DOA Rapid Urine Test Device Strip/Cassette/Panel(Colloidal Gold)

Strip/Cassette/Panel

Instruction for Use

A lateral flow chromatographic immunoassay for the qualitative detection of amphetamines,tetrahydrocannabinol,benzodiazepines,cocaine and morphine in urine.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The DOA Rapid Urine Test Device Strip/Cassette/Panel is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and/or drug metabolites in urine at the following cut-off concentrations:

Item	Calibrator	Cut-off
Amphetamine (AMP)	S(+)-Amphetamine	1,000ng/mL
Benzodiazepines (BZO)	Oxazepam	300ng/mL
Cocaine (COC)	Benzoyleogomine	300ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50ng/mL
Morphine (MOP)	Morphine	300ng/mL

SUMMARY

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by presecription 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 does 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 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.

It yields a positive result when the concentration of amphetamine in urine exceeds 1,000ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

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 the Benzodiazepines in the urine is 3-7 days.

It yields a positive result when the concentration of Benzodiazepines in urine exceeds 300ng/mL.

Cocaine (COC)

Cocaine is a potent central nervous system (CNS) 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, and 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. 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.

It yields a positive result when the cocaine metabolite in urine exceeds 300ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Marijuana (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana 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 (Δ9-THC-COOH).

It yields a positive result when the concentration of marijuana in urine exceeds 50ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Morphine (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 substance which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance level and 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.

It yields a positive result when the concentration of morphine in urine exceeds 300ng/mL.

TEST PRINCIPLE

The product 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 to saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible line will show up in the test region. The presence of drug above the cut-off concentration able to saturate all the binding sites of the antibody. Therefore, the line will not form in the test line region.

To serve as a procedural control, a line will always appear at the control region, indicating that proper volume of specimen has been added and proper procedural has been conducted.

MATERIALS PROVIDED

Each box contains test strip/cassette/panels and package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer
3. External controls

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For healthcare professionals and professionals at point of care sites.
3. Do not use after the expiration date.
4. Please read all the information in this leaflet before performing the test.
5. The test panel should remain in the sealed pouch until use.
6. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. The used test panel should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (2-30℃).
2. The kit is stable within the expiration date printed on the labeling.
3. Do not freeze.
4. Once open the pouch, the test should be used within one hour.
5. Prolonged exposure to hot and humid environment will cause product deterioration.

The stability of the kit under these storage conditions is 24 months.

ASSAY PROCEDURES

Instructions must be read entirely before taking the test. Allow the test device to equilibrate to room temperature (10°C-30°C) to testing. Do not open the inner package until ready, it must be used within one hour if opened (Humidity≤60%, Temp: 10°C-30°C). Please use immediately when the humidity exceeded to 60%.

Cassette:

1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 2-3 drops (approx. 60μl) of urine to the specimen well of the test cassette, and then begin timing. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results at 5 minutes. Do not read results after 10 minutes

Strip\Cassette

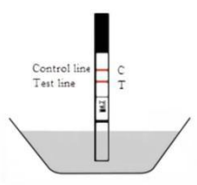
1. Remove the cap from the end of the test card. With arrows pointing toward the urine sample, immerse the sample pad area of the test card vertically in the urine sample for at least 5-10seconds. Dip the test card in the urine, but not above the arrow(s) on the test card. See the illustration below, that listed one type of combinations.

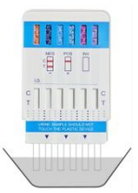
2.Place the test card on a non-absorbent flat surface.

3.Start the timer and the result should be read after 5 minutes.

4. Positive test results must be confirmed by another test. Please transport the panel and urine sample intact to a toxicology laboratory for confirmation.

5. We recommend not to interpret the drug test results in case of any positive result for any adulteration test. Please collect another sample to test.





INTERPRETATION OF ASSAY RESULT

Negative Result

Two lines appear. One line should be in the control region (C), and another apparent red or pink should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

NOTE: The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

Positive Result

Only one line appears in the control region (C). This positive result indicates that the drug concentration is above the detectable level.

Invalid Result

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. The 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 product provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other 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.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE

1. Accuracy

A side-by-side comparison was conducted using the product and commercially available drug rapid test products. Testing was performed on approximately 380 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BZO	Oxazepam, Diazepam
COC	Benzoylecgonine
THC	11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid
MOP	Morphine, Codeine

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZO	THC	MOP
Positive Agreement	98%	100%	100%	100%	97%
Negative Agreement	100%	100%	97%	99%	96%
Total esults	99%	100%	98%	>99%	97%

2. Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Amphetamine (AMP)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1,500	15	0	15	0	15	0	15

Secobarbital（BAR）

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Benzodiazepines (BZO)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15
conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
100	15	15	0	15	0	15	0
300	15	0	15	0	15	0	15

Marijuana (THC)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	15	0
75	15	0	15	0	15	0	15

Morphine (MOP 300)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

3. Effect of Urinaru 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 product was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

4. Effect of the 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 product. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

5. 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. The following compounds show no cross-reactivity when tested with the product at a concentration of 100μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Phenelzine	L(–)-Epinephrine
N-Acetylprocainamide	L-Phenylephrine	Fenoprofen
Aminopyrine	Phenylpropanolamine	Gentisic acid
Ampicillin	Prednisone	Hydralazine
Atropine	Quinacrine	Hydrocortisone
Benzoic acid	Quindine	Ibuprofen
Bilirubin	Salicylic acid	D/L-Isoproterenol
Caffeine	Sulfamethazine	Labetalol
Chloralhydrate	Tetracycline	Methoxyphenamine
Chlorothiazide	Tetrahydrozoline	Nalidixic acid
Chlorpromazine	Thiamine	Niacinamide
Cholesterol	D/L-Tyrosine	Norethindrone
Cortisone	Triamterene	Noscapine
Creatinine	Trimethoprim	Oxalic acid
Dextromethorphan	D/L-Tryptophan	Oxymetazoline
Diflunisal	Uric acid	Penicillin-G
Estrone-3-sulfate	Zomepirac	Perphenazine
Erythromycin	Acetophenetidin	Trans-2-phenylcyclo-propylamine hydrochloride
Furosemide	Acetylsalicylic acid	β-Phenylethylamine
Hemoglobin	Amoxicillin	Prednisolone
Hydrochlorothiazide	L-Ascorbic acid	D/L-Propranolol
O-Hydorxyhippuric acid	Aspartame	Quinine
p-Hydroxytyramine	Benzilic acid	Ranitidine
Iproniazid	Benzphetamine*	Serotonin
Isoxsuprine	D/L-Brompheniramine	Sulindac
Ketoprofen	Chloramphenicol	Tetrahydrocortisone 3-acetate
Loperamide	D/L-Chloropheniramine	Tetrahydrocortisone 3 (β-D-glucuronide)
Meprobamate	Chloroquine	Thioridazine
Methylphenidate	Clonidine	Tolbutamide
Naproxen	Deoxycorticosterone	Trifluoperazine
Nifedipine	Diclofenac	Tryptamine
D/L-Octopamine	Digoxin	
Oxolinic acid	β-Estradiol	Verapamil
Pentazocine hydrochloride	Ethyl-p-aminobenzoate	

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Code:GKPD043-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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