MTD

One Step
Methadone Test Device
Package Insert

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

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The MTD One Step Methadone Test Device is a lateral flow chromatographic immunoassay for the detection of Methadone in human urine.

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

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, etc.) addiction. Oral Methadone is very different than 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. [1]

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

PRINCIPLE

The MTD One Step Methadone Test Device 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 device. The antibody-coated particles will then be captured by immobilized Methadone 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 lower 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 device contains mouse monoclonal anti-Methadone antibody-coupled particles and Methadone-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- 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

Store as packaged in the sealed pouch at 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 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 prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

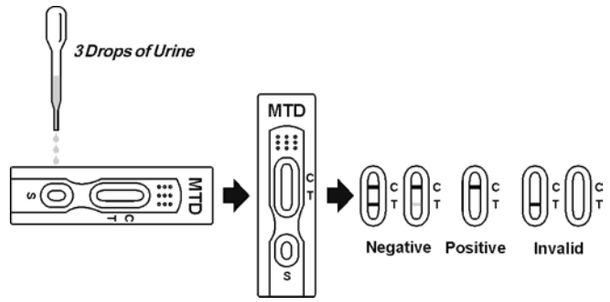
Materials Required But Not Provided

- Specimen collection container
- Timer
- External Controls

DIRECTIONS FOR USE

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 below.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes.



Do not interpret the result after 10 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 should be in the test region (T). This negative result indicates that the Methadone concentration is below the detectable level (300 ng/mL).

*** NOTE:** The shade of red in the test line region (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 (T). This positive result indicates that the Methadone concentration exceeds the detectable 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 positive 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.

LIMITATION

1. The MTD One Step Methadone Test Device 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) are the preferred confirmatory methods. [2,3]
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 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 cutoff 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 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
MTD One Step Test Device	Results	Positive	Negative	Results
	Positive	132	0	132
	Negative	0	168	168
Total Results		132	168	300
% Agreement with this commercial kit		>99%	>99%	>99%

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

Method		GC/MS		Total
MTD One Step Test Device	Results	Positive	Negative	Results
	Positive	122	10	132
	Negative	1	167	168
Total Results		123	177	300
% Agreement with GC/MS Analysis		99%	94%	96%

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

Specificity

The following table lists compounds that are positively detected in urine by the MTD One Step Methadone Test Device 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 conc. (ng/mL)	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 of normal, high, and low specific gravity ranges were spiked with Methadone to 150 ng/mL and 450 ng/mL respectively. The MTD One Step Methadone Test Device was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does 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 in duplicate. The results demonstrate that varying ranges of pH does 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 at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic acid
DL-Amphetamine sulfate
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
(±) - Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(±) - Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaethylene
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
EDDP
EMDP
Ecgonine hydrochloride
Ecgonine methylester
(-) -Ψ-Ephedrine
[1R,2S] (-) Ephedrine
(L) - Epinephrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxyamphetamine
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Mephentermine
Maprotiline
Meperidine
Meprobamate
Methamphetamine
Methoxyphenamine
(±) - 3,4-Methylenedioxy-amphetamine hydrochloride
(±) - 3,4-Methylenedioxymeth-amphetamine hydrochloride
Morphine-3-β-D glucuronide
Morphine Sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
DL-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
Trans-2-phenylcyclo-propylamine hydrochloride
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-acetate
Tetrahydrocortisone 3-(β-D-glucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

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