Multi-drug 8 Panel Dip Card (Urine)

Catalogue No.: DOA8DIP01

Instruction of use for testing of any combination of the following drugs:

AMP1000/BZO300/COC300/ETG500/MET1000/MTD300/OPI2000/THC50

Rapid Single/multi-drug Test Dipcard is a rapid, screening test for the qualitative detection of single/multiple drugs and drug metabolites in human urine at specified cut off levels.

For professional use only. For in vitro diagnostic use only.

INTENDED USE

Rapid Single/multi-drug Test Dipcard is an immuno-chromatographic assay for the qualitative determination of the presence of drugs listed in the table below.

Drug(Identifier)	Calibrator	Cut-off level
Amphetamine (AMP)	d-Amphetamine	1000ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Ethylglucuronide (ETG)	Ethyl -glucuronide	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Opiate 2000 (OPI)	Morphine	2000ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL

The test you purchased may test for any combination of drugs listed in the table above. This assay provides only a preliminary analytical test 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

Amphetamine (AMP)

Amphetamine and the structurally related “designer” drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthemic , and cardiovascular properties. They are usually taken orally, intraveneously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine . Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structural in the brain. 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. It can be detected in the urine for 1 to 2 days after use.

BENZODIAZEPINES (BZO)

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to

glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse.

Cocaine (COC)

Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time.

Ethylglucuronide (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

Methamphetamine (MET)

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

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). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12 – 24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylprryolidine), and EMDP (2- ethyl-5-methy -3, 3-diphenylpyrrolidine).

Opiate(OPI2000)

Opiates refer 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. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake.

Marijuana (THC)

Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

PRINCIPLE

Rapid Single/multi-drug Test Dipcard is a competitive immunoassay that is used to screen for the presence of various drugs *and drug metabolites* in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each strip, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Immunoassay for *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test dipcard should remain in the sealed pouch until use.
- The used test dipcard should be discarded according to local regulations.

CONTENTS OF THE KITS

- Drug Test Dipcard.
- Desiccant .
- Leaflet with instruction for use.

ADDITIONAL REQUIREMENTS

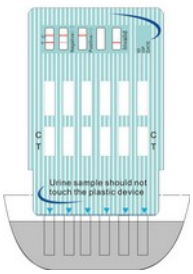
- A clean, dry, plastic or glass container to collect the urine.
- Timer (watch or clock)
- External controls

STORAGE AND STABILITY

- Store at 39 ~ 86 ºF (4 ~ 30 ºC) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND PREPARATION

- Collect urine sample with a clean, dry container. Urine collected at any time of the day may be used.
- For best results, test specimens immediately following collection.
- Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours.
  For longer storage, freeze the samples (-20°C or below).
- Bring frozen or refrigerated samples to room temperature before testing.



HOW TO PERFORM THE TEST?

Test must be in room temperature (15ºC to 30ºC)

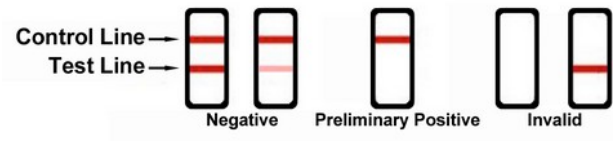
1. Open the sealed pouch by tearing along the notch. Remove the test dipcard from the pouch.
2. Immerse the dipcard into the urine with the arrow pointing towards the urine. Take the dipcard out after 10 seconds.

   IMPORTANT：Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.
3. Lay the test dipcard on a clean, dry, non-absorbent surface.
4. **Read the results at 5 minutes. The drug test results remain stable for up to thirty minutes.**

READING THE RESULTS

Preliminary positive (+)

A rose-pink band is visible in each control region. If no color band appears in appropriate test “T” region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.



the

Negative (-)

If a rose-pink band is visible in each control region and the appropriate test “T” region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control “C” region or a color band is only visible in the test “T” region, the test is invalid. Another test should opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.

Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.

Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST “T” REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEAGATIVE RESULT.

***IMPORTANT*:** This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Rapid Single/multi-drug Test Dipcard. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn’t detected by Rapid Single/multi-drug Test Dipcard. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.

2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.

3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.

4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

5. A positive result does not indicate level or intoxication, administration route or concentration in urine.

6. 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.

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 run with each new lot, and every 30 days to check storage stability. Positive and negative control should give the expected results.

Users can commercially obtain control materials (For example from Sigma-Aldrich Corporation).The concentration of drug(s) in positive and negative controls are approximately 50% above and below the cutoff concentration of the assay.

PERFORMANCE CHARACTERISTICS

Accuracy

The comparison studies were conducted using Rapid Single/multi-drug Test Dipcard and commercially available rapid drugs of abuse tests. The studies were performed on approximately 600 clinical specimens per drug type previous collected from the clinical settings. Results were as follows:

Format	% Agreement with Predicate Test		Format	% Agreement with Predicate Test		Format	% Agreement with Predicate Test	
AMP	Positive	100.00%	K2	Positive	100.00%	OPI2000	Positive	98.53%
	Negative	99.31%		Negative	99.65%		Negative	99.25%
BAR	Positive	100%	KET	Positive	98.65%	OXY	Positive	100%
	Negative	99.30%		Negative	99.05%		Negative	99.10%
BUP	Positive	100.00%	MAM	Positive	97.62%	PCP	Positive	100%
	Negative	98.78%		Negative	99.28%		Negative	99.30%
BZO	Positive	100%	MDMA	Positive	100%	PPX	Positive	100.00%
	Negative	99.20%		Negative	99.50%		Negative	98.09%
COC	Positive	100.00%	MET	Positive	98.15%	TCA	Positive	100.00%
	Negative	99.66%		Negative	99.08%		Negative	98.74%
COT	Positive	98.55%	MOP300	Positive	100.00%	THC	Positive	100.00%
	Negative	99.44%		Negative	99.29%		Negative	99.48%
ETG	Positive	97.83%	MQL	Positive	98.41%	TRA	Positive	98.28%
	Negative	99.46%		Negative	99.44%		Negative	99.45%
FYL	Positive	100.00%	MTD	Positive	100%			
	Negative	99.64%		Negative	99.40%			

TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.

Specificity and cross reactivity

To test the specificity and cross reactivity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Compound	Response equivalent to cutoff in ng/mL	Compound	Response equivalent to cutoff in ng/mL
Amphetamine (AMP)		**6-Acetylmorphine (MAM)**	
d-Amphetamin	1,000	6-Monoacetylmorphine(6-MAN)	10
d.l-Amphetamine	2,500	Morphine	100
1-Amphetamine	50,000	Codeine	100
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,000	Hydrocodone	1000
Barbiturates (BAR)		Hydromorphine	1000
Secobarbital	300	Morphine 3-b-D-glucuronide	50
Amobarbital	500	**Methylenedioxymethamphetamine - ecstasy (MDMA)**	
Alphenol	150	D-Amphetamine	>100000
Aprobarbital	200	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500
Butabarbital	75	3,4-methylenedioxyamphetamine (MDA)	2200
Butalbital	1,500	3,4-Methylenedioxyethylamphetamine (MDEA)	240
Butethal	100	**Methamphetamine (MET)**	
Cyclopentobarbital	600	D(+)-Methamphetamine	1,000
Pentobarbital	700	L(-)-Methamphetamine	8,000
Phenobarbital	300	(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
Buprenorphine(BUP)		p-hydroxymethamphetamine	30,000
Buprenorphine	10	3,4-Methylenedioxyethylamphetamine(MDEA)	10,000
Norbuprenorphine	20	**Morphine(MOP300)**	
Buprenorphine 3-D-glucuronide	15	Morphine	300
Norbuprenorphine 3-D-glucuronide	200	Codeine	300
Benzodiazepines (BZO)		Hydrocodone	2000
Oxazepam	300	Hydromorphine	1500
Alprazolam	200	6-Monoacetylmorphine(6-MAN)	750
α-Hydroxyalprazolam	1100	Morphine 3-b-D-glucuronide	300
Bromazepam	1000	**Methaqualone (MQL)**	
Chlordiazepoxide	2000	Methaqualone	300
Clobazam	100	**Methadone (MTD)**	
Clonazepam	800	Methadone	300
Clorazepate	200	(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000
Delorazepam	1600	Doxylamine	50000
Diazepam	200	**Opiate 2000 (OPI)**	
Estazolam	1000	Morphine	2,000
Flunitrazepam	350	Codeine	2,000
Lorazepam	1200	Hydrocodone	15,000

