DRG® Morphine/Opiates (RAP-4917)

CE

Revised 18 Nov. 2010 rm (Vers. 3.1) **USA: RUO**

Please use only the valid version of the package insert provided with the kit.
This kit is intended for Research Use Only. Not for use in diagnostic procedures.

INTENDED USE

The Morphine (MOR) Test Device is a lateral flow, one-step immunoassay for the qualitative detection of Morphines and other opiates in human urine. The detection limit (cut-off) is 300 ng/ml.

SUMMARY

The MOR-Test Device is a competitive immunoassay for the qualitative detection of morphine. The detection limit of the test is 300 ng/ml.

The Test Device use highly-specific antigen-antibody reactions for the detection of drugs in human urine.

The test is interpreted visually and provides a qualitative result. In case there is no drug in the urine (non-consumer) two red lines (test- and control-line) appear at the reaction zone of the device. If there is the according drug in the urine sample (consumer) only one control-line appears at the reaction zone.

RELEVANT INFORMATION

This assay provides only a preliminary analytical test result. 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 Substance Abuse and Mental Services Administration (SAMSHA). Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

BASICS

The opiates (OPI) such as heroin, morphine (MOR/MOP), 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. The body also changes codeine to morphine. Thus the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use. But a positive test result does not automatically mean that an abuse of drugs has been taken place since also some fully legally taken medicaments do contain opiates (e.g. codeine).

The MOR-Test Device is a rapid, competitive immunoassay that can be used for the qualitative detection of morphines and other opiates in human urine at a cut-off concentration 300 ng/ml. Test devices with the cut-off 100 ng/ml, 200 ng/ml and 2000 ng/ml are available on request.

Methods of Examination of specimens range from simple immune-chemical to complex analytical methods. The immuno-assays are acknowledged for these examinations because of their short reaction-time and high sensitivity.

Maximum expected urine concentrations and the half-life of drugs of abuse and psychotropics (1)

Drug of abuse/psychotropics	Expected urine concentrations (*)	Half-life
Opiates, Morphine	14000 ng/ml	3-20 min (diacetylmorphine), 9-40 min (6-monoacetylmorphine), 1-7 h (Morphine)

(*) The concentrations are the lowest published concentrations in urine (1) after consumption of respective drugs underneath lethal doses.

Times of detection of various drugs of abuse in urine (2)

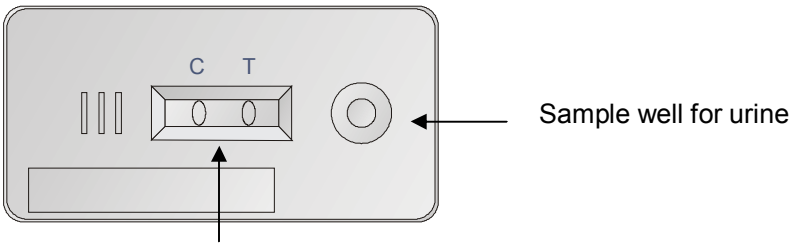
Drug of abuse/psychotropics	Times of detection
Opiates, Morphine	Up to 48 h after use (in individual cases up to 72 h)

1.1 Cut-off

The cut-off describes the sensitivity of the drug test. It describes the drug concentration at which the test line starts to disappear and is thus the limit to decide whether a drug is regarded as being detected and tested positive. Depending on the application it is useful to have a high or low detection limit (cut-off) to enable an easier interpretation of the result. This is explained by the following example: If the test is very sensitive it might appear that harmless opioids of poppy-pastries are detected. Common abuse of opium would lead to a much higher concentration in the urine. Thus, the tests should be more insensitive to detect the drug consum on the one hand and to avoid the false positive results on the other hand.

SET-UP OF THE TEST DEVICE

The plastic case of the test cassette encloses one test strip. At the right end of the strip there is the sample well and at the left part there is the opening of the reaction zone. At the reaction zone you find the test (T) and the control (C) zone. The labelling next to the reaction zone marks the test and control zone. Because the strip encloses in a plastic case you can only imagine its position by the openings in the case.



Reaction zone with the test- (T) and the control- (C) zone (with ellipses marked)

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TEST PRINCIPLE

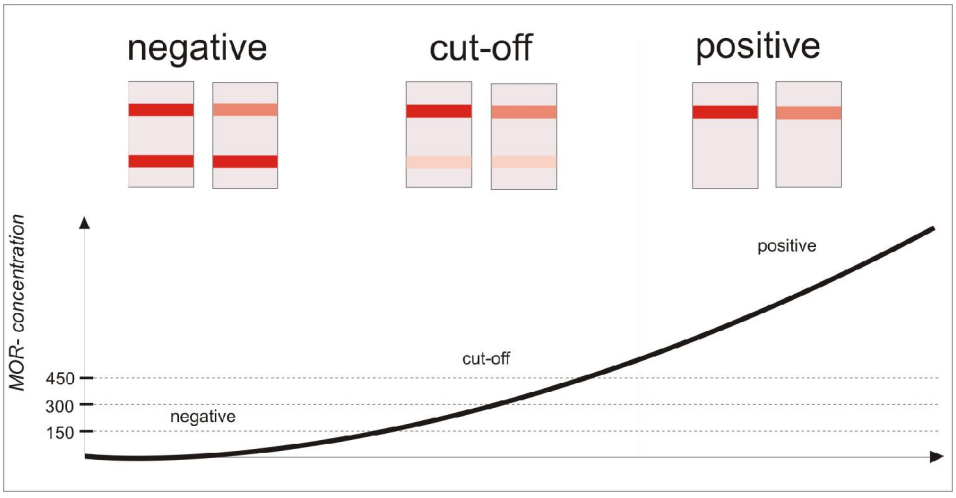
The drug tests are competitive immunoassays in which immobilised drug conjugate from the test competes with free drug which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which is pre-coated with immobilized drug conjugate as antigen in the test zone (T). Dye-labelled anti- drug -antibodies are placed in the red coloured conjugate pad below the sample well.

After soaking the membrane with urine by dropping urine in the sample well the antibodies move upwards by capillary action and get to the test zone (T). If there is no drug in the urine the labelled antibodies attach to the immobilized drug conjugate and a visible line is formed. Therefore, a line in the T-zone indicates that no drug is present in the urine (negative result) or that the drug concentration is below the cut-off.

If drug molecules are present in the urine, they compete with the immobilized drug conjugate in the test zone for the limited antibody binding sites. With increasing concentrations of the drug in the sample the binding of the antibody is more and more inhibited and the color of the test line becomes weaker. When the amount of drug is equal or more than the cut-off, it will prevent the binding of the antibody to the drug conjugate of the test zone and the line gradually vanishes. Therefore, the absence of a colored line in the test zone (T) indicates a positive result.

A control line with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control zone (C) to indicate that the test has been performed properly. The presence of this control line serves as verification that sufficient volume has been added, and that proper flow was obtained. The control line should always appear, regardless of the presence of the examined drug.

This means that negative urine will produce two colored lines (non-consumer), where as positive urine will produce only one colored line in the reaction zone (consumer).



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STORAGE AND STABILITY

The test is to be stored refrigerated or at room temperature (2-30°C) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- This kit is intended for Research Use Only. Not for use in diagnostic procedures.
- Use only once!
- Do not use more than the required amount of liquid.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.
- Do not touch the reaction zone of the device to avoid contamination.
- Do not spill the samples into the reaction zone.
- Use only urine as liquid and no other one instead.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the cassette after expiration date.
- Use test right after unwrapping because it is humidity-sensitive!
- Therefore do not use the test after damage of the packaging foil!
- Please be aware of the developing time of the test before evaluation.
- Please take the specificity and the cross reactivity into account for evaluation.
- Store and transport the test device always at the stated temperature.
- The used test should be discarded according to local regulations.

