

Saliva Rapid Drug Test Kit

THC (12ng/mL)

MDMA (80ng/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. Liquid chromatography/mass spectrometry (LC/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

The Oral Fluid Drug Test Device is an 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 along the test strip by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. 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 Oral Fluid Drug Test Device contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device 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 local regulations.
- Safety data sheets available for professional user upon request

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30° C). The test device 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 should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this test. Oral fluid collected at anytime of the day may be used. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8° C or -20° C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8° C).

MATERIALS

Materials provided

- Test device
- Procedure card
- Package insert

Materials required but not provided

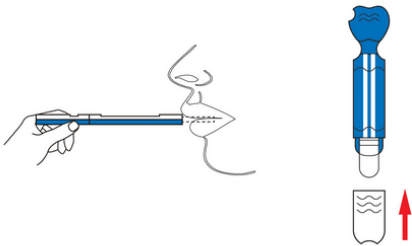
- Timer
- Gloves

DIRECTIONS FOR USE

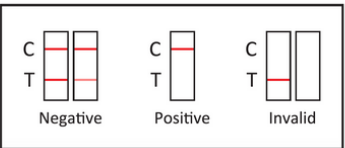
Allow the test device, specimen, and/or controls to reach room temperature (15-30° C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Remove the cap by holding the sides and pulling gently. This will expose the collection pad. Open mouth and gently rub the collection pad inside mouth against cheek, opposite cheek, on top of the tongue and underneath the tongue in a circular motion several (approximately each site for 5-10 times). **Make sure to keep head level.**
- Place the collection pad underneath the tongue for approximately 3-8 min to collect saliva until the control line appears. **Instruct the donor to hold it in place with hand to make sure the test device in horizontal level.**
- Remove from mouth as soon as the control line appears. Re-cap the device.
- Lay the device on a flat surface, and read results in approximately 10 minutes**

Note: If no wicking issue occurred, repeat 2-4 steps, but make sure keep balance level to avoid flooding.



INTERPRETATION OF RESULTS



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(Please refer to the previous illustration)

NEGATIVE: A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

***NOTE:** Preliminary positive results should be confirmed with a more specific method before positive determinations are made.

INVALID: Control line (C) 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 using a new test device. If the problem persists, discontinue using the lot 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. Control standards are not supplied with this kit; however, 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

- The Oral Fluid Drug Test Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result may be obtained from certain foods or food supplements.