MET Rapid Test (Oral Fluid) Package Insert

A rapid test for the qualitative detection of Methamphetamine in human oral fluid.
For professional in vitro diagnostic use only.

INTENDED USE

The MET Rapid Test (Oral fluid) is a rapid chromatographic immunoassay for the detection of MET in human oral fluid at a cut-off concentration of 50ng/ml
This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrophotometry (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

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use. Methamphetamine can be detected in oral fluids for up to 72 hours after use[1].

PRINCIPLE

MET Rapid Test (Oral fluid) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a portion of the oral fluid specimen migrates upward by capillary action. Methamphetamine, if present in the oral fluid specimen below 50ng/ml, will not saturate the binding sites of the antibody coated particles in the Device. The antibody coated particles will then be captured by immobilized. Methamphetamine 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 Methamphetamine level is above 50ng/ml because it will saturate all the binding sites of anti-Methamphetamine antibodies. A drug-positive oral fluid specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative oral fluid 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 MET antibody-coupled particles and MET-protein conjugate. A goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to MET.

PRECAUTIONS

- 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 collector and Device should be discarded according to federal regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen is collected by the absorbent wick of the Device, Follow the detailed Directions for Use below. No other collection Device should be used with this assay. Oral fluid collected at any time of the day may be used.

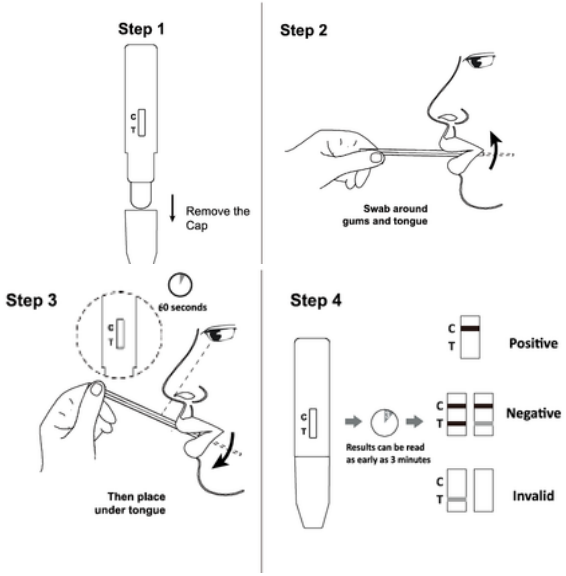
Materials provided
- Test device
- Package insert

Materials required but not provided
- Timer

DIRECTIONS FOR USE

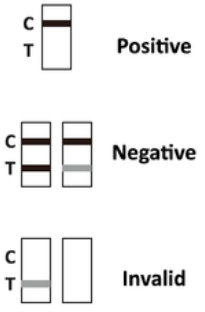
Allow the test Device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Take off the Device cap and collect oral fluid specimen as follows. Important: Place the tongue against the upper and lower jaws and roots to enrich the oral fluid. Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth (10-15 times) to assist saturation. Put the absorbent wick under the tongue to collect oral fluid until the flow appear in the test windows (approximately 60 seconds) and then take out the Device and start a timer. If no flow appeared repeat the procedure in steps above until the flow appear. If no flow appeared after triplicate of steps above, discard the device, review procedures with the donor and repeat the test using a new device.
3. Place the test Device on a clean and level surface.
4. Read the test result at 3-10 minutes. If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re-read at 10 minutes.



INTERPRETATION OF RESULTS

Please refer to the illustration



NEGATIVE:* Two colored lines appear.
One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable level of 50ng/ml
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of Methamphetamine present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.
POSITIVE: One colored line appears in the control region (C).
No line appears in the test region (T). This positive result indicates that the Methamphetamine concentration is above the detectable level of 50ng/ml.
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 Device. If the problem persists, discontinue using the test Device 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, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. MET Rapid Test (Oral fluid) provides only a qualitative, preliminary analytical 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
2. A positive result indicates presence of the drug or its metabolites but does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate drug-free specimen. Negative results can be obtained when drug is present but below the cut-off level of the test.
4. Test does not distinguish between drugs of abuse and certain medications.
5. A positive test result might be obtained from certain foods or food supplements.

EXPECTED VALUES

This negative result indicates that the Methamphetamine metabolite concentration is below the detectable level of 50ng/mL. Positive result means the concentration of Methamphetamine metabolite is above the level of 50ng/ml. The MET Rapid Test has a sensitivity of 50ng/ml.