OPI Opiate cassette CE

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REF	4451240	Opiate	40 tests
For professional *in vitro* diagnostic use only			

OPI Opiate

A rapid test for the qualitative detection of Opiate (OPI) in human urine.
ONE STEP

PRINCIPLE

The LINEAR OPI Opiate cassette 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.

REAGENT COMPOSITION

The LINEAR OPI Opiate cassette contains mouse monoclonal anti-Morphine antibody-coupled particles and Morphine-protein conjugate. A goat antibody is employed in the control line system.

PACKAGING CONTENTS

REF 4451240 40 MOP Morphine test devices.
Disposable specimen dropper.

STORAGE AND STABILITY

Store at 2-30ºC.
The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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 supernatant for testing.
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.

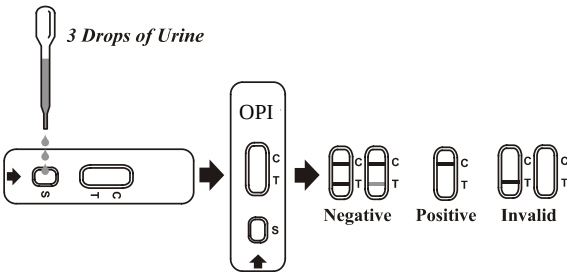
MATERIAL REQUIRED

- Timer.
- Specimen collection container .

PROCEDURE

Allow the test cassette, urine or serum specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette 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 cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the 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 15 minutes.



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 red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume 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.

CLINICAL SIGNIFICANCE

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 LINEAR OPI Opiate cassette 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 LINEAR OPI Opiate cassette 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).
Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

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ANALYTICAL PERFORMANCE

A. Accuracy

The accuracy of the LINEAR OPI Opiate cassette was compared and checked against a commercially available test with a threshold value of 2,000 ng/mL. 120 urine samples taken from volunteer test persons who claim to be non-consumers was examined under both tests. The results were 100% in agreement.

B. Reproducibility

The reproducibility of the LINEAR OPI Opiate cassette was verified by blind tests performed at a four different locations. All 60 utilized samples with a MOR-concentration of 1,000 ng/mL yielded a negative result. All 60 samples with a MOR-concentration of 4,000 ng/mL yielded a positive result. No significant differences were observed between test results of the different evaluation sites.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with a MOR-concentration of 1,000 ng/mL yield a negative result. Controls with a MOR-concentration of 3,000 ng/mL provide a positive result.

D. Specificity

The specificity of the LINEAR OPI Opiate cassette was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances was added to normal drug free urine.

The following compounds with a similar chemical structure yield a positive result at the specified concentration:

COMPOUND	CONCENTRATION (ng/mL)
Morphine	2,000
Codeine	2,000
Diacetyl Morphine (Heroine)	2,000
Ethylmorphine	600
Hydromorphone	15,000
Hydrocodone	15,000
Merperidine	>100,000
6-Monoacetylmorphine	5,000
Morphine-3-β-d-glucuronide	10,000
Oxycodone	>20,000
Oxymorphone	>20,000
Rifampicine	>50,000
Thebaine	20,000
Thebaine	2,50
Trimipramine	>20,000

All following listed compounds reacted negative up to a concentration of 100 µg/mL.

Acetamidophene
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
(+/-)-Chlorpheniramine
Chlorpheniramine
Creatine
Dexbrompheniramine
Guaiacol Glyceryl Ether
Hemoglobin
Imipramine
(+/-)-Isoproterenol
Lidocaine
(+)-Naproxen
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
Phenylethylamine
Procaine
Quinidine
Ranitidine
Riboflavine
Sodium Chloride
Dextromethorphan
4-Dimethylaminoantipyrine
Dopamine
Erythromycin
Ethanol
Furosemide
Glucose
Sulindac
Thioridazine
Trifluoperazine
Trimethobenzamide
Tyramine
Vitamin C

NOTES

1. The LINEAR OPI Opiate cassette 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. 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.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
4. 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.
5. Test does not distinguish between drugs of abuse and certain medications.

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