Atlas Medical

CE

MOP One Step
Morphine Test Device (Urine)

A rapid, one step test for the qualitative detection of Morphine, Opiates, and Heroin in human urine.

IVD *For in vitro diagnostic use only.*

Store at (2-30º C)

INTENDED USE

Atlas MOP One Step Morphine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 300 ng/ml. This test will detect other compounds, please refer to 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.**

INTRODUCTION

Opioid analgesics comprise a large group of substances, which control pain by depressing the central nervous system. Large doses of Morphine can produce higher tolerance levels and physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose. Atlas MOP One Step Morphine 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 Morphine in urine. Atlas MOP One Step Morphine Test Device (Urine) yields a positive result when the Morphine in urine reaches 300ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

Atlas MOP One Step Morphine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs, which 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. Morphine, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of the antibody coated particles in the test Device. The antibody coated particles will then be captured by immobilized Morphine 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 Morphine level is at or above 300 ng/mL because it will saturate all the binding sites of anti-Morphine 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 cutoff 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 the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test Devices (Contain mouse monoclonal anti-Morphine antibody-coupled particles and Morphine-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

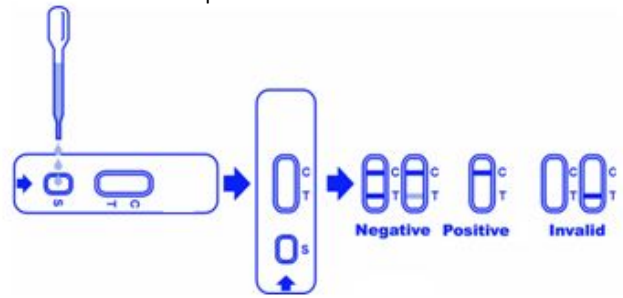
Urine Assay

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

PROCEDURE

Allow the 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 tapping air bubbles in the specimen well (S) . See 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

Control line should appear in all tests in order to consider the result as valid. The sensitivity of the color of control line (C) will be assigned the value +4.

Interpretation of test line (T):

Color Intensity	Meaning	Result
+1 to +3	Clearly visible line	Negative <50% of the cut-off value
+/-	Very faint line	Borderline Concentration is from 50% to 150% of the cut-off value
Shadow line or no line	Extremely faint line that might not be seen by all users or no line at all	Positive Concentration is > 150% of the cut-off value

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.

LIMITATIONS

1. Atlas MOP One Step Morphine 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 MOP One Step Morphine Test Device (Urine) and a leading commercially available MOP rapid test. Testing was performed on 300 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Morphine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other MOP Rapid Test		Total Results
MOP One Step Test Device	Results	Positive	Negative	150
	Positive	150	0	150
	Negative	0	150	150
Total Results		150	150	300
Agreement with this Rapid Test Kit		100%	100%	100%

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

Method		Other MOP Rapid Test		Total Results
MOP One Step Test Device	Results	Positive	Negative	150
	Positive	141	9	150
	Negative	0	150	150
Total Results		141	159	300
% Agreement with GC/MS Analysis		100%	94%	97%

Analytical Sensitivity

A drug-free urine pool was spiked with Morphine 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:

Morphine conc. (ng/mL)	**n**	**Site A**		**Site B**		**Site C**	
		-	**+**	**-**	**+**	**-**	**+**
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	12	3	11	4	13	2
375	15	4	11	0	15	7	8
450	15	1	14	2	13	0	15

Analytical Specificity

The following list has compounds that are positively detected in urine by the MOP One Step Morphine Test Device (Urine) at 5 minutes.

Compound	**Concentration (ng/mL)**
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levophanol	1,500
6-Monoacethylmorphine	400
Morphine	300
Morphine 3-(3-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250

Precision

A study was conducted at 3 physicians' 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, according to GC/MS, no Morphine, 25% Morphine above and below the cut-off and 50% Morphine above and below the 300 ng/mL cut-off was provided to each site. The results are given below:

MOP Concentration (ng/mL)	Percent of Cut-off	n	Visual	Result
			Negative	Positive
	0	30	30	0
150	-50%	30	30	0
225	-25%	30	28	2
300	Cut-off	30	20	10
375	+25%	30	3	27
450	+50%	30	0	30

Effect of Urinary Specific Gravity

Fifteen (15) urine specimens with specific gravity ranging from 1.001 to 1.032 were spiked with 150 ng/mL and 450 ng/mL of Morphine. The MOP One Step morphine Test Device (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 Morphine to 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the MOP One Step Morphine 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 Morphine positive urine. The following compounds show no cross-reactivity when tested with the MOP One Step Morphine Test Device (Urine) at a concentration of 100 µg/mL. Non Cross-Reacting Compounds:

4-Acetamidophenol	Erythromycin	Oxymetazoline
Acetophenetidin	-Estradiol	Papaverine
Estrone-3-sulfate	Ethyl-paminobenzoa	Pentazocine

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Aminopyrine	Fenoprofen	Pentobarbital
Amitryptyline	Furosemide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
L-Ascorbic acid	Hydrochlorothiazide	Phentermine
D,L-Amphetamine	Hydrocortisone	L-Phenylephrine
Apomorphine	0-Hydroxyhippuric acid	B-PHenylethylamine
Aspartame	0-Hydroxyhippuric acid	B-PHenylethylamine
Aspartame	p-Hydroxy-	Phenylpropanolamin
Atropine	methamohetamine	Prednisone
Benzilic acid	3-Hydroxytyramine	D,L-Propanolol
Benzoic acid	Ibuprofen	D-Propoxyphene
Benzoylecgonine	Imipramine	D-Pseudoephedrine
Benzphetamine	Iproniazid	Quinidine
Bilirubin	(±)-Isoproterenol	Quinine
(+)-Brompheniramine	Isoxsuprine	Ranitidine
Caffeine	Ketamine	Salicylic acid
Cannabidiol	Ketoprofen	Secobarbital
Chloralhydrate	Labetalol	Serotonin (5-
Chloramphenicol	Loperamide	Hvdroxvtvramine)
Chlordiazepoxide	Maprotiline	Sulfamethazine
Chlorothiazide	Meperidine	Sulindac
(+) Chlorpheniramine	Meprobamate	Temazepam
Chlorpromazine	Methadone	Tetracycline
Chlorquine	Methoxyphenamine	Tetrahydrocortisone
Cholesterol	(+) 3,4-Methylenedioxy- 3-Acetate	
Clornipramine	Amohetamine Tetrahydrocortisone	
Clonidine	(+) 3,4-Methylenedioxy-3 (β-D alucuronide)	
Cocaine	methamohetamine	Tetrahydrozoline
Cortisone	Nalidixic acid	Thiamine
(-) Cotinine	Nalorphine	Thioridazine
Creatinine	Naloxone	D, L-Tyrosine
Deoxycorticosterone	Naltrexone	Tolbutamide
Dextromethorphan	Naproxen	Triamterene
Diazepam	Niacinamide	Trifluoperazine
Diclofenac	Nifedipine	Trimethoprim
Diflunisal	Norethindrone	Trimipramine
Diqoxin	D-Norpropoxyphene	Tryptamine
Diphenhydramine	Noscapine	D, L-Tryptophan

Doxylamine	D,L-Octopamine	Tyramine
Ecgonine	Oxalic acid	Uric acid
Ecgonine	Oxazepam	Verapamil
(-)-w-Ephedrine	Oxolinic acid	Zomepirac

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REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	Caution.		**Store at 2 - 30°C.**
	Read product insert before use.	Σ	**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	Expiry date.		**Manufacturer telephone number.**
	Manufacturer fax number.		