MD Drug Test

Product Code:MD5PDOA001
Version: 221021

The Medical Diagnostech MD Drug Test offers any combination of 12 drugs from a possible selection of 14 drugs of abuse, namely: Amphetamine (AMP), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), 3,4-methylenedioxy-N- methylamphetamine (MDMA), Methamphetamine (MET), Methaqualone (MQL), Morphine/Opiates (MOP), Ketamine (KET), Phencyclidine (PCP), Propoxyphene (PPX), Methadone (MTD), Tricyclic acid (TCA) and Barbiturates (BAR).

This package insert applies to all combinations of MD Drug Test panels. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.

A rapid one step test for the qualitative detection of drugs of abuse and their principal metabolites in human urine at specified cut off levels.

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

INTENDED USE

The Medical Diagnostech MD Drug Test consists of individual one-step immunoassays. The test is a lateral flow, one-stepimmunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut off (ng/ml)
Amphetamine (Speed)	Amphetamine	1000
Benzodiazepines (Prescription)	Oxazepam	300
Cocaine	Benzoylecgonine	300
MDMA (Ecstasy)	MDMA	500
THC (Marijuana)	THC	50
Methamphetamine (Tik)	Methamphetamine	1000
Methaqualone (Mandrax)	MQL	300
Morphine / Opiates / Heroin (Prescription)	Morphine	2000
Ketamine (KET)	Ketamine	1000
Methadone (MTD)	Methadone	300
Tricyclic acid (TCA)	Tricyclic acid	1000
Barbiturates (BAR)	Barbiturates	300
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	**300**

PRINCIPLE OF THE TEST

The Medical Diagnostech MD Drug Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample competitively bind to a limited number of antibody-gold conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-gold conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cut-off, the free drug in the sample binds to the antibody-gold conjugate preventing the antibody-gold conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored line in the test region, indicating a positive result.

When sample drug levels are zero or below the target cut-off (the detection sensitivity of the test), the antibody-gold conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

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

WARNING AND PRECAUTIONS

- This kit is for external use only.
- Discard after first use. The test cannot be used more than once.
- Do not use the test kit beyond the expiry date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Read the results at 5 minutes for the most accurate results. **Do not read after 15 minutes.**
- Do not use a urine collection cup more than once to avoid cross contamination of the urine.

STORAGE AND STABILITY

- Store at 4-30 ºC in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- Do not freeze.

MATERIAL

Urine test strips and package insert.

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Urine cup

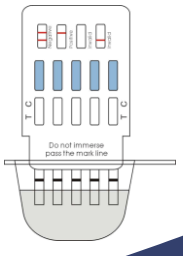
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2-8°C) and stored for up to forty-eight (48) hours. For longer storage, freeze the samples (-20°C or below).
Bring frozen or refrigerated samples to room temperature before testing. Use only clear urine aliquots for testing.

TEST PROCEDURE

The test must be at room temperature (18ºC to 30ºC) prior to use:

1. Open the sealed pouch by tearing along the notch. Remove the test from the pouch.
2. Hold the one side of the device with one hand and use the other hand to pull the cap off and expose the absorbent ends.
3. Immerse the absorbent ends into the urine sample for 10 seconds or until all lanes run. Make sure that the urine does not touch the plastic cassette housing.
4. Replace the cap and lay the device on the flat, clean, dry, non-absorbent surface.
5. Read the result at 5 minutes for the most accurate result. **Do not read after 15 minutes.**



Manufactured by:
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MEDICAL DIAGNOSTECH

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INTERPRETATION OF RESULTS

Positive (+):
A rose-pink line is visible in each control region. No color line appears in the test region. It indicates a positive result for the corresponding drug of that specific test zone.

Negative (-):
A rose-pink line is visible in each control region and the test region.It indicates that the concentration of the corresponding drug of that specific test zone is below the cut-off or the detection limit of the test.

Invalid:
If a color line is not visible in each of the control region or a color line is visible only in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store where the product was purchased. The lot numberand a description of the problem will be required.

Note: A very faint line is also considered negative.

Positive Negative Invalid Invalid

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when a drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements but rarely occurs.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using each of the tests and commercially available drug rapid test (Acon One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key IM Cup (Urine)). 580 specimens were used in the test. Positive results were confirmed by GC/MS. The results are listed as follows:

% Agreement with commercial kit:

Specimen	AMP	BZO	COC	THC	MET	MOP 2000	MDMA	MQL
Positive	> 99%	95%	100%	95%	> 99%	97.5%	98%	98%
Negative	> 99%	100%	99%	99%	> 99%	99%	98%	98%
Total	> 99%	97.9%	> 99%	97.9%	> 99%	98.6%	98%	98%

% Agreement with commercial kit:

Specimen	AMP	BZO	COC	THC	MET	MOP 2000	MDMA	MQL
Positive	94%	97%	96%	95%	99%	98%	98%	98%
Negative	99%	97%	99%	96%	99%	98%	98%	98%
Total	97%	97%	98%	96%	99%	98%	98%	98%

CROSS-REACTIVITY

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with MD Drug Test at a concentration of 100 µg/ml.

List of Non-Crossing-Reactivity Compounds Tested

Acetophenetidin	Creatinine	Loperamide	Quinidine
Nalidixic acid	Deoxycorticosterone	Meprobamate	Quinine
Acetylsalicylic acid	Dextromethorphan	Methoxyphenamine	Ranitidine
Aminopyrine	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diflunisal	Naloxone	Serotonin
Ampicillin	Digoxin	Naltrexone	Sulfamethazine
L-Phenylephrine	Diphenhydramine	Naproxen	Sulindac
Apomorphine	L-ψ-Ephedrine	Niacinamide	Tetracycline
Aspartame	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate
Benzilic acid	β-Estradiol	D-Norpropoxyphene	Tetrahydrocortisone,
Benzoic acid	Estrone-3-sulfate	Noscapine	(β-D-glucuronide)
Benzphetamine	Erythromycin	D,L-Octopamine	Tetrahydrozoline
Bilirubin	Fenoprofen	Oxalic acid	Thiamine
Deoxycorticosterone	Furosemide	Oxolinic acid	Thioridazine
Caffeine	Gentisic acid	Oxymetazoline	D,L-Tyrosine
Chloralhydrate	Hemoglobin	Papaverine	Tolbutamide
Chloramphenicol	Hydralazine	Penicillin-G	Triamterene
Chlorathiazide	Hydrochlorothiazide	Perphenazine	Trifluoperazine
D,L-Chlorpheniramine	Hydrocortisone	Phenelzine	Trimethoprim
Chlorpromazine	O-Hydroxyhippuric acid	L-Phenylephrine	Tyramine
Chlorquine	3-Hydroxytyramine	β-Phenylethylamine	D,L-Tryptophan
Cholesterol	D,L-Isoproterenol	Phenylpropanolamine	Urine acid
Clonidine	Isoxsuprine	Prednisone	Verapamil
Cortisone	Ketamine	D,L-Propanolol	Zomepirac
L-Cotinine	Ketoprofen	D-Propoxyphene	

From the results above, it is clear that the MD Drug Test performs well against interference from these substances.

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INDEX OF SYMBOLS

IVD	For in-vitro diagnostic use only	For single use only	
Σ	Content	Expiry date	
LOT	Lot number	Storage temperature	

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