
Verify®
Accurato
Facile da usare
Risultato rapido
MARIJUANA THC RAPID TEST
(Oral Fluid)-3.5ng/mL
Per auto-test, non per uso diagnostico in vitro.
contiene 1 test
RISULTATO IN 5 MINUTI

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade Name:	**THC (Parent) Rapid Test Cassette (Oral Fluid)**
Catalog Number:	**DTH-P802H**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Rapid Test kit for Self-testing use..

1.3 Details of the supplier of the safety data sheet

Manufacturer:	Hangzhou Alltest Biotech Co., Ltd
Address:	No 550, Yinhai Street, Hangzhou Economic and Technological Development Area, Zhejiang Province, China
Phone number:	Phone number is available during office hours (8 am-5 pm Mon-Fri) as follows: +86-0571-56267850
Fax number:	+86-0571-56267856
E-Mail Contact Person:	Yan.Zhang@alltests.com.cn

1.4 Emergency Telephone Number

Telephone No.: (+352) 8002 5500
Other comments: Information available 24/7 in French, Dutch and English.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 (CLP)

Not Classified

2.1.2 Additional information

For full text of hazard and EU hazard statements: see SECTION 16.

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008 (CLP)

Hazard picograms and Signal word:	*No*
Hazardous components for labeling:	*No*
Hazard statements:	*No*
Precautionary statements:	*No*
Supplemental Hazard information (EU):	*No*

2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested . ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture.

3.2 Mixtures

Hazardous ingredients	CAS No.	EC No.	Index No.	REACH Registration No.	Classification according to Regulation (EC) No. 1272/2008 (CLP)	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	N/A	613-167-00-5	N/A	Acute Tox. 3: H301 Acute Tox. 2: H310 Skin Corr. 1C: H314 Eye Dam. 1: H318 Skin Sens. 1A: H317 Acute Tox. 2: H330 Aquatic Acute 1: H400 Aquatic Chronic 1: H410	<0.001 %

Specific concentration limits, M-factors, Acute Toxicity Estimates (ATEs) and generic cut-off values of hazard substance:

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1):

- Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1%
- Specific concentration limits, M-factors, Acute Toxicity Estimates (ATEs) according to Table 3.1 Annex VI:

Skin Corr. 1C; H314: C ≥ 0.6 %

Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %

Eye Dam. 1; H318: C ≥ 0.6 %

Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 %

Skin Sens. 1A; H317: C ≥ 0.0015 %

M(Acute) = 100

M(Chronic)=100

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

General notes	Due to lack of classification, negative symptoms or effects are not expected where the product is used as foreseen.
After inhalation	No specific first aid measures noted. If you feel unwell, seek medical advice.
After skin contact	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact: May cause skin irritation.
Symptoms/effects after eye contact: Liquid splashes in the eye may cause irritation.
Symptoms/effects after ingestion: Ingestion may cause nausea and vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	The common fire extinguish media can be used
Unsuitable extinguishing media:	There are no unsuitable extinguishing media expected

5.2 Special hazards arising from the substance or mixture

No specific hazardous decomposition products noted.

5.3 Advice for firefighters

1. Wear usual Firefighter Personal Protective Equipment.
2. Use dry-chemical fire extinguisher.
3. Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
4. Protection during firefighting: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

(a) General measures: Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) - see Section 8.
(b) Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

6.2 Environmental precautions

Keep away from drains surface and ground water. Dispose as infections material.

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:	Kept in the primary package and secondary package before use.
6.3.2 For cleaning up:	Clean up with broom
6.3.3 Other information:	No data applicable

