.[7]

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 behaviour, 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 oxidised 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 Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilises a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine.

MORPHINE (MOP)

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 unmetabolised, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]

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 Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilises a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine.

PREGABALIN (PGB or LYRICA)

Pregabalin, also known as ß-isobutyl-y-amino butyric acid (beta-isobutyl-GABA), is a medication used to treat epilepsy, neuropathic pain, fibromyalgia, and generalised anxiety disorder.[30] Common side effects include: sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, and weight gain. Potentially serious side effects include angioedema, drug misuse, and an increased suicide risk.[31]

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. The Pregabalin is predominantly excreted unchanged in urine (≥ 98%)[32]. Pregabalin mean elimination half-life is 6.3 hours.[33] 50% would be expected to have negative urine specimens in the subject with the maximum urinary concentration measured.[34]

TRAMADOL (TML)

Tramadol(TML) is a quasi-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-Drug Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilises a monoclonal antibody to selectively detect elevated levels of Tramadol in urine.

PRINCIPLE (FOR DOA TESTS)

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 coloured 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 coloured line will not form in the test region. A drug-positive urine specimen will not generate a coloured 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 coloured line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

• Test Scans • Package insert

Materials Required But Not Provided

• Timer

INSTRUCTIONS FOR USE

STEP

1. Remove Dip Scan from foil pouch.

2. Collect urine specimen in a collection device.

3. Remove Dip Scan cap from end of the scan exposing the 6 fingers.

4. Insert Dip Scan into urine cup to the marked control line. Do not allow urine to touch the body of the scan.

5. Wait 20 seconds.

6. Remove the scan from the urine specimen and replace the cap.

7. For best results, Dip Scan should be laid on a flat surface.

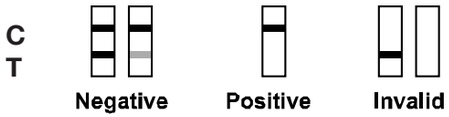
8. Wait 2 to 5 minutes.

9. **Top line** that appears on the rapid drug kit is that Is the **CONTROL** line which shows the screen is working.

10. If the control line does not appear, discard the drug screen kit.

11. The **second line** is the **SCREEN** line. It will be **FAINTER** than the control line. Any line present, **NO MATTER HOW FAINT**, indicates a negative result.

12. If **NO LINE APPEARS** after five minutes this indicates a substance in your system is greater than the screening standard and has prevented the line from forming for that particular drug group (where the line has not formed).



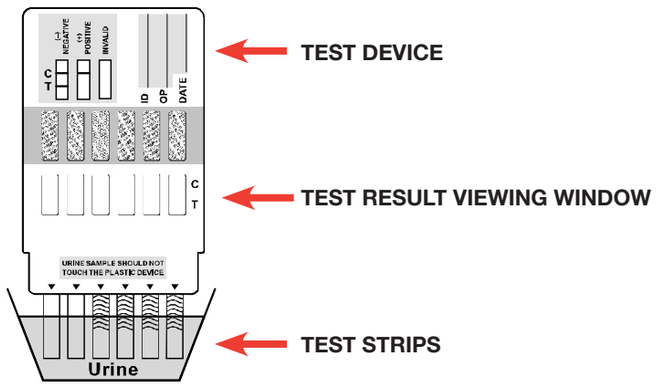


DIAGRAM 1 DEPICTS 12 PANEL DEVICE AS DEMONSTRATION ONLY SHOWING 1 SIDE OF KIT ONLY

INTERPRETATION OF RESULTS

(Please refer to the illustration above)
NEGATIVE:* A coloured line appears in the Control region (C) and coloured lines appear 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. (See DIAGRAM 1)

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

POSITIVE: A coloured 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 cup. If the result is still invalid, contact LaneWorkSafe.

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.

NON CROSS-REACTING COMPOUNDS

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

PRECAUTIONS

The test device 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 Cup should be discarded according to local regulations.

BIBLIOGRAPHY

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Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	LWS	Authorised Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

Manufactured for:
LaneWorkSafe Pty Ltd
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