

MOP Morphine cassette

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REF	4450240	Morphine	40 tests
For professional <i>in vitro</i> diagnostic use only			

Morphine

A rapid test for the qualitative detection of Morphine, Opiates and Heroin in human urine.
ONE STEP

PRINCIPLE

The LINEAR MOP Morphine cassette (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 strip. 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 the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT COMPOSITION

MOP Morphine test devices, 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 4450240 40 MOP Morphine test devices.
Disposable specimen dropper.

STORAGE AND STABILITY

 Store at 2-30°C.

The test strip is stable through the expiration date printed on the sealed pouch. The test strip 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.

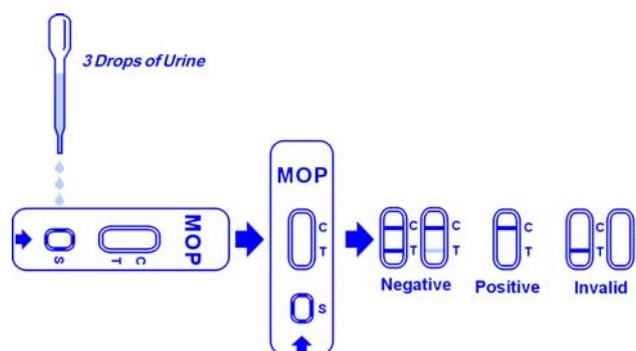
MATERIAL REQUIRED

- 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 region (C), and another apparent 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 red 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 region (C).** No line appears in the test region (T). This positive result indicates that the Morphine concentration is above 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 strip. 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

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 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 LINEAR MOP Morphine 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 MOP Morphine cassette (urine) yields a positive result when the 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). Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

ANALYTICAL PERFORMANCE

A. Accuracy

The accuracy of the LINEAR MOP Morphine cassette was compared and checked against a commercially available test with a threshold value of 300 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 MOP Morphine cassette was verified by blind tests performed at a four different locations. All 60 utilized samples with a MOR-concentration of 150 ng/mL yielded a negative result. All 60 samples with a MOR-concentration of 600 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 150 ng/mL yield a negative result. Controls with a MOR-concentration of 450 ng/mL provide a positive result.

D. Specificity

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

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

COMPOUND	CONCENTRATION (ng/mL)
Morphine	300
Codeine	300
Diacetyl morphine (Heroin)	300
Ethylmorphine	300
Hydromorphone	1,500
Hydrocodone	1,500
Merperidine	>100,000
6-Monoacetylmorphine	300
Morphine-3- β -d-glucuronide	6,000
Oxycodone	>20,000
Oxymorphone	>20,000
Promethazine	>250,000
Rifampicine	25,000
Thebaine	2,50
Trimipramine	>20,000

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

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

Erythromycin	Trimethobenzamide
Ethanol	Tyramine
Furosemide	Vitamin C
Glucose	

NOTES

- The LINEAR MOP Morphine 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.^{1,2}
- 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.
- 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.

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