

## Methadone Test Device (Urine)

A rapid test for the qualitative detection of Methadone in human urine.

**IVD** For *in vitro* diagnostic use only.



Store at (2-30°C)

### INTENDED USE

The MTD One Step Methadone Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Methadone in human urine at a cut-off concentration of 300ng/ml. 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.

### INTRODUCTION

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of Heroin (Opiate dependence: Vicodin, Percocet, Morphine, ect) 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. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.

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.

The MTD One Step Methadone Test Device (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 One Step Methadone Test Device (Urine) yields a positive result when the Methadone in urine exceeds 300 ng/ml.

### PRINCIPLE

The MTD One Step Methadone Test Device (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.

### MATERIALS

#### Materials Provided

- Test devices (contain mouse anti-Methadone antibody coupled particles

and Methadone-protein conjugate. A goat antibody is employed in the control line system).

- Disposable specimen droppers
- Package insert

#### Materials Required But Not Provided

- Specimen collection container
- Timer

#### PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 device should be discarded according to federal, state and local regulations.

#### STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device 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 precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

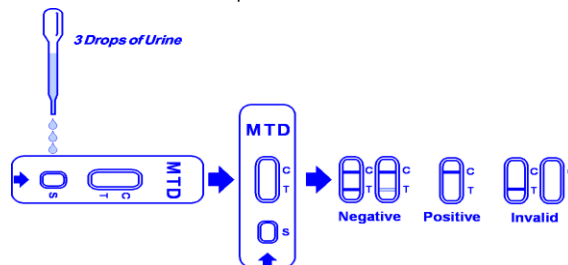
##### Specimen Storage

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

#### PROCEDURE

**Allow test device, 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 device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. minutes. Do not interpret the result after 10 minutes.



#### INTERPRETATION OF RESULTS

(Please refer to the illustration.)

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

**\*NOTE:** The shade of red in the test line region (T) may 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 (T). This positive result indicates that the Methadone concentration exceeds the detectable cut-off level (300 ng/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 device. 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 red 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 testing practice to confirm the test procedure and to verify proper test performance.

#### LIMITATION

1. The MTD One Step Methadone Test Device (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. It is possible 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 indicates presence of the drug or its metabolites but does not indicate level of 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.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

A side-by-side comparison was conducted using the MTD One Step Methadone Test Device (Urine) and a leading commercially available MTD rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other MTD Rapid Test		Total Results
	Positive	Negative	
Atlas One Step Test Device	Positive	132	132
	Negative	0	168
<b>Total Results</b>		132	168
<b>% Agreement with this Rapid Test Kit</b>		>99%	>99%

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
Atlas One Step Test Device	Positive	122	132
	Negative	1	167
<b>Total Results</b>		123	177
<b>% Agreement with GC/MS Analysis</b>		99%	94%

### Analytical Sensitivity

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

MTD (ng/mL)	Concentration	Percent of Cut-off	n	Visual Result	
				Negative	Positive
0	0		30	30	0
150	-50%		30	30	0
225	-25%		30	26	4
300	Cut-off		30	16	14
375	+25%		30	4	26
450	+50%		30	0	30

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the MTD One Step Methadone Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Methadone	300
Doxylamine	50,000

### Precision

A study was conducted at 3 physician's offices by untrained operators using 3 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 300 ng/mL cut-off was provided to each site. The following results were tabulated:

Methadone (ng/mL)	conc.	n per site	Site A		Site B		Site C	
			-	+	-	+	-	+
0		15	15	0	15	0	15	0
150		15	10	5	13	2	14	1
225		15	4	11	13	2	13	2
375		15	0	15	1	14	0	15
450		15	0	15	0	15	0	15

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples with specific gravity ranging from 1.001 to 1.032 were spiked with 150 ng/mL and 450 ng/mL of Methadone respectively. The MTD One Step Methadone Test Device (Urine) was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### 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 Methadone to 150 ng/ml and 450 ng/ml. The spiked, pH-adjusted urine was tested with the MTD One Step Methadone Test Device (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 One Step Methadone Test Device (Urine) at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

















Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentazocine hydrochloride
Aminopyrine	Gentisic acid	Pentobarbital
Amitypyline	Hemoglobin	Perphenazine
Amobarbital	Hydralazine	Phencyclidine
Amoxicillin	Hydrochlorothiazide	Phenelzine
Ampicillin	Hydrocodone	Phenobarbital
L-Ascorbic acid	Hydrocortisone	Phentermine
DL-Amphetamine sulfate	O-Hydroxyhippuric acid	Trans-2-phenylcyclo-

Apomorphine	p-Hydroxyamphetamine	propylamine hydrochloride
Aspartame	p-Hydroxy-methamphetamine	L-Phenylephrine
Atropine	3-Hydroxytyramine	β-Phenylethylamine
Benzilic acid	Imipramine	Phenylpropanolamine
Benzoylcegonine	lproniazid	Prednisolone
Benzphetamine	(±) - Isoprotterolol	Prednisone
Bilirubin	Isoxsuprine	Procaine
(±) - Brompheniramine	Ketamine	Promazine
Caffeine	Ketoprofen	Promethazine
Cannabidiol	Labetalol	DL-Propranolol
Cannabinol	Levorphanol	D-Propoxyphene
Chloralhydrate	Loperamide	D-Pseudoephedrine
Chloramphenicol	Mephentermine	Quinacrine
Chlorothiazide	Maprotiline	Quinine
(±) - Chlorpheniramine	Meperidine	Ranitidine
Chlorpromazine	Meprobamate	Salicylic acid
Chlorquine	Methamphetamine	Secobarbital
Cholesterol	Methoxyphenamine	Serotonin
Clomipramine	(±) - 3,4-Methylenedioxy-amphetamine hydrochloride	Sulfamethazine
Clonidine	hydrochloride	Sulindac
Cocaethylene	(±) -	Temazepam
Cocaine hydrochloride	(±) -	3,4-Tetracycline
Codeine	Methylenedioxymethamphetamine hydrochloride	Tetrahydrocortisone, 3-acetate
Cortisone	Morphine-3-β-D-glucuronide	Tetrahydrocortisone 3-(β-D-glucuronide)
(-) Cotinine	Morphine Sulfate	Tetrahydrozoline
Creatinine	Nalidixic acid	Thebaine
Deoxycorticosterone	Naloxone	Thiamine
Dextromethorphan	Naltrexone	Thioridazine
Diazepam	Naproxen	DL-Tyrosine
Diclofenac	Niacinamide	Tolbutamide
Diflunisal	Nifedipine	Triamterene
Digoxin	Norcodein	Trifluoperazine
Diphenhydramine	Norethindrone	Trimethoprim
EDDP	D-Norpropoxyphene	Trimipramine
EMDP	Noscapine	Tryptamine
Egionine hydrochloride	DL-Octopamine	DL-Tryptophan
Egionine methylester	Oxalic acid	Tyramine
(-) -ψ -Ephedrine	Oxazepam	Uric acid
[1R,2S] (-) Ephedrine	Oxolinic acid	Verapamil
(L) - Epinephrine	Oxycodone	Zomepirac
Erythromycin	β-Estradiol	

### BIBLIOGRAPHY

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry