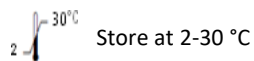




Methadone Test Strip (Urine)

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

IVD For *in vitro* diagnostic use only.



INTENDED USE

The MTD One Step Methadone Test Strip (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.¹

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

PRINCIPLE

The MTD One Step Methadone Test Strip (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 strips (contain mouse anti-Methadone antibody coupled particles and Methadone-protein conjugate. A goat antibody is employed in the control line system).
- 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 Strip 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 Strip 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 Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette 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

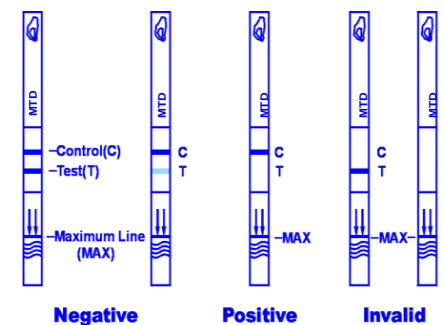
Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Allow the test strip, 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 strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen until the specimen start to migrate**. Do not pass the maximum line

(MAX) on the test strip when immersing the strip. See the illustration below.



Place the test strip on a non-absorbent flat surface, start the timer and 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 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 Strip. 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 Strip (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}
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.

- 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 Atlas MTD test strip (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

	Positive Agreement	Negative Agreement	Total Results
MTD	99%	>99%	>99%

% Agreement with GC/MS

	Positive Agreement	Negative Agreement	Total Results
MTD	99%	>94%	>96%

Analytical Sensitivity

A drug-free urine pool was spiked with Methadone at the following concentrations: 0 ng/mL, 5 ng/mL, 7.5 ng/mL, 12.5 ng/mL and 15 ng/mL. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration.

Methadone Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	25	25	0
150	-50%	25	25	0
225	-25%	25	25	0
325	+25%	25	0	25
450	+50%	25	0	25

Analytical Specificity

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

METHADONE	(ng/ml)
Methadone	300
Doxylamine	50,000

REFERENCES

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- 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



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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		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