

MOP**One Step
Opiate Test Device
Package Insert**

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

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The MOP One Step Opiate Test Device is a lateral flow chromatographic immunoassay for the detection of opiates in urine at a cut-off concentration of 300 ng/mL. This test will detect other opiates, please refer to analytical specificity table in this package insert. 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

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substance which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance level 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 Opiate 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 opiates in urine. The MOP One Step Opiate Test Device yields a positive result when the concentration of opiates in urine exceeds the cutoff level.

PRINCIPLE

The MOP One Step Opiate Test Device 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. Opiates, if present in the urine specimen below the cutoff level, will not saturate the binding sites of the antibody in the test device. The morphine conjugate will be captured by antibody 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 opiates level exceeds the cutoff concentration 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 will generate a line in the test line region because of the absence of drug competition.

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 monoclonal anti-morphine antibody-coupled particles and morphine-protein conjugates. A goat antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For professional *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 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 particles 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.

MATERIALS**Materials Provided**

- Test devices
- Disposable specimen droppers
- Package insert

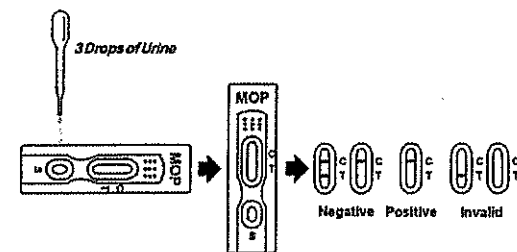
Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

Allow 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 trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored 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 illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another colored line should be in the test region (T). This negative result indicates that the morphine concentration is below the detectable level (300 ng/mL).

* NOTE: The shade of the color in the test region (T) may vary, but it should be considered negative whenever there is even a faint line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test 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 with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored 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. The MOP One Step Opiate 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) 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.
4. Certain medications containing opiate derivatives may produce a positive result. Additionally, foods and tea containing poppy products (the origin of the opiate) may also produce a positive result.
5. A Positive Result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
6. 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.

7. 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 Opiate Test Device and a leading commercially available MOP 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 OPI Rapid Test		Total Results
	Results	Positive	
OPI One Step Test Device	Positive	150	150
	Negative	0	150
Total Results			300
% Agreement with this commercial kit			>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	Positive	
OPI One Step Test Device	Positive	141	150
	Negative	0	150
Total Results			300
% Agreement with GC/MS Analysis			>99%

Eighty (80) of these samples were also run using the MOP One Step Opiate Test Device by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

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 Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
150	-50%	30	30	0
225	-25%	30	28	2
300	Cutoff	30	20	10
375	+25%	30	3	27
450	+50%	30	0	30

Specificity

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

Compound	Concentration (ng/mL)
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levophanol	1,500
6-Monoacetylmorphine	400
Morphine	300

Compound	Concentration (ng/mL)
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250

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 blind labeled and tested at each site. The results are given below:

Morphine conc. (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	45	15	0	15	0	15	0
150	45	15	0	15	0	15	0
225	45	12	3	11	4	13	2
375	45	4	11	0	15	7	8
450	45	1	14	2	13	0	15

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 150 ng/ml and 450 ng/ml of Morphine respectively. The MOP One Step Opiate 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 Morphine to 150 ng/ml and 450 ng/ml. The spiked, pH-adjusted urine was tested with the MOP One Step Opiate Test Device in duplicate and interpreted according to the package insert. 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 morphine positive urine. The following compounds show no cross-reactivity when tested with the MOP One Step Opiate Test Device at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Erythromycin	Oxymetazoline
Acetophenetidin	β-Estadiol	Papaverine
N-Acetylprocainamide	Estrone-3-sulfate	Penicillin-G
Acetylsalicylic acid	Ethyl-p-aminobenzotazote	Pentazocine
Aminopyrine	Fenpropfen	Pentobarbital
Amitypyline	Furosenide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
	Hydralazine	Phenobarbital
L-Ascorbic acid	Hydrochlorothiazide	Phentermine
D,L-Amphetamine	Hydrocortisone	L-Phenylephrine
Apomorphine	O-Hydroxyhippuric acid	β-Phenylethylamine
Aspartame	p-Hydroxy-	Phenylpropanolamine

Atropine	methamphetamine	Prednisone
Benzilic acid	3-Hydroxytyramine	D,L-Propriolol
Benzoic acid	Ibuprofen	D-Propoxyphene
Benzoyllecgonine	Imipramine	D-Pseudoephedrine
Benzphetamine	Iproniazid	Quinidine
Biliubin	(±) Isoproterenol	Quinine
(±)-Brompheniramine	Isoxsuprine	Ranitidine
Caffeine	Ketamine	Salicylic acid
Cannabidiol	Ketoprofen	Secobarbital
Chloralhydrate	Labelal	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Loperamide	Sulfamethazine
Chlordiazepoxide	Maprotiline	Sulfindac
Chlorothiazide	Meprobamate	Tenuazepam
(±) Chlorpheniramine	Methadone	Tetracycline
Chlorpromazine	Methoxyphenamine	Tetrahydrocortisone, 3
Chloroquine	(+) 3,4-Methylenedioxy-amphetamine	Acetate
Cholesterol	(+) 3,4-Methylenedioxy-methamphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Clomipramine	Nalidixic acid	Tetrazolinone
Clonidine		Thiamine
Cocaine hydrochloride		Thioridazine
Cortisone		D, L-Tyrosine
(-) Cotinine		Tolbutamide
Creatinine	Naloxone	Triamterene
Deoxycorticosterone	Naltrexone	Trifluoperazine
Dextromethorphan	Naproxen	Trimethoprim
Diazepam	Niacinamide	Trimipramine
Diclofenac	Nifedipine	Tryptamine
Diffunisal	Norethindrone	D, L-Tryptophan
Digoxin	D-Nortropoxyphene	Tyramine
Diphenhydramine	Noacapine	Uric acid
Doxylamine	D,L-Octopamine	Verapamil
Ecgonine hydrochloride	Oxalic acid	Zomepirac
Ecgonine methyl ester	Oxazepam	
(-) Ψ Ephedrine	Oxolinic acid	

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