MD DrugScreen OPI

One Step Morphine Test Dipcard

CLIA Waived/OTC Package Insert

Package insert for testing of any combination of the following drugs: Opiate

A rapid, one step screening test for the simultaneous, qualitative detection of Cocaine metabolites in human urine.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

INTENDED USE& SUMMARY

Urine based CLIA Waived/OTC Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The MD DrugScreen **OPI One Step Opiate Test Dip card** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Opiate (OPI)	Morphine	2,000

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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 used.

SUMMARY

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 central nervous system. 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. Morphine is detectable in the urine for several days after an opiate dose [1-4]

The MD DrugScreen **OPI One Step Opiate Test Dip card**is a rapid urine screening test that can be performed without the use of an instrument. The test is intended for over-the-counter (OTC) use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing - the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug(Identifier)	Cut-off level	Minimum detection time	Maximum detection time
Morphine	2,000 ng/mL	2 hours	Up to 3 days

PRINCIPLE

The MD DrugScreen **OPI One Step Opiate Test Dip card** is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Morphine, if present in the urine specimen below2,000 ng/mL, will not saturate the binding sites of the antibody coated particles in the test strip. The antibody coated particles will then be captured by immobilized morphine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the morphine level is above 300 ng/mL because it will saturate all the binding sites of anti-morphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test strip contains mouse monoclonal anti-morphine antibody-coupled particles and morphine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The Test Strip 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 Test Strip should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The Test Strip is stable through the expiration date printed on the sealed pouch. The Test Strip must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat.**DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time is 2 hours, so you may collect urine samples 2 hours after suspected drug use.

HOW TO COLLECT URINE?

1. Urinate directly into the provided urine cup.

2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.

3. The residual urine sample in the urine cup is for your self-testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

•Test Strip • Desiccants • Package insert •Urine cups

The below contents only included for the OTC use:

1. Labeled Vials for shipping "preliminary" sample to the laboratory for confirmation
2. Plastic transportation bags
3. Mailing boxes
4. Personal identification numbers

DIRECTIONS FOR USE

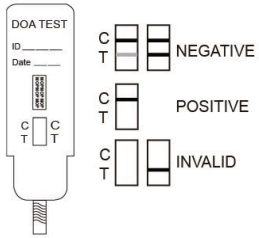
Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the strip from the foil wrapper or the desiccated container (bring the container to the roomtemperature before opening to avoid condensation of moisture in container). Label the strip with patientor control identifications.

2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urineover the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after aminimum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface.

3) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 5 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: 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 manufacturer.

Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by MD DrugScreen OPI One Step Opiate Urine Test. 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 Morphineis present but isn't detected by MD DrugScreen OPI One Step Opiate Urine Test. If the sample is diluted, or the sample is adulterated that may cause false negative result.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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.Please contact our Technical Support at 1-866-982-3818 for controls that work with the device.

LIMITATIONS

1. The MD DrugScreen **OPI One Step Opiate Test Dip card**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. 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. 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.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test do?

These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.

2. What is "cut-off level"?

The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

4. How accurate is the test?

The tests are sensitive to the presence of drugs in urine sample. These tests are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits..

5. Does a preliminary positive screen test mean that you have found of abuse?

This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

6. What should I do, if the lab test confirms a positive result?

If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will

help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

1. Ensure that the Labeled Vial is about two third (2/3) full and that the cap is tightly closed.
2. Check the label identifying the drug that was a preliminary positive result.
3. Be sure to write your Cell Phone Number on the mailing box that the laboratory can send you the message with the confirmed results along with the Personal Identification Number.
4. Place the Labeled Vial in the plastic bag and seal the plastic bag.
5. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. ***Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.***
6. Place the mailing box in any US Postal Service Office.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the MD DrugScreen OPI One Step Opiate Test Dip card. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator B	Positive	0	0	0	12	23
	Negative	10	16	14	5	0
Operator C	Positive	0	0	0	12	23
	Negative	10	16	14	5	0

% agreement among positives is 88.3%
% agreement among negatives is 100%

ANALYTICAL SENSITIVITY

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Morphine. The cut-off value 2,000ng/mL for the device is verified

Morphine Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	90	90	0
1,000	-50%	90	90	0
1,500	-25%	90	90	0
2,000	Cutoff	90	43	47
2,500	+25%	90	0	90
3,000	+50%	90	0	90

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the MD DrugScreen OPI One Step Opiate Test Dip cardDevice.

