MOP Rapid Test Cassette (Urine) Package Insert

REF DMO-102	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 Cassette is a rapid chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 300 ng/mL. This test will detect other compounds, please refer to Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary 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. [1]

The MOP Rapid Test 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 MOP Rapid Test Cassette yields a positive result when Morphine in urine reaches 300 ng/mL.

【PRINCIPLE】

The MOP Rapid Test 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 300 ng/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 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 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 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 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 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 assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

- Test cassettes
- Droppers
- Package insert

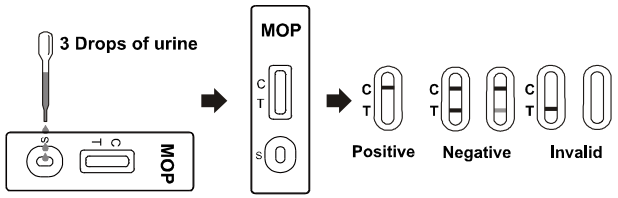
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, 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 cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine (approx. 120 μL)** 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 colored 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 above)

NEGATIVE:* **Two colored lines appear**. One colored line should be in the control region (C) and another colored 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 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 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 cassette. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored 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 practices to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The MOP Rapid Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.[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. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the MOP Rapid Test Cassette 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
MOP Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	0	43
	Negative	0	57	57
Total Results		43	57	100
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the MOP Rapid Test Cassette and GC/MS at the cut-off of 300 ng/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
MOP Rapid Test Cassette	Results	Positive	Negative	
	Positive	95	7	102
	Negative	5	143	148
Total Results		100	150	250
% Agreement		95.0%	95.3%	95.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Morphine at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL, 450 ng/mL and 900 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
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 Cassette at 5 minutes.

Compound	Concentration (ng/mL)
Codeine	200
Ethylmorphine	6,000
Hydrocodone	50,000
Hydromorphone	3,000
Levorphanol	1,500
6-Monoacethylmorphine	300
Morphine 3-β-D-glucuronide	800
Morphine	300
Norcodeine	6,000
Normorphone	50,000
Oxycodone	30,000
Oxymorphone	50,000
Procaine	15,000
Thebaine	6,000

Precision

A study was conducted at three hospitals 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 300 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	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 150 ng/mL and 450 ng/mL of Morphine. The MOP Rapid Test Cassette 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 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the MOP Rapid Test Cassette 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 Cassette at a concentration of 100 μg/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-Propanolol
Aminopyrine	Diclofenac	Methadone	D-Propoxyphene
Amitryptyline	Diflunisal	Methoxyphenamine	D-Pseudoephedrine
Amobarbital	Digoxin	L-Phenylephrine	Quinidine
Amoxicillin	Diphenhydramine	Labetalol	Quinine
Ampicillin	Doxylamine	(-) Cotinine	Ranitidine
L-Ascorbic acid	Ecgonine hydrochloride	Ketoprofen	Salicylic acid
D,L-Amphetamine	Ecgonine methylester	Nalidixic acid	Secobarbital
Apomorphine	(-)-ψ-Ephedrine	Nalorphine	Serotonin
Aspartame	Erythromycin	Naloxone	(5-Hydroxytyramine)
Atropine	β-Estradiol	Naltrexone	Sulfamethazine
Benzilic acid	Estrone-3-sulfate	Naproxen	Sulindac
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Temazepam
Benzoylecgonine	Fenoprofen	Nifedipine	Tetracycline
Benzphetamine	Furosemide	Norethindrone	Verapamil
Bilirubin	Gentisic acid	D-Norpropoxyphene	Zomepirac
(±) - Brompheniramine	Hemoglobin	Noscapine	Tetrahydrocortisone
Caffeine	Hydralazine	D,L-Octopamine	3-(β-D glucuronide)
Cannabidiol	Hydrochlorothiazide	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrocortisone	Oxazepam	Thiamine
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Thioridazine
Chlordiazepoxide	Cortisone	Oxymetazoline	D, L-Tyrosine
Chlorothiazide	Uric acid	Papaverine	Tolbutamide
(±) Chlorpheniramine	3-Hydroxytyramine	Penicillin-G	Triamterene
Chlorpromazine	Ibuprofen	Pentazocine	Trifluoperazine
Chlorquine	Imipramine	Pentobarbital	Trimethoprim
Cholesterol	Iproniazid	Perphenazine	Trimipramine
Clomipramine	(±) Isoproterenol	Phencyclidine	Tryptamine
Clonidine	Isoxsuprine	Phenelzine	D, L-Tryptophan
Cocaine hydrochloride	Ketamine	Phenobarbital	Tyramine
(+) 3,4-Methylenedioxy-amphetamine	(+) 3,4-Methylenedioxy-methamphetamine	Tetrahydrocortisone, 3-Acetate	p-Hydroxy-methamphetamine
Phentermine			

【BIBLIOGRAPHY】

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: 145012103
Revision date: 2023-07-25