OPI

One Step
Opiate Test Strip
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 OPI One Step Opiate Test Strip is a lateral flow chromatographic immunoassay for the detection of morphine in urine at a cut-off concentration of 2000 ng/mL.

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 substances which control pain by depressing the central nervous system. Large dose of morphine can produce higher tolerance levels, 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 Strip 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 Strip yields a positive result when the morphine in urine exceeds 2000 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 Strip 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 2000 ng/mL, will not saturate the binding sites of the antibody in the test strip. 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 2000 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 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 strip contains monoclonal anti-morphine antibody-coupled particles and morphine-protein conjugates. A gold anti-rabbit antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- 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

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strips 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 prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

- Test strips
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

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 for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. 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

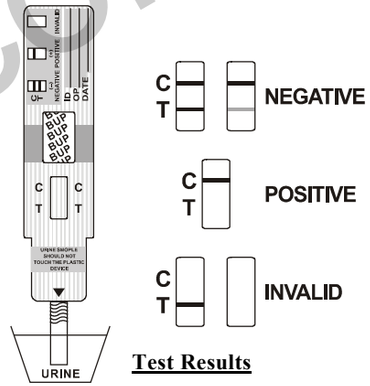
(Please refer to the illustration below)

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 morphine concentration is below the detectable level (2000 ng/mL).

*** NOTE:** The shade of red in the test line region (T) will 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 morphine concentration exceeds the detectable level (2000 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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Test Results

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive 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 OPI One Step Opiate Test Strip 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) are the preferred confirmatory methods. [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 or 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 OPI One Step Opiate Test Strip and a leading commercially available OPI 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
OPI One Step Test Strip	Results	Positive	Negative	Results
	Positive	150	0	150
	Negative	0	150	150
Total Results		150	150	300
% Agreement with this commercial kit		>99%	>99%	>99%

When compared to GC/MS at the cut-off of 2000 ng/mL, the following results were tabulated:

Method		GC/MS		Total
OPI One Step Test Strip	Results	Positive	Negative	Results
	Positive	134	16	150
	Negative	0	150	150
Total Results		134	166	300
% Agreement with GC/MS Analysis		>99%	90%	95%

Eighty (80) of these samples were also run using the OPI One Step Opiate Test Strip 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, 1000 ng/ml, 1500 ng/ml, 2000 ng/ml, 2500 ng/ml and 3000 ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

OPI Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
1000	-50%	30	30	0
1500	-25%	30	30	0
2000	Cutoff	30	13	17
2500	+25%	30	4	20
3000	+50%	30	0	30

Specificity

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

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

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

OPI conc. (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1000	15	15	0	15	0	14	1
1500	15	13	2	11	4	7	8
2500	15	4	11	1	14	2	13
3000	15	0	15	0	15	2	13

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 1000 ng/ml and 3000 ng/ml of Morphine respectively. The OPI One Step Opiate Test Strip 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 1000 ng/ml and 3000 ng/ml. The spiked, pH-adjusted urine was tested with the OPI One Step Opiate Test Strip 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 *OPI* One Step Opiate Test Strip at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Erythromycin	Oxymetazoline
Acetophenetidin	β-Estradiol	Papaverine
N-Acetylprocainamide	Estrone-3-sulfate	Penicillin-G
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Pentazocine
Aminopyrine	Fenoprofen	Pentobarbital
Amitryptyline	Furosemide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Phenobarbital
Ascorbic acid	Hydrochlorothiazide	Phentermine
D,L-Amphetamine	Hydrocortisone	L-Phenylephrine
Apomorphine	O-Hydroxyhippuric acid	β-Phenylethylamine
Aspartame	p-Hydroxy-methamphetamine	Phenylpropanolamine
Atropine		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-Hydroxytyramine)
Chloramphenicol	Loperamide	Sulfamethazine
Chlordiazepoxide	Maprotiline	Sulindac
Chlorothiazide	Meperidine	Temazepam
(±) Chlorpheniramine	Meprobamate	Tetracycline
Chlorpromazine	Methadone	Tetrahydrocortisone, 3 Acetate
Chlorquine	Methoxyphenamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cholesterol	(+) 3,4-Methylenedioxy-amphetamine	Tetrahydrozoline
Clomipramine	(+) 3,4-Methylenedioxy-methamphetamine	Thiamine
Clonidine	Nalidixic acid	Thioridazine
Cocaine hydrochloride	Nalorphine	D, L-Tyrosine
Cortisone	Naloxone	Tolbutamide
(-) Cotinine	Naltrexone	Triamterene
Creatinine	Naproxen	Trifluoperazine
Deoxycorticosterone	Niacinamide	Trimethoprim
Dextromethorphan	Nifedipine	Trimipramine
Diazepam	Norethindrone	Tryptamine
Diclofenac	D-Norpropoxyphene	D, L-Tryptophan
Diflunisal	Noscapine	Tyramine
Digoxin	D,L-Octopamine	Uric acid
Diphenhydramine	Oxalic acid	Verapamil
Doxylamine	Oxazepam	Zomepirac
Ecgonine hydrochloride	Oxolinic acid	
Ecgonine methylester		
(-) Y Ephedrine		

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