

SureStep™ MOP

One Step Morphine Test Device (Urine) Package Insert

English

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

INTENDED USE

The 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 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

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.¹

The 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. The MOP One Step Morphine Test Device (Urine) yields a positive result when Morphine in urine reaches 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The 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. 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 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 monoclonal anti-Morphine antibody-coupled particles and Morphine-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 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-termed 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

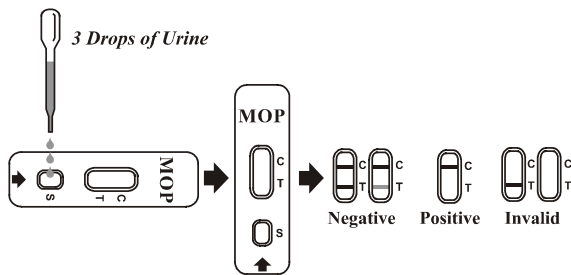
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the 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 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 Morphine concentration is below the detectable 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 Morphine 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. 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.

LIMITATIONS

- The 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.^{2,3}
- 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.
- Certain medications containing opiate derivatives may produce a positive result. Additionally, foods and tea containing poppy products (the origin of opiates) may also produce a positive result.
- 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 MOP One Step Morphine Test Device (Urine) and a leading commercially available MOP 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 Morphine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other MOP Rapid Test		Total Results
	Results		
MOP One Step Test Device	Positive	150	150
	Negative	0	150
	Total Results	150	300
% Agreement	>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 Results
	Results		
MOP One Step Test Device	Positive	141	150
	Negative	0	150
	Total Results	141	300
% Agreement	>99%	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 Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	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

Analytical Specificity

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

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Codeine	300	Morphine	300
Ethylmorphine	6,250	Norcodeine	6,250
Hydrocodone	50,000	Normorphine	100,000
Hydromorphone	3,125	Oxycodone	30,000
Levorphanol	1,500	Oxymorphone	100,000
6-Monoacetylmorphine	400	Procaine	15,000
Morphine 3-β-D-glucuronide	1,000	Thebaine	6,250

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, 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:

Morphine Concentration (ng/mL)	n per Site	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

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges 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	Creatinine	Loperamide	β-Phenylethylamine
Acetophenetidin	Dextromethorphan	Maprotiline	Phenylpropanolamine
N-Acetylprocainamide	Diazepam	Meprobamate	Prednisone
Acetylsalicylic acid	Diclofenac	Methadone	D-L-Propranolol
Aminopyrine	Amitypyline	Methoxyphenamine	D-Propoxyphene
Amobarbital	Digoxin	(+) 3,4-Methylenedioxyamphetamine	D-Pseudoephedrine
Amoxicillin	Diphenhydramine	(+) 3,4-Methylenedioxy-methamphetamine	Quinidine
Ampicillin	Doxylamine	Egonine hydrochloride	Quinine
L-Ascorbic acid	Egonine methylester	Naloxone	Ranitidine
D,L-Amphetamine	(-) 9-β-Ephedrine	Naltrexone	Salicylic acid
Apomorphine	Erythromycin	Naproxen	Scabicylic acid
Aspartame	β-Estradiol	Ethyl-p-aminobenzoate	Serotonin
Atropine	Benzoic acid	Fenpropfen	(5-Hydroxytryptamine)
Benzilic acid	Benzoylecgonine	Furosemide	Sulfamethazine
Benzoic acid	Benzphetamine	Bilirubin	Sulindac
Benzyl alcohol	Brompheniramine	(±) Brompheniramine	Tamazepam
Benzyl alcohol	Caffeine	Hydralazine	Tecacycline
Cannabidiol	Cannabidiol	Hydrochlorothiazide	Tetrahydrocortisone, 3-Acetate
Chloralhydrate	Chloralhydrate	Oxalic acid	Tetrahydrocortisone, 3-(β-D glucuronide)
Chloramphenicol	Chloramphenicol	Oxazepam	Tetrahydrozoline
Chlorazepoxide	Chlorazepoxide	Oxymetazoline	Thiamine
Chlorothalidate	Chlorothalidate	Papaverine	Thioridazine
Chlorpromazine	Chlorpromazine	Penicillin-G	D, L-Tyrosine
Chlorzoxiprone	Chlorzoxiprone	Pentazocine	Tolbutamide
Cholesterol	Cholesterol	Phenacazine	Triamterene
Clonidine	Clonidine	Phenazone	Trifluoperazine
Clonidine	Clonidine	Phenylephrine	Trimethoprim
Cocaine hydrochloride	Cocaine hydrochloride	Phenylzine	Trimipramine
Cortisone	Cortisone	Phenylzine	Tryptamine
(-) Cotinine	(-) Cotinine	Phenylzine	D, L-Tryptophan
		Phenylzine	Tyramine
		Phenylzine	Uric acid
		Phenylzine	Verapamil
		Phenylzine	Zomepirac

BIBLIOGRAPHY

- Tietz NW. *Textbook of Clinical Chemistry*. W.B. Saunders Company. 1986; 1735
- 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
	For <i>in vitro</i> diagnostic use only
	Store between 2-30°C
	Tests per kit
	Use by
	Lot Number
	Authorized Representative
	Do not reuse
	Catalog #



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