MOP
One Step Morphine Test Strip

INTENDED USE

The MOP One Step Morphine Test Strip (Urine) is a lateral flow 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.

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 One Step Morphine Test Strip (Urine) is a rapid urine screening test that can be performed withoutthe use ofan instrument.Thetestutilizes a monoclonalantibodytoselectivelydetect elevatedlevels of Morphine in urine. The MOP One Step Morphine Test Strip (Urine) yields a positive result when 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).

PRINCIPLE

The MOP One Step Morphine Test Strip (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 proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed Test Strips	Each Strip contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Disposable pipettes	For adding specimens use.
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.

PRECAUTIONS

- 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

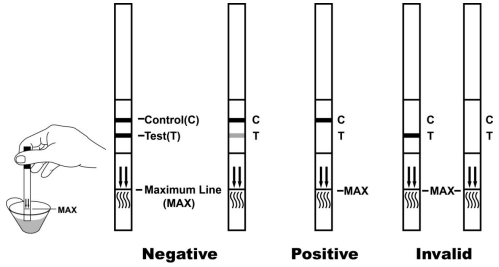
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- 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.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

1. Allow the test and urine samples to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.
2. Remove the test strip from the sealed pouch and use it as soon as possible.
3. Immerse the strip vertically into the urine specimen with the arrow end pointing towards the urine. Do not immerse the strip past the Max Line. See the illustration below.
4. Remove the strip after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface.
5. Start the timer and wait for the colored line(s) to appear.
6. Interpret the test results at 3-5 minutes. Do not read results after 10 minutes.



(The picture is for reference only, please refer to the material object.)

INTERPRETATION OF RESULTS

POSITIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

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, 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 MOP One Step Morphine Test Strip (Urine) 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. 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 One Step Morphine Test Strip (Urine) and a leading commercially available MOP rapid test. Testing was performed on 341 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Morphine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method		**GC/MS**		**Total Results**
MOP One Step Test Strip	**Results**	Positive	Negative	
	Positive	159	10	169
	Negative	0	172	172
Total Results		159	182	341

Relative Sensitivity: >99% (99.8%~100.0%)
Relative Specificity: 94.5% (91.2%~97.8%)
Overall Agreement: 97.1% (95.3%~98.9%)
***95% Confidence Interval**

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 and 450 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

MOP Conc. (ng/mL)	**Percent of Cut-off**	**n**	**Visual Result**	
			Negative	Positive
0	0	20	20	0
150	-50%	20	20	0
225	-25%	20	20	0
300	Cut-off	20	12	8
375	+25%	20	2	18
450	+50%	20	0	20

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MOP One Step Morphine Test Strip (Urine) at 5 minutes.

Compound	**Concentration (ng/mL)**
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levophanol	1,500
6-Monoacethylmorphine	400

Morphine	300
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250

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 One Step Morphine Test Strip (Urine) 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
L-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	
Chlordiazepoxide	Maprotiline	Sulfamethazine
Chlorothiazide	Meperidine	Sulindac
(±) Chlorpheniramine	Meprobamate	Temazepam
Chlorpromazine	Methadone	Tetracycline
Chlorquine	Methoxyphenamine	Tetrahydrocortisone, 3-Acetate
Cholesterol	(+) 3,4-Methylenedioxy-amphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Clomipramine		
Clonidine	(+) 3,4-Methylenedioxy-methamphetamine	Tetrahydrozoline
Cocaine hydrochloride		Thiamine
Cortisone	Nalidixic acid	Thioridazine
(-) Cotinine	Nalorphine	D, L-Tyrosine
Creatinine	Naloxone	Tolbutamide
Deoxycorticosterone	Naltrexone	Triamterene
Dextromethorphan	Naproxen	Trifluoperazine
Diazepam	Niacinamide	Trimethoprim
Diclofenac	Nifedipine	Trimipramine
Diflunisal	Norethindrone	Tryptamine
Digoxin	D-Norpropoxyphene	D, L-Tryptophan
Diphenhydramine	Noscapine	Tyramine
Doxylamine	D,L-Octopamine	Uric acid
Ecgonine hydrochloride	Oxalic acid	Verapamil
Ecgonine methylester	Oxazepam	Zomepirac
(-)-ψ-Ephedrine	Oxolinic acid	

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

Zhejiang Anji Saianfu Biotech Co.,Ltd.
Add:2nd Floor,No.3 Factory, No.489 WenYun Road,TangPu Industrial Park,Dipu Subdistrict, Anji county, 313303 HuZhou City, ZheJiang Province , P. R. China
Tel: +86-18105829268 Fax: +86-572-5068177
Web site: www.seinofy.com E-mail:sales@seinofy.com

EC REP
Lotus NL B.V.
Add :Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email:peter@lotusnl.com

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				