



MTD Rapid Test Cassette (Urine)

Package Insert

REF DMT-102 English

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 Cassette (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 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, Percolate, 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 Cassette (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 Cassette (Urine) yields a positive result when the Methadone in urine exceeds 300 ng/mL.

【PRINCIPLE】

The MTD Rapid Test Cassette (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 in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【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】

Materials Provided

- Test cassettes
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Timer

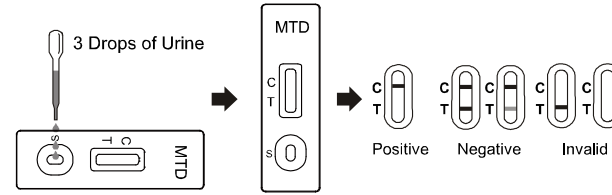
【DIRECTIONS FOR USE】

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the

sealed pouch and use it within one hour.

- Place the test Cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test Cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the color 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 colored lines appear. One colored line should be in the control line region (C) and another 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 Cassette (Urine) provides only a qualitative, preliminary 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.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the MTD Rapid Test Cassette (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	Negative	
MTD Rapid Test Cassette	Positive	0	39
	Negative	58	58
	Total Results	39	58
% Agreement	>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the MTD Rapid Test Cassette (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	Negative	
MTD Rapid Test Cassette	Positive	2	91
	Negative	158	159
	Total Results	90	160
% 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% above and 50% below the cut-off concentration. The data are summarized below:

Methadone Concentration (ng/mL)	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	3X	30	0	30

Analytical Specificity

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

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

Precision

A study was conducted at three hospitals 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 were provided to each site. The following results were tabulated:

Methadone Concentration (ng/mL)	n per Site	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	8	2	9	1
375	10	2	8	1	9	2	8
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 Cassette (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 Cassette (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 Cassette (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diazepam	Maprotiline	Phenylethylamine
Acetophenetidin	Diclofenac	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diflunisal	Meprobamate	Prednisolone
Acetylsalicylic acid	Digoxin	Methamphetamine	Prednisone
Aminopyrine	Diphenhydramine	Methoxyphenamine	Procaine
Amtryptiline	EDDP	(±) - 3,4-Methylenedioxyamphetamine	Promazine
Amobarbital	EMDP		Promethazine
		(±)	
Amoxicillin	Ecgonine hydrochloride	3,4-Methylenedioxy-methamphetamine	D,L-Propranolol
Ampicillin	Ecgoninemethylester	Amphetamine	D-Proxephene
L-Ascorbic acid	(-) -ψ-Ephedrine	Morphine-3-	D-Propoxyphedrine
D,L-Amphetamine sulfate	[1R,2S] (-) Ephedrine	β-D glucuronide	Quinacrine
Apomorphine	L - Epinephrine	Morphine Sulfate	Quinidine
Aspartame	Erythromycin	Nalidixic acid	Quinine
Atropine	-Estradiol	Naloxone	Ranitidine
Benzilic acid	Estrone-3-sulfate	Naltrexone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Benzoylcegonine	Fenoprofen	Niacinamide	Serotonin
Benzphetamine	Furosemide	Nifedipine	Sulfamethazine
Bilirubin	Genitisc acid	Norcodein	Sulindac
(±) - Brompheniramine	Hemoglobin	Norethindrone	Temazepam
Caffeine	Hydralazine	D-Norpropoxyphene	Tetracycline
Cannabidiol	Hydrochlorothiazide	Noscapine	Tetrahydrocortisone,
Cannabinol	Hydrocodone	D,L-Octopamine	3-Acetate
Chloralhydrate	Hydrocortisone	Oxalic acid	Tetrahydrocortisone
Chloramphenicol	O-Hydroxyhippuric acid	Oxazepam	3-(β-D-glucuronide)
Chlorothiazide	p-Hydroxyamphetamine	Oxolinic acid	Tetrahydrozoline
(±) - Chlorpheniramine	p-Hydroxy-methamphetamine	Oxycodone	Thebaine
Chlorpromazine	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chlorquine	Ibuprofen	Penicillin-G	Thioridazine
Cholesterol	Imipramine	Pentazocin hydrochloride	D,L-Tyrosine
Clomipramine	lproniazid	Pentobarbital	Tolbutamide
Clonidine			Triamterene

Cocaeethylene	(±) - Isoproterenol	Perphenazine	Trifluoperazine
Cocaine hydrochloride	Isoxsuprine	Phencyclidine	Trimethoprim
Codeine	Ketamine	Phenelzine	Trimipramine
Cortisone	Ketoprofen	Phenobarbital	Tryptamine
(-) Cotinine	Labetalol	Phentermine	D,L-Tryptophan
Creatinine	Levorphanol	Trans-2-phenyl	Tyramine
Deoxycorticosterone	Loperamide	Cyclopropylamine	Uric acid
Dextromethorphan	Mephentermine	L-Phenylephrine	Verapamil

Zomepirac

【BIBLIOGRAPHY】

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

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	<i>In vitro</i> diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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