

MTD Rapid Test Dipstick (Urine) Package Insert

REF PKG-101	English
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A rapid, test for the qualitative detection of Methadone in human urine.
For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The MTD Rapid Test Dipstick (Urine) is a lateral flow chromatographic immunoassay for the detection of Methadone in human urine at a cut-off concentration of 300ng/ml. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, 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

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of Heroin (Opiate dependence: Vicodin, Percalate, Morphine, etc) addiction. Oral Methadone is very different than the IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like Heroin.

Methadone is a long acting pain reliever producing effects that last between 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.¹

The MTD Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methadone in urine. The MTD Rapid Test Dipstick (Urine) yields a positive result when the Methadone in urine exceeds 300 ng/mL.

PRINCIPLE

The MTD Rapid Test Dipstick (Urine) is an immunoassay based on the principle of competitive binding. Drugs that 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. Methadone, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody coated particles will then be captured by immobilized Methadone-protein 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 Methadone level exceeds 300 ng/mL because it will saturate all the binding sites of anti-Methadone 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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-Methadone antibody coupled particles and Methadone-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 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 should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

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

MATERIALS

- Test Dipsticks

Materials Provided

- Package insert

Materials Required But Not Provided

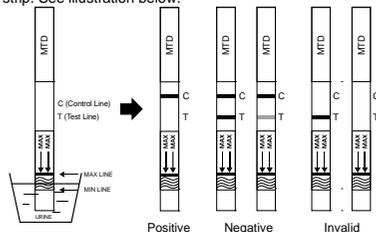
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.

2. With arrows pointing toward the urine specimen, **immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See illustration below.



3. Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to illustration above)

NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Methadone concentration is below the detectable cut-off level (300ng/ml).

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Methadone concentration exceeds the detectable cut-off level (300ng/ml).

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. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The MTD Rapid Test Dipstick (Urine) 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.^{2,3}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

EXPECTED VALUES

This negative result indicates that the Methadone concentration is below the detectable level of 300ng/ml. Positive result means the concentration of Methadone is above the level of 300ng/ml. The MTD Rapid Test Dipstick has a sensitivity of 300ng/ml.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The MTD Rapid Test Dipstick (Urine) and a commercially available MTD rapid test. Testing was performed on 97 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	Other MTD Rapid Test		Total Results	
	Results	Positive		
MTD Rapid Test Dipstick	Positive	39	0	39
	Negative	0	58	58
	Total Results	39	58	97
% Agreement	>99.9%	>99.9%	>99.9%	

A side-by-side comparison was conducted using The MTD Rapid Test Dipstick (Urine) and GC/MS at the cut-off of 300ng/ml. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results	
	Results	Positive		
MTD Rapid Test Dipstick	Positive	89	2	91
	Negative	1	158	159
	Total Results	90	160	250
% Agreement	98.9%	98.8%	98.8%	

Analytical Sensitivity

A drug-free urine pool was spiked with Methadone at the following concentrations: 0ng/ml, 150ng/ml, 225ng/ml, 300ng/ml, 375ng/ml, 450ng/ml and 900ng/ml. The result demonstrates >99% accuracy at 50% and above the cut-off concentration. The data are summarized below:

Methadone Concentration	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
150	-50%	30	30	0
225	-25%	30	27	3
300	Cut-off	30	13	17
375	+25%	30	4	26
450	+50%	30	0	30
900	+300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MTD Rapid Test Dipstick (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Methadone	300
Doxylamine	100,000

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Methadone, 25% Methadone above and below the cut-off and 50% Methadone above and below the 300ng/ml cut-off was provided to each site. The following results were tabulated:

Methadone Concentration	n per	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 150ng/ml and 450ng/ml of Methadone. The MTD Rapid Test Dipstick (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity

do not affect the test results.

Effect of 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 Methadone to 150ng/ml and 450ng/ml. The spiked, pH-adjusted urine was tested with the MTD Rapid Test Dipstick (Urine) in duplicate. 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 Methadone-positive urine. The following compounds show no cross-reactivity when tested with the MTD Rapid Test Dipstick (Urine) at a concentration of 100 µg/ml.

Non Cross-Reacting Compounds

Acetaminophen	Diazepam	Maprotiline	β-Phenylethylamine
Acetophenetidin	Diclofenac	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diffusional	Meprobamate	Prednisolone
Acetylsalicylic acid	Digoxin	Methamphetamine	Prednisone
Aminopyrine	Diphenhydramine	Methoxyphenamine	Procaine
Amitypyline	EDDP	(±) - 3,4-Methylenedioxy-amphetamine	Promazine
Amobarbital	EMDP	(±) - 3,4-Methylenedioxy-methamphetamine	Promethazine
Amoxicillin	Egonine hydrochloride	Amphetamine	D,L-Propranolol
Ampicillin	Egonine methylester	Morphine-3-β-D-glucuronide	D-Propoxyphene
L-Ascorbic acid	(-) -ψ-Ephedrine	Morphine Sulfate	D-Pseudoephedrine
D,L-Amphetamine sulfate	L - Ephedrine	Nalidixic acid	Quinacrine
Apomorphine	Erythromycin	Naloxone	Quinine
Aspartame	β-Estradiol	Estroline-3-sulfate	Ranitidine
Atropine	Estrone-3-sulfate	Naltrexone	Salicylic acid
Benzilic acid	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Benzoic acid	Fenoprofen	Niacinamide	Serotonin
Benzoylcegonine	Furosemide	Nifedipine	Sulfamethazine
Benzphetamine	Gentisic acid	Norcocaine	Sulindac
Bilirubin	Hemoglobin	Norethindrone	Temazepam
(±) - Brompheniramine	Hydralazine	D-Norpropoxyphene	Tetracycline
Caffeine	Hydrochlorothiazide	Noscapine	Tetrahydrocortisone, 3-Acetate
Cannabidiol	Hydrocodone	D,L-Octopamine	Tetrahydrocortisone, 3-(β-D-glucuronide)
Cannabinol	Hydrocortisone	Oxalic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxazepam	Thebaine
Chloramphenicol	p-Hydroxyamphetamine	Oxolinic acid	Thiamine
Chlorothiazide	(±) - Chlorpheniramine	Oxycodone	Thiazidiazine
(±) - Chlorpheniramine	Chlorpromazine	Oxymetazoline	Thiamine
Chlorpropazine	Chlorquine	Papaverine	Thiouridiazine
Cholesterol	Chloxytyramine	Penicillin-G	D,L-Tyrosine
Clomipramine	Ibuprofen	Imipramine	Tolbutamide
Clonidine	Imipramine	Pentazocine hydrochloride	Triamterene
Cocacethylene	Iproniazid	Pentobarbital	Trifluoperazine
Cocaine hydrochloride	(±) - Isoproterenol	Perphenazine	Trimethoprim
Cocaine	Isoxsuprine	Phencyclidine	Trimipramine
Cortisone	Ketamine	Phenelzine	Tryptamine
(-) Cotinine	Ketoprofen	Phenobarbital	D,L-Tryptophan
Creatinine	Labetalol	Pertemrine	Tyramine
Deoxycorticosterone	Levopranolol	Trans-2-phenyl	Uric acid
Dextromethorphan	Loperamide	Cyclopropylamine	Verapamil
	Mephentermine	L-Phenylephrine	Zomepirac

BIBLIOGRAPHY

- Glass, IB. *The International Handbook of Addiction Behavior*. Routledge Publishing, New York, NY. 1991; 216
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

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				

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