

SureStep™ MTD

One Step
Methadone Test Device (Urine)
Package Insert
English

A rapid, one step test for the qualitative detection of Methadone in human urine.
For medical and other professional *in vitro* diagnostic use only.

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 300 ng/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, Percocet, 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.

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.

REAGENTS

The test contains mouse 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 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.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Package insert

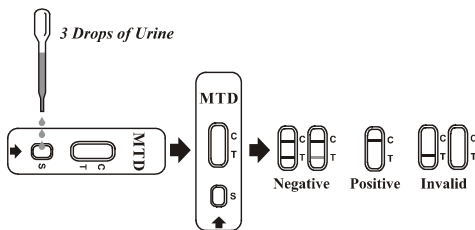
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow 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 device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) 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.
- 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 the 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 (300 ng/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 (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. 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.

LIMITATION

- 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.^{2,3}
- 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 One Step Methadone Test Device (Urine) and a leading commercially available MTD rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Methadone. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other MTD Rapid Test		Total Results
	Positive	Negative	
MTD One Step Test Device	Positive	132	132
	Negative	0	168
	Total Results	132	168
% Agreement		>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	
MTD One Step Test Device	Positive	122	132
	Negative	1	167
	Total Results	123	177
% Agreement		99%	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:

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

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 three physicians' offices by untrained operators 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 300 ng/mL cut-off was provided to each site. The following results were tabulated:

Methadone Concentration (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 urine samples of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Methadone. 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 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	Diazepam	Maprotiline	β-Phenylethylamine
Acetophenetidin	Diclofenac	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diffunisal	Meprobamate	Prenisilone
Acetylsalicylic acid	Digoxin	Methamphetamine	Prednisone
Aminopyrine	Diphenhydramine	Methoxyphenamine	Procaine
Amitypyline	EDDP	(±) - 3,4-Methylenedioxyamphetamine	Promazine
Amobarbital	EMDP	(±) - 3,4-Methylenedioxy-methamphetamine	Promethazine
Amoxicillin	Egonine hydrochloride	(±) - 3,4-Methylenedioxy-methamphetamine	D,L-Propranolol
Ampicillin	Egonine methyl ester	D-Propoxyphene	D-Pseudoephedrine
L-Ascorbic acid	(-) - v - Ephedrine	Morphine-3	Quinacrine
D,L-Amphetamine sulfate	[1R,2S] (-) Ephedrine	β-D glucuronide	Quinidine
Apomorphine	L - Epinephrine	Morphine Sulfate	Quinine
Aspartame	Erythroycin	Nalidixic acid	Ranitidine
Atropine	β-Estradiol	Naloxone	Salicylic acid
Benzic acid	Estrone-3-sulfate	Naltrexone	Secobarbital
Benzoic acid	Ethyl-p-aminobenzoate	Naproxen	Serotonin
Benzoylgonine	Fenofenol	Niacinamide	Sulfamethazine
Benzphetamine	Furosemide	Nifedipine	Sulfindac
Bilirubin	Genistic acid	Norcodeine	Temazepam
(±) - Brompheniramine	Hemoglobin	Norethindrone	Tetracycline
Caffeine	Hydralazine	D-Norpropoxyphene	Tetrahydrocortisone
Cannabidiol	Hydrochlorothiazide	Noscapine	3-Acetate
Cannabinol	Hydrocodone	D,L-Octopamine	Tetrahydrocortisone
Chloralhydrate	Hydrocortisone	Oxalic acid	3-β-D-glucuronide
Chloramphenicol	O-Hydroxyhippuric acid	Oxazepam	Tetrahydrozoline
Chlorothiazide	p-Hydroxyamphetamine	Oxalic acid	Thebaine
(±) - Chlorpheniramine	p-Hydroxy-methamphetamine	Oxycodone	Thiamine
Chlorpromazine	3-Hydroxyamphetamine	Oxymetazoline	Thioridazine
Cholesterol	Ibuprofen	Papaverine	D,L-Tyrosine
Clomipramine	Imipramine	Penicillin-G	Tolbutamide
Clonidine	Ipromiazid	Pentazocine hydrochloride	Triamterene
Coacetylene	(±) - Isoproterenol	Perphenazine	Trifluoperazine
Cocaine hydrochloride	Isosuprine	Phencyclidine	Trimethoprim
Codeme	Ketamine	Phenelzine	Tripramine
Cortisone	Ketoprofan	Phenobarbital	Tryptamine
(-) Cotinine	Labeltol	Phentermine	D,L-Tryptophan
Creatinine	Levorphanol	Trans-2-phenyl cyclopropylamine	Tyramine
Deoxycorticosterone	Loperamide	Uric acid	Verapamil
Dextromethorphan	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 <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #



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