Drug	**Concentration (ng/ml)**	% Cross-Reactivity
O6-Acetylmorphine	2,500	80%
Codeine	1,000	50%
EthylMorphine	250	800%
Heroin	5,000	40%
Hydromorphone	2,500	80%
Hydrocodone	5,000	50%
Morphine Hydrochloride	2,000	100%
Oxycodone	75,000	3%
Thebaine	13,000	15%
Procaine	15000	2%
Thebaine	6240	5%

PRECISION

This study is performed 2 runs/day and lasts 25 days for each format with three lots.Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Morphine concentration (ng/mL)	n	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
75	50	50	0	50	0	50	0
150	50	50	0	50	0	50	0
225	50	50	0	50	0	50	0
300	50	22	28	22	28	22	28
375	50	0	50	0	50	0	50
450	50	0	50	0	50	0	50
525	50	0	50	0	50	0	50
600	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The MD DrugScreen **OPI One Step Opiate Test Dip card**was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The MD DrugScreen **OPI One Step Opiate Test Dip card**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cocaine, positive urine. The following compounds show no cross-reactivity when tested with the **MD DrugScreen OPI One Step Opiate Test Dip card**at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acebutolol	(-) Y Ephedrine	Maprotiline	L-Phenylephrine
Acetopromazine—d6	Erythromycin	Meprobamate	β-Phenylethlamine
4-Acetamidophenol	β-Estradiol	Methoxyphenamine	Phenylpropanolamine
Acetophenetidin	Estrone-3-sulfate	(+) 3,4-Methylenedioxyamphetamine	Prednisolone
N-Acetylprocainamide	Ethyl-p-aminobenzoate	(+)3,4-Methylenedioxymethamphetamine	Prednisone
Acetylsalicylic acid	Fenoprofen	Methadone	Promazine
D,L-Amphetamine	Furosemide	Methylphenidate	Promethazine
L-Amphetamine	Gentisic acid	Methyprylon	D,L-Propanolol
Aminopyrine	Hemoglobin	Nalorphine	D-Propoxyphene
Amitryptyline	Hydralazine	Nalidixic acid	D-Pseudoephedrine
Amobarbital	Hydrochlorothiazide	Naloxone	Quinidine
Amoxicillin	Hydrocortisone	Naltrexone	Quinine
Ampicillin	O-Hydroxyhippuric acid	Naproxen	Salicylic acid
Ascorbic acid	3-Hydroxytyramine	Niacinamide	Secobarbital
Apomorphine	Ibuprofen	Nifedipine	Serotonin
Aspartame	Imipramine	Norcodein	Sulfamethazine
Atropine	Iproniazid	Norethindrone	Sulindac
Benzilic acid	(-) Isoproterenol	D-Norpropoxyphene	Temazepam
Benzoic acid	Isoxsuprine	Noscapine	Tetracycline
Benzoylecgonine	Ketamine	D,L-Octopamine	Tetrahydrozoline
Benzphetamine	Ketoprofen	Oxalic acid	Tetrahydrocortisone, 3 Acetate
Bilirubin	Labetalol	Oxazepam	Tetrahydrocortisone3 (5-Dglucuronide)
Brompheniramine	Loperamide	Oxolinic acid	Thiamine
Caffeine	(-) Y Ephedrine	Oxymetazoline	Thioridazine
Chloramphenicol	Erythromycin	p-Hydroxymethamphetamine	D,L-Thyroxine
Chlordiazepoxide	β-Estradiol	Papaverine	Tolbutamine
Chlorothiazide	Estrone-3-sulfate	Penicillin-G	Triamterene
(±) Chlorpheniramine	Ethyl-p-aminobenzoate	Pentazocaine	Trifluoperazine
Chlorpromazine	Fenoprofen	Pentobarbital	Trimethoprim
Chlorquine	Furosemide	Perphenazine	Trimipramine
Cholesterol	Gentisic acid	Phencyclidine	Tryptamine
Clomipramine	Hemoglobin	Phenelzine	D, L-Tyrosine
Clonidine	Hydralazine	Phenobarbital	Uric acid
Cocaine hydrochloride	Hydrochlorothiazide	Phentermine	Verapamil
Cortisone	Hydrocortisone	β-Phenyllethylamine	Zomepirac

Lay User Study

A lay user study was performed at three intended user sites with 140 lay persons. For aDipcarddevice study, participants were 66 females and 74 males tested the Morphinesample. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The typical results are summarized below.

% of Cutoff	Number of samples	MOP Concentration by GC/MS(ng/mL)	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	17	3	85%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

BIBLIOGRAPHY

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), ResearchMonograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to beUsed by the Consumer, 1997.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight


Store between2 C and 30 C


Keep dry


Do not re-use

B20735-01