



MOP Rapid Test Dipstick (Urine) Package Insert

REF DMO-101/111 English

A rapid test for the qualitative detection of Morphine in human urine. For professional *in vitro* diagnostic use only.

INTENDED USE

The MOP Rapid Test Dipstick is a rapid chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 300ng/ml. This test will detect other compounds, please refer to 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

Opioid analgesics comprise a large group of substances 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.

The MOP Rapid Test Dipstick 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 MOP Rapid Test Dipstick yields a positive result when Morphine in urine reaches 300ng/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 MOP Rapid Test Dipstick 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 300ng/ml, will not saturate the binding sites of the antibody coated particles in the test device. 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 300ng/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 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.
The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

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 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

- Test Dipsticks

Materials Provided

- Package insert

Materials Required But Not Provided

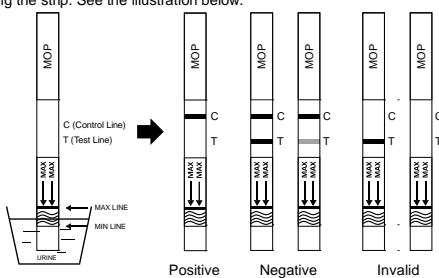
- Timer

- Specimen collection container

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 Dipstick from the sealed pouch and use it within one hour.
With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.



- Place the Test Dipstick on a non-absorbent flat surface, start the timer and 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 the illustration above)

NEGATIVE: Two lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Morphine concentration is below the detectable cutoff level.

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

POSITIVE: One color 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 cutoff level.

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 Dipstick. If the problem persists, discontinue using the Test Dipstick immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A color 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 Test Dipstick; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The MOP Rapid Test Dipstick provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.
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.
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.

EXPECTED VALUES

This negative result indicates that the Morphine concentration is below the detectable level of 300ng/ml. Positive result means the concentration of Morphine is above the level of 300ng/ml. The MOP Rapid Test Dipstick has a sensitivity of 300ng/ml

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The MOP Rapid Test Dipstick and a commercially available MOP rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:.

Method	Other MOP Rapid Test		Total Results	
	Results	Positive		Negative
The MOP Rapid Test Dipstick	Positive	43	0	43
	Negative	0	57	57
	Total Results	43	57	100
% Agreement with this Rapid Test		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The MOP Rapid Test Dipstick and GC/MS at the cut-off of 300ng/ml. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results	
	Results	Positive		Negative
The MOP Rapid Test Dipstick	Positive	95	7	102
	Negative	5	143	148
	Total Results	100	150	250
% Agreement with this Rapid Test		95.0%	95.3%	95.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Morphine at the following concentrations: 0ng/ml, 150ng/ml, 225ng/ml, 300ng/ml, 375ng/m, 450ng/ml and 900ng/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
150	-50%	30	30	0
225	-25%	30	26	4
300	Cut-off	30	15	15
375	+25%	30	3	27
450	+50%	30	0	30
900	3x	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MOP Rapid Test Dipstick at 5 minutes.

Compound	Concentration	Compound	Concentration
Codeine	200	Morphine	300
Ethylmorphine	6,000	Norcodeine	6,000
Hydrocodone	50,000	Normorphine	50,000
Hydromorphone	3,000	Oxycodone	30,000
Levorphanol	1,500	Oxymorphone	50,000
6-Monoacetylmorphine	300	Procaine	15,000
Morphine 3-β-D-glucuronide	800	Thebaine	6,000

Precision

A study was conducted at three hospitals by laypersons 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 300ng/ml cut-off was provided at each site. The results are given below:

Morphine Concentration	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	2	8
450	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 150ng/ml and 450ng/ml of Morphine. The MOP Rapid Test Dipstick was tested in duplicate using the fifteen neat and spiked urine specimens. 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 150ng/ml and 450ng/ml. The spiked, pH-adjusted urine was tested with The MOP Rapid Test Dipstick 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 MOP Rapid Test Dipstick at a concentration of 100µg/ml.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Loperamide	β-Phenylethylamine
Acetophenetidin	Deoxycorticosterone	Maprotiline	Phenylpropanolamine
N-Acetylprocainamide	Dextromethorphan	Meperidine	Prednisone
Acetylsalicylic acid	Diazepam	Meprobamate	D,L-Propranolol
Aminopyrine	Diclofenac	Methadone	D-Propoxyphene
Amitypyline	Diflunisal	Methoxyphenamine	D-Pseudoephedrine
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-amphetamine	Quinidine
Amoxicillin	Diphenhydramine	(+) 3,4-Methylenedioxy-methamphetamine	Quinine
Ampicillin	Doxylamine	Egonine hydrochloride	Ranitidine
L-Ascorbic acid	Egonine methyl ester	Egonine methylester	Salicylic acid
D,L-Amphetamine	(-) ψ-Ephedrine	Erythromycin	Secobarbital
Apomorphine	Aspartame	β-Estradiol	Serotonin
Atropine	Benzoic acid	Estro-3-sulfate	(5-Hydroxytryptamine)
Benzoic acid	Benzoic acid	Estro-3-sulfate	Sulfamethazine
Benzoylecgonine	Fenpropfen	Furosemide	Sulindac
Benzphetamine	Fluorethone	Genicisic acid	Tamazepam
Bilirubin	Glutathione	Hemoglobin	Tetracycline
(±) - Brompheniramine	Caffeine	Hydralazine	Tetrahydrocortisone, 3-Acetate
Cannabidiol	Chloramphenicol	Chlorazepoxide	Tetrahydrocortisone, 3-(β-D-glucuronide)
Chlorazepoxide	Chlorothiazide	Chlorothiazide	Oxalic acid
Chlorothiazide	(±) Chlorpheniramine	Chlorpromazine	Oxalonic acid
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Oxymetazoline
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Papaverine
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Penicillin-G
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Pentazocine
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Tripropylamine
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Trimethoprim
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Trimipramine
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Trypamine
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Uric acid
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Verapamil
Chlorzoxiprone	Chlorzoxiprone	Chlorzoxiprone	Zemipirac

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 in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged				

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