DRG® Methamphetamine (RAP-4915)

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 Methamphetamine (MET) Rapid Test Device is a lateral flow, one-step immunoassay for detection of Methamphetamine in human urine.

SUMMARY

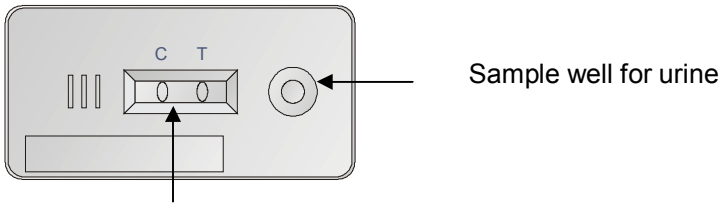
The MET-Test Device is a competitive immunoassay for detection of methamphetamine. The detection limit of the test is 1000 ng/ml.

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

The test is interpreted visually. 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.

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)

TEST PRINCIPLE

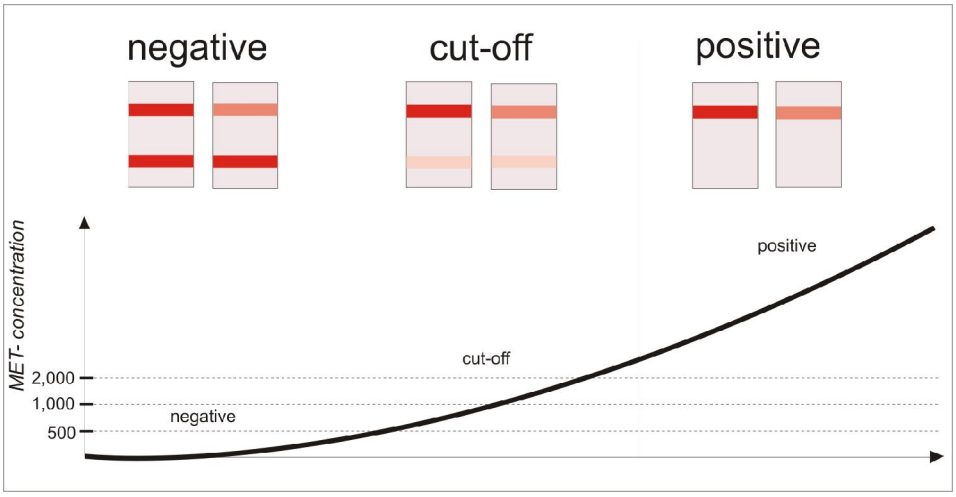
This drug test is a competitive immunoassay in which immobilised drug conjugate from the test competes with free drug which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which is pre-coated with immobilized drug conjugate as antigen in the test 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 band 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).



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

- 50 individually wrapped test device
- Disposable pipettes
- Instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

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.

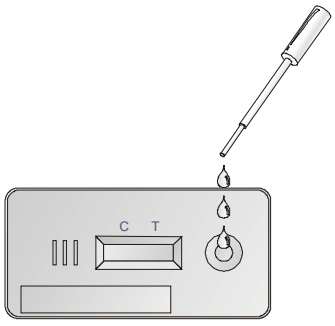
LIMITATIONS OF PROCEDURE

- 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. 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 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!



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

LITERATURE / LITERATURE

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6. Gilman, A.G., & Goodman, L.S. The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.