

## Package Insert

### Instruction Sheet for testing of any combination of the following drugs:

A rapid, test for the detection of drugs on surfaces and in solids.

Test intended to be used as analytical device to detect drugs on surface.

#### 【INTENDED USE】

The Multi-Drug Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites on surfaces and in solids at the following cut-off concentrations:

Test & Abbreviation code on panel	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylcegonine	300
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methylenedioxyamphetamine (MDMA)	d,l-Methylenedioxyamphetamine	500
Morphine (MOP)	Morphine	300
Ketamine (KET)	Ketamine	1,000

#### 【SUMMARY】

The Multi-Drug Rapid Test Panel is a rapid surfaces or solids 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 on surfaces and in solids.

#### 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.

#### 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.

#### 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.

#### 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.

#### 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 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.

#### 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>

#### Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in

illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

#### Methylenedioxyamphetamine (MDMA)

Methylenedioxyamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.<sup>5</sup> 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.

#### 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 unmetabolized, and is also the major metabolic product of codeine and heroin..

#### 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.

#### 【PRINCIPLE】

During testing, specimen migrates upward by capillary action. A drug, if present in the 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 specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative 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.

#### 【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.

#### 【MATERIALS】

- Panel
- Package insert
- Buffer
- Specimen collection container
- timer

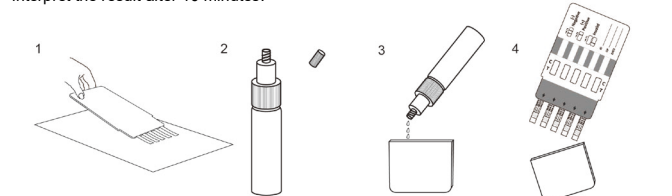
#### 【DIRECTIONS FOR USE】

Test device (in closed pouches), samples, and controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

Remove the test device from its protective pouch and label the device with patient's identification or control label.

#### FOR SURFACES

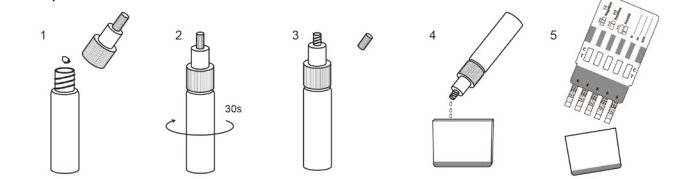
1. Wipe with the strips over the surface in which the drugs are expected
2. Take off the cap of supplied tube;
3. Fill all buffers from the supplied tube of buffer into the protection cover.
4. Insert the Multi Test slowly and carefully into the protection cover with buffer
4. Wait for lines to appear on the membrane and read the results after 5 minutes and do not interpret the result after 10 minutes.



#### FOR SOLIDS

1. Open the tube and put the solid in to the buffer. (crush tablets before adding)
2. Close the tube with dropper and cap. Shake it a short time. Wait for 30 sec.
3. Take off the cap of supplied tube;
4. Fill all buffers with dissolved substances into the protection cover.
5. Insert the Multi Test slowly and carefully into the protection cover with buffer.

6. Wait for lines to appear on the membrane and read the results after 5 minutes and 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 appear in the Test region (T). This negative result means that the concentrations in the 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 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 your 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-Drug Rapid Test Panel 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. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.

3. This test does not distinguish between drugs of abuse and certain medications.

#### 【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.

#### Non Cross-Reacting Compounds

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

#### Index of Symbols

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