



MOR-U23

Morphine/Heroin MOR
Rapid Test Device
(Urine)

For professional in vitro diagnostic use only.

INTENDED USE

The MOR Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative presumptive detection of morphine and other opiates in human urine specimens at the cut-off concentrations listed below:

Table with 3 columns: Parameter, Calibrator, Cut-off (ng/mL). Row: MOR 300 (Morphine/Heroin), Morphine, 300

INTRODUCTION

The opiates (OP) such as heroin, morphine (MORMOP), and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the urine of a person who has taken only heroin.

PRINCIPLE

The MOR Rapid Test Device (Urine) has been designed to detect morphine and other opiates through visual interpretation of color development in the strip. The membrane was immobilized with morphine conjugates on the test region, and the sample pad was pre-coated with colored anti-morphine antibodies colloidal gold conjugates.

REAGENTS

Each test consists of a reagent strip mounted in a plastic housing. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.

The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

MATERIALS

Materials Provided

- Individually packed test devices
Disposable pipettes
Package insert

Materials Required but Not provided

- Positive and negative controls
Centrifuge
Timer

PRECAUTIONS

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch or canister is damaged. Do not reuse tests.
This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
Read the entire procedure carefully prior to testing.
Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
Humidity and temperature can adversely affect results.
Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch or canister.
The test must remain in the sealed pouch or closed canister until use.
Do not freeze.
Kits should be kept out of direct sunlight.
Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The MOR Rapid Test Device (Urine) is intended for use with human urine specimens only.
Urine collected at any time of the day may be used.
Urine specimens must be collected in clean, dry containers.
Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. 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.
If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

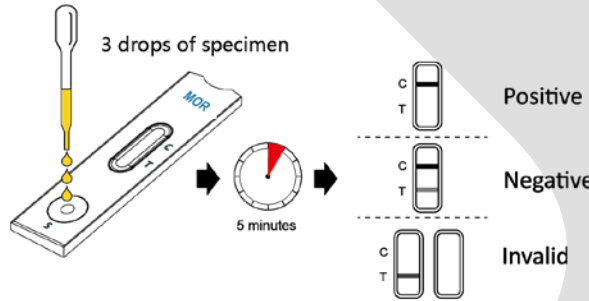
PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
Using the provided disposable pipette, transfer 3 drops of specimen (approximately 120 µL) to the specimen well (S) of the device and start the timer.

Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

- As the test begins to work, color will migrate across the membrane.
Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS



POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T). A positive result indicates that the drug concentration exceeds the detectable level.



NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). A negative result indicates that the drug concentration is below the detectable level.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- The MOR Rapid Test Device (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Morphine/Heroin.
This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National

- Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
A positive result indicates the presence of a Morphine/Heroin only, and does not indicate or measure intoxication.
A negative result does not at any time rule out the presence of Morphine/Heroin in urine, as they may be present below the minimum detection level of the test.
This test does not distinguish between Morphine/Heroin and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the MOR Rapid Test Device (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >98.2% in agreement.

B. Reproducibility

The reproducibility of the MOR Rapid Test Device (Urine) was verified by blind tests performed at four different locations. Samples with Morphine/Heroin concentrations at 50% of the cut-off were all determined to be negative, while samples with Morphine/Heroin concentrations at 200% of the cut-off were all determined to be positive.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with Morphine/Heroin concentrations at 50% of the cut-off yielded negative results, and controls with Morphine/Heroin concentrations at 150% of the cut-off yielded positive results.

D. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the MOR Rapid Test Device (Urine) identified positive results at 5 minutes.

Table with 2 columns: Morphine 300 related compounds, Concentration (ng/mL). Lists various compounds and their concentrations.

The following compounds yielded negative results up to a concentration of 100µg/mL:

Table with 3 columns: Compound name, generic name, and specific name. Lists various compounds that yield negative results up to 100µg/mL.

LITERATURE REFERENCES

- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
McBay AJ. Drug analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
Ι	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
γ	CE marking according to IVD Medical Devices Directive 98/79/EC		



μ

Assure Tech (Hangzhou) Co., Ltd.
2nd, 6th, Floor, Building 1, No.10, Xiyuansan Rd, Westlake Economic Zone Hangzhou 310030
Zhejiang China

A

Lotus Global Co., Ltd.
1 Four Seasons Terrace West
Drayton, Middlesex London, UB7
9GG, United Kingdom