Midazolam	2500	Hydromorphine	10,000
Nitrazepam	100	6-Monoacetylmorphine	5,000
Nordiazepam	400	Morphine 3-b-D-glucuronide	2,000
Temazepam	120	**Oxycodone (OXY)**	
Triazolam	1000	Oxycodone	100
Cocaine (COC)		Naloxone	50000
Benzoylecgonine	300	Naltrexone	50000
Cocaine	800	Morphine 3-β-D-glucuronide	50000
Cocaethylene	12,500	Hydrocodone	3000
Ecgonine HCl	35,000	Hydromorphone	75000
Cotinine (COT)		Oxymorphone	1000
(-)-Cotinine	200	**Phencyclidine (PCP)**	
(-)-Nicotine	6,250	Phencyclidine	25
Ethylglucuronide (ETG)		4-Hydroxyphencyclidine	15000
Ethyl-β-D-glucuronide	500	**Propoxyphene(PPX)**	
Ethyl-β-D-glucuronide-D5	500	d-Propoxyphene	300
Fentanyl (FYL)		d-Norpropoxyphene	300
Fentanyl	200	**Tri-cyclic Antidepressants (TCA)**	
Synthetic Cannabinoid (K2)		Notriptyline	1000
JWH-018 Pentanoic Acid metabolite	50	Nordoxepin	1000
JWH-073 Butanoic Acid metabolite	50	Trimipramine	5000
JWH-018 N-4-hydroxypentyl	16,000	Promazine	3000
JAM2201 N-Pentanoic Acid metabolite	400	Desipramine	1000
JWH398 N-Pentanoic Acid metabolite	800	Imipramine	1000
JWH-210 N-(5-carboxypentyl) metabolite	5,000	Chomipramine	12500
JWH-073 3-hydroxypentyl metabolite	5,000	Doxepin	2000
JWH-019 5-hydroxypentyl metabolite	80,000	Maprotiline	2000
JWH-018 5-hydroxypentyl metabolite	90,000	Amitriptyline	1000
JWH-073 4-hydroxypentyl metabolite	80,000	**Marijuana (THC)**	
Ketamine (KET)		11-nor-Δ9-THC-9-COOH	50
Ketamine	1,000	11-nor-Δ8-THC-9-COOH	50
Norketamine	3,000	Δ8- Tetrahydrocannabinol	10,000
Methoxy-amphetamine	12,500	Δ9- Tetrahydrocannabinol	15,000
Promethazine	25,000	Cannabinol	20,000
4 - hydroxyphenyl cyclohexyl piperidine	50,000	Cannabidiol	>100,000
		Tramadol (TRA)	
		Tramadol	200

Effect of Urinary Specific Gravity

The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine or drug positive urine with the concentration at 50% below and 50% above cutoff level. Each sample was tested by the test device. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with each drug at 50% below and 50% above cutoff levels. Each sample was tested by the ctest device. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

APPLICABLE STANDARDS

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests

EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 13640:2002.

INDEX OF SYMBOLS

	Consult instructions for use		Sufficient for		Date of manufacture
IVD	In vitro diagnostic medical device		Use by		Do not reuse
	Store between 4 ~ 30 ℃	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight		Keep dry	EC REP	Authorised Representative in the EU

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