



THC (Parent) Rapid Test Cassette (Oral Fluid)

User Instruction For Self-testing

REF DTH-P802H English

A rapid test for the qualitative detection of THC(Parent) in human oral fluid. For self-testing, not for in vitro diagnostic use.

【INTENDED USE】

The THC (Parent) Rapid Test Cassette (Oral Fluid) is competitive binding, lateral flow immunochromatographic assay for qualitative detection of THC in human oral fluid at the cutoff concentrations of 3.5ng/mL.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

【SUMMARY】

11-nor-9-tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH), the metabolite of THC (Δ^9 -tetrahydrocannabinol), is detectable in oral fluid shortly after use.¹ The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.² Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.³

The THC (Parent) Rapid Test Cassette (Oral Fluid) is a rapid oral fluid screening test that can be performed without the use of an instrument. The THC (Parent) Rapid Test Cassette (Oral Fluid) yields a positive result when THC in oral fluid exceeds 3.5ng/mL.

【PRINCIPLE】

The THC (Parent) Rapid Test Cassette (Oral Fluid) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the oral fluid specimen compete against the drug conjugate for binding sites on the antibody.

During testing, oral fluid specimen migrates upward by capillary action. THC, if present in the oral fluid specimen below 3.5ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized THC 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 THC level exceeds 3.5 ng/mL because it will saturate all the binding sites of anti-THC antibodies.

A drug-positive oral fluid specimen will not generate a colored line in the test line region, 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 anti-THC antibody-coupled particles and THC-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- Read the entire user instructions prior to performing test.
- For self-testing, not for *in vitro* diagnostic use.
- For external use only.
- Do not use the test after expiration date printed on the package.
- Do not use the test if its foil pouch is torn or damaged.
- For single use. Discard after first use
- The test device should remain in the sealed pouch until use.
- Contaminated or tainted oral fluid sample may give false results.
- Keep out of reach of children.

【MATERIALS PROVIDED】

- Test Cassette (sealed in foil pouch with a desiccant)
- Collector
- Collection Chamber
- User Instruction

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Watch, clock or timer

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C up to the date of expiration. **Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.**

【DIRECTIONS FOR USE】

Allow the test to reach room temperature before testing.

Not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

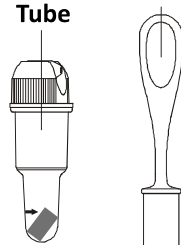
Collect oral fluid sample

Step 1:

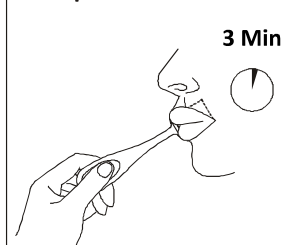
- Remove the collector from the sealed pouch and collect oral fluid specimen as follows:

Important: Place the tongue against the upper and lower jaws and roots to enrich the oral fluid before oral fluid collection. Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth and under the tongue and chew the sponge tenderly, place the sponge end under the tongue for **at least 3 minutes** until the sponge becomes fully saturated.

Collection Tube Collector

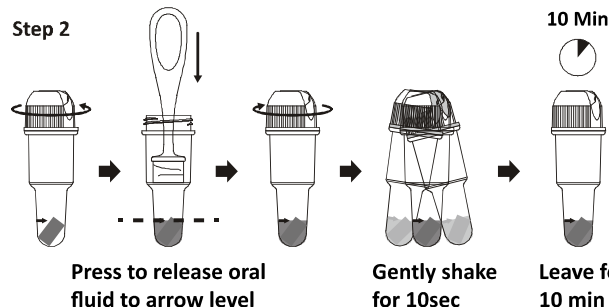


Step 1



Step 2

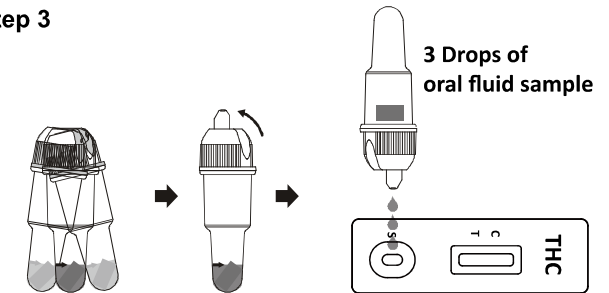
- Take the collection chamber out of the sealed pouch and have it unscrewed. Remove the oral fluid saturated collector from the mouth and place it into the collection chamber. Press sponge fully against the strainer to release oral fluid to the **arrowed point level** and then screw it back tightly. Discard the collector
- Gently shake the collection chamber for 10 seconds and then **leave it for 10 minutes**.



Step 3: Testing

- Open the foil pouch, remove the test cassette, discard the desiccant.
- Place the test cassette on a clean and level surface. Again **gently shake the collection chamber for 10 seconds** and snap the tip open. Invert the collection tube and transfer **3 full drops of oral fluid** into specimen well next to the letter "S" on the test cassette. **Do not spill oral fluid into the test window.** Screw the cap on the collection tube.
- Start a timer.

Step 3

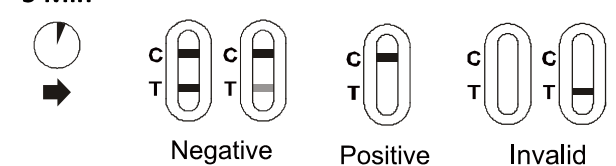


Gently shake again

Step 4: Read Results

- **Read the test results at 5 minutes**, do not read results after 10 minutes..

5 Min



【INTERPRETATION OF RESULTS】

	NEGATIVE: Two colored lines appear. One line appears next to the letter 'C' and the other line appears next to the letter 'T'.
	POSITIVE: Only one colored line appears next to the letter 'C'. No colored line appears next to the letter 'T'.
	INVALID: Control line fails to appear.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to confirm the result.

Detection Items, Levels and Approximate Detection Times			
Drug Name (Abbreviation)	Detectable Level (ng/mL)	Minimum Detection Time *	Maximum Detection Time *
THC	3.5	0.5hours	14hours

* NOTE: The times are only estimates.

【Q&A】

1. How do I know if the Test worked well?

When the control line(C) appears, it means that the test unit is working well.

2. How soon can I read my results?

You can read your results after 5 minutes as long as a red line or pink colored line has appeared next to the Control region(C), do not read results after 10 minutes.

3. When is the best time to run the test?

You can run the test at any time of the day.

4. How to read the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as negative whatever the color

intensity of the test line (T) is.

5. What is A False Positive Test?

A false positive test result means the drug is not present but shows detected by the device. The most common causes of a false positive test are cross reactants.

6. What is A False Negative Test?

A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.











【LIMITATIONS】

1. The Test is for use with human oral fluid only.
2. The Test only provides a preliminary result.
3. Test does not distinguish between drugs of abuse and certain medications.
4. A positive test result may be obtained from certain foods or food supplements.

【BIBLIOGRAPHY】

1. Schramm, W. et al, "Drugs of Abuse in Oral fluid: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Do not use if package is damaged and consult instructions for use		Batch code		Catalogue number
	Caution		Use-by date		Do not re-use
	Manufacturer				



Hangzhou AllTest Biotech Co.,Ltd.

#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn



Number:
Revision date: 2024-06-26