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test device
- One disposable pipette
- One instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

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SPECIMEN COLLECTION AND HANDLING

Collect the urine specimen in a clean and dry collection container. Ensure that a sufficient quantity of the specimen is collected.

The drug test devices are formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. The test of the urine specimens should be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2-8°C for two days, or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing.

Note:
Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only. Due to too low specific weight (e.g. absence of ions) in other mediums it might be possible, that false results occur.
- A positive result with any of the tests indicates the presence of a drug/metabolite in urine only, and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results. See chapter "Specificity" for lists of substances that will produce positive results, or that do not interfere with test performance.
- If it is suspected that the samples have been mislabelled or tampered with, a new specimen should be collected and the test should be repeated.

TEST PROCEDURE

The test should be performed immediately after opening the protective pouch, because the test is humidity-sensitive. Refrigerated cassettes should be brought to room temperature (15-30°C) before opening to avoid condensation of moisture on the test. Refrigerated Patient's samples, and controls should be brought to room temperature (15-30°C) prior to testing. Ensure that a sufficient quantity of the specimen has been collected.

1. Open the pouch and remove the cassette. Once opened, the cassette must be used immediately.
2. Draw the urine sample to the line marked on the pipette.
3. Dispense 3 drops (120-150 µl) into the sample well. Use a separate pipette and device for each sample or control. Start the timer.
   Caution: If the urine directly touches the reaction zone, the test gets invalid!

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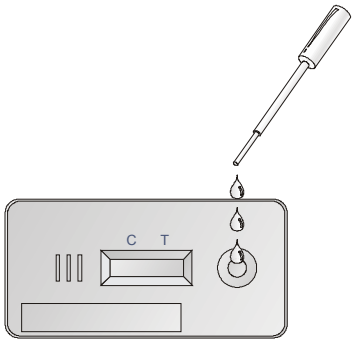


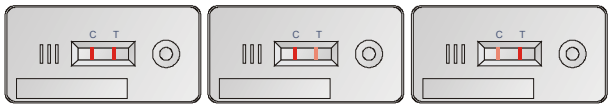
4. At the end of five minutes read the result.
   Do not interpret the result later than 15 minutes after starting the assay.

INTERPRETATION OF RESULTS

For interpretation the reaction zone is regarded. One or two red lines will appear there.

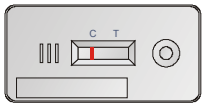
Negative Result:

Two colored lines appear. The line in the test zone (T) is the drug line; the line in the control zone (C) is the control line, which is used to indicate proper performance of the strip. The color intensity of the test line may be weaker or stronger than that of the control line.



Positive Result:

Only one red colored line appears in the control zone (C). The absence of a red test line indicates a positive result. Keep the sample for further confirmation of the result.

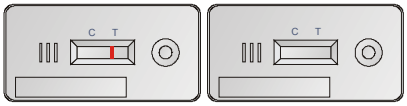


Note:

A very faint line in the test zone indicates that the drug in the sample is near the cut-off level of the test. These samples should be re-tested or confirmed with a more specific method before a positive determination is made.

Invalid Result:

No line appears in the control zone (C). Under no circumstances should a positive sample be identified until the control line forms. Repeat the assay with a new test device. Paying special attention to the required amount of liquid and reaction time. If problems persist, contact your manufacturer.



QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. For testing the positive and negative controls are used in the same way as urine specimen.

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

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COMPOUND	CONCENTRATION (ng/ml)
Morphine	300
Codeine	300
Diacetyl morphine (Heroine)	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	2,500
Trimipramine	>20,000

All following listed compounds reacted negative up to a concentration of 100 µg/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

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Ethanol	Tyramine
Furosemide	Vitamin C
Glucose	

LITERATURE

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