

SureStep™ OPI

**One Step
Opiate Test Device (Urine)
Package Insert
English**

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

INTENDED USE

The OPI One Step Opiate Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 2,000 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

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 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 OPI One Step Opiate 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 OPI One Step Opiate Test Device (Urine) yields a positive result when Morphine in urine exceeds 2,000 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 OPI One Step Opiate 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 2,000 ng/mL, will not saturate the binding sites of the antibody in the test. 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 Morphine level exceeds 2,000 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 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 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.
- 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

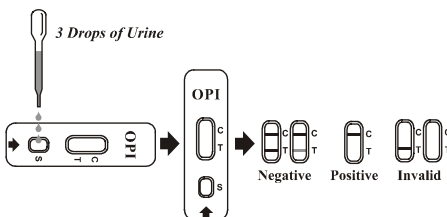
Materials Required But Not Provided

- 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 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 (2,000 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 (2,000 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 OPI One Step Opiate 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 opiate) 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 OPI One Step Opiate Test Device (Urine) and a leading commercially available OPI 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 2,000 ng/mL Morphine. 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
	Negative	0	150
Total Results		150	300
% Agreement		>99%	>99%

When compared to GC/MS at the cut-off of 2,000 ng/mL, the following results were tabulated:

Method	GC/MS		Total Results
	Results	Positive	
OPI One Step Test Device	Positive	134	150
	Negative	0	150
	Negative	0	150
Total Results		134	300
% Agreement		>99%	95%

Analytical Sensitivity

A drug-free urine pool was spiked with Morphine at the following concentrations: 0 ng/mL, 1,000 ng/mL, 1,500 ng/mL, 2,000 ng/mL, 2,500 ng/mL and 3,000 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
1,000	-50%	30	30	0
1,500	-25%	30	30	0
2,000	Cut-off	30	5	25
2,500	+25%	30	4	26
3,000	+50%	30	0	30

Analytical Specificity

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

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Codeine	2,000	Morphine	2,000
Ethylmorphine	5,000	Norcodeine	12,500
Hydrocodone	12,500	Normorphine	50,000
Hydromorphone	5,000	Oxycodone	25,000
Levophanol	75,000	Oxymorphone	25,000
6-Monoacetylmorphine	5,000	Procaine	150,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	100,000

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, according to GC/MS, no Morphine, 25% Morphine above and below the cut-off and 50% Morphine above and below the 2,000 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
1,000	15	15	0	15	0	14	1
1,500	15	13	2	10	5	5	10
2,500	15	4	11	0	15	3	12
3,000	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 1,000 ng/mL and 3,000 ng/mL of Morphine. The OPI One Step Opiate 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 Morphine to 1,000 ng/mL and 3,000 ng/mL. The spiked, pH-adjusted urine was tested with the OPI One Step Opiate 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 OPI One Step Opiate Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Maprotiline	Phenylpropanolamine
Acetophenetidin	Deoxycorticosterone	Meperidine	Prednisone
N-Acetylprocainamide	Dextromethorphan	Meprobamate	D,L-Propranolol
Acetylsalicylic acid	Diazepam	Methadone	D-Propoxyphene
Aminopyrine	Diclofenac	Methoxyphenamine	D-Pseudoephedrine
Amtryptiline	Diflunisal	(+)-3,4-Methylenedioxy-	Quinidine
Amorbutal	Digoxin	Amphetamine	Quinine
Amoxicillin	Diphenhydramine	(+)-3,4-Methylenedioxy-	Ranitidine
Ampicillin	Doxylamine	Mephentermine	Salicylic acid
Ascorbic acid	Egonine hydrochloride	Nalidixic acid	Secobarbital
D,L-Amphetamine	Egonine methyl ester	Nalorphine	Serotonin (5-Hydroxy-
Apomorphine	(-) - <i>l</i> -Ephedrine	Naloxone	tyramine)
Ethyl-p-aminobenzoate	Erythromycin	Nalrexone	Sulfamethazine
Atropine	β-Estradiol	Naproxen	Sulindac
Benzilic acid	Estrone-3-sulfate	Niacinamide	Temazepam
Benzoic acid	Aspartame	Nifedipine	Tetracycline
Benzoylcegonine	Fenpropfen	Norethindrone	Tetrahydrocortisone,
Benzphetamine	Furosemide	D-Norpropoxyphene	3-Acetate
Bilirubin	Genisteic acid	Noscapine	Tetrahydrocortisone
Brompheniramine	Hemoglobin	D,L-Octopamine	3-(β-D glucuronide)
Caffeine	Hydralazine	Oxalic acid	Tetrahydrozoline
Cannabidiol	Hydrochlorothiazide	Oxazepam	Thiamine
Chloralhydrate	Hydrocortisone	Oxolinic acid	Thioridazine
Chloramphenicol	O-Hydroxyhippuric acid	Oxymetazoline	D, L-Tyrosine
Chloridiazepoxide	p-Hydroxy-Methamphetamine	Papaverine	Tolbutamide
Chlorothiazide	3-Hydroxytyramine	Penicillin-G	Triamterene
(±) Chlorpheniramine	lbutrofen	Pentazocine	Trifluoperazine
Chlorpromazine	Chlorpromazine	Pentobarbital	Trimethoprim
Chlorquine	lproniazide	Perphenazine	Trimipramine
Cholesterol	(±) Isoproterenol	Phencyclidine	Tryptamine
Clomipramine	Isosuprine	Phenelzine	D, L-Tryptophan
Clonidine	Ketamine	Phenobarbital	Tyramine
Cocaine hydrochloride	Ketoprofen	Phentermine	Uric acid
Cortisone	Labetalol	L-Phenylephrine	Verapamil
(-) Cotinine	Loperamide	β-Phenylethylamine	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		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 #

Manufacturer

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