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Recommendations
Wear appropriate personal protective equipment - see Section 8. Used device to be handled as infectious.
7.1.2 General hygiene measures:
Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.
7.2 Conditions for safe storage, including any incompatibilities
Information about storage conditions: Note the storage conditions on product packaging. **Requirements for storage rooms and containers:** Store 2-30℃. Keep away from sunlight and Keep dry.
7.3 Specific end use(s)
A rapid test for the qualitative detection of THC(Parent) in human oral fluid. For self-testing use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.	
8.2 Exposure controls	
8.2.1 Appropriate engineering controls	
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.	
8.2.2 Personal protective equipment	
General protective and hygienic measures:	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use. Common medical gloves are acceptable.
Eye Protection	Safety glasses
Body protection	Lab personal protective equipment (PPE)
8.2.3 Environmental exposure controls	
There are no special precautions and measures. See section 6 and 7!	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
Physical State:	Solid
Colour:	White appearance and some content of the test strip is colored
Odour:	Odourless
Melting point/freezing point	Not applicable to mixture.
Boiling point:	Not applicable to mixture.
Flammability:	No data applicable
Lower and upper explosion limit	There is no substances in the kit could lead to the danger of explosion
Flash point:	No data applicable
Auto-ignition temperature:	Product is not known to be self-igniting
Decomposition temperature	No data applicable
pH-value at 20°C:	Not established
Kinematic viscosity	Not applicable to mixture.
Solubility	No data applicable
Partition coefficient n-octanol/water (log value)	Not applicable to mixture.
Vapour pressure:	No data applicable
Density and/or relative density	No data applicable
Relative vapour density	Not applicable to solids.
Particle characteristics	No data applicable
Solubility in water:	Not determined
9.2 Other safety information:	
No data applicable	

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
The product is stable in accordance with the recommended storage conditions.
10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
There are no known hazardous reactions under normal conditions of storage and use.
10.4 Conditions to avoid
No known conditions.
10.5 Incompatible materials
No
10.6 Hazardous decomposition products
No

SECTION 11: TOXICOLOGICAL INFORMATION	
11.1 Information on hazard classes as defined in Regulation (EC) No. 1272/2008	
Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation:	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.
Other Information	Based on available data, the classification criteria are not met.
11.2 Information on other hazards	
11.2.1 Endocrine disrupting properties	
Not applicable	
11.2.2 Other information	
No data applicable	

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
No data available
12.2 Persistence and degradability
No data available
12.3 Bioaccumulative potential
No data available
12.4 Mobility in soil
No data available
12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Endocrine disrupting properties
This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.
12.7 Other adverse effects
No data available

SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product:	Do not discharge into drains or the environment. Used device to be handled as infectious. Can be disposed or incinerated according to local regulations. Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 03 wastes whose collection and disposable is subject to special requirements in order to prevent infection.

Packaging:	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further informations.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number

Not applicable.

14.2 UN proper shipping name

ADR/RID: Not applicable.

IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packing group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☑ no
Marine Pollutant : ☐ yes / ☑ no

14.6 Special precautions for user

See sections 6-8

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H301	Toxic if swallowed
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H317	May cause an allergic skin reaction
H330	Fatal if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Indication of changes

2022-12-13	Update according to *COMMISION REGULATION(EU) 2020/878 of 18 June 2020* and *Guidance on the compilation of safety data sheets Version 4.0*.

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].
The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user`s responsibility to determine the suitability of the information for their particular purposes.

Registration Technical File of THC Rapid Test (Oral Fluid)

DTH-P802H

HANGZHOU ALLTEST BIOTECH CO., LTD

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area,

Hangzhou-310018, P.R. China

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1. BACKGROUND

The THC Rapid Test (Oral Fluid) for is a rapid, saliva screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human saliva.

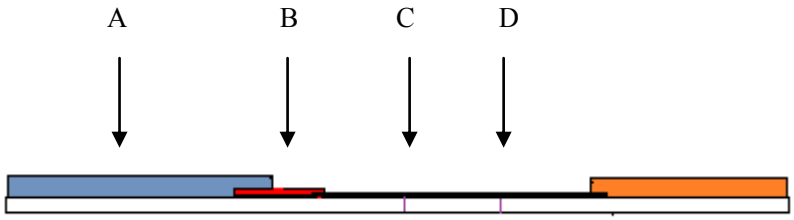
11-nor-9-tetrahydrocannabinol-9-carboxylic acid (9-THC-COOH), the metabolite of THC (△9-tetrahydrocannabinol), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and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

1.1 PRINCIPLES

The THC Rapid Test (Oral Fluid) 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 saliva specimen migrates upward by capillary action. Marijuana, if present in the saliva specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the THC-protein conjugate and a visible colored line will show up in the test line region. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive saliva specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative saliva 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.



As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B) Marijuana present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. Marijuana antigen immobilized in the test zone of the membrane captures the test region (C). The formation of a visible color line in the test region indicates a negative result. The absence of a color line in the test zones suggests a positive result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.2 PERFORMANCE AND SPECIFICATION

The THC Rapid Test (Oral Fluid) is a rapid chromatographic immunoassay for the detection of Marijuana in Oral Fluid. The test utilizes a combination of THC antigen to selectively detect levels of THC in Oral Fluid. At the level of claimed sensitivity, The THC Rapid Test (Oral Fluid) shows no cross-reactivity interference from the drugs of Acetophenetidin, Bilirubin, Isoxsuprine, and so on.

1.2.1 Storage and Stability

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

1.2.2 Standard testing procedure

Allow the test cassette, 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 5 minutes prior to collection.

Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

Cassette Format:

Allow the test to reach room temperature before testing.

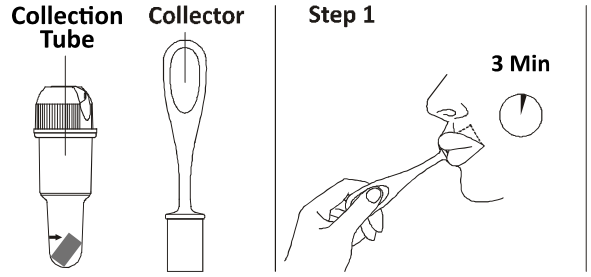
Not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

Collect oral fluid sample

Step 1:

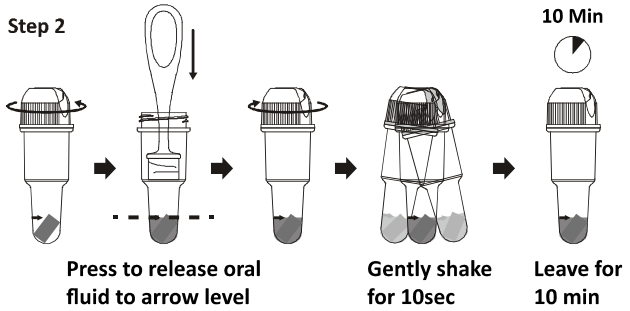
Remove the collector from the sealed pouch and collect oral fluid specimen as follows:

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.



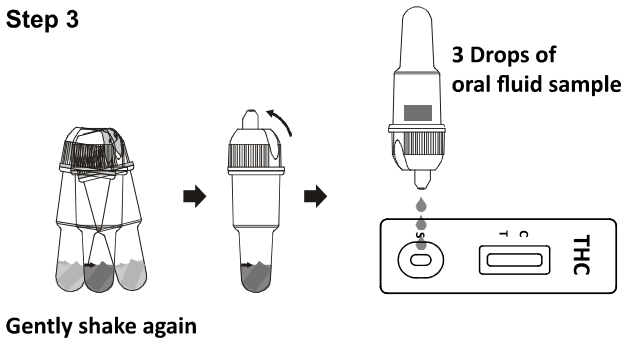
Step 2

- 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.**



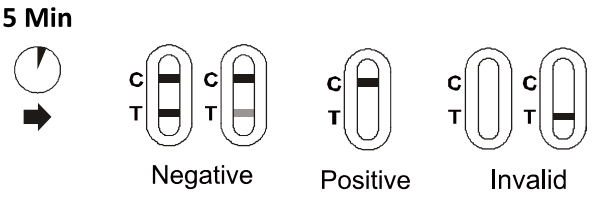
Step 3: Testing

- 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 4: Read Results

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



1.2.3 Interpretation of results

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

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 using a new test cassette. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

1.2.4LIMITATIONS

1.2.1.The Test is for use with human oral fluid only.

1.2.2.The Test only provides a preliminary result.

1.2.3.Test does not distinguish between drugs of abuse and certain medications.

1.2.4.A positive test result may be obtained from certain foods or food supplements.

1.3 Composition of Product

A) Monoclone THC antibody， THC antigen	B) NC Membrane
C) Goat anti rabbit IgG, Rabbit IgG	D) Label pad
E) Adhesive plastic backing	F) Sample pad
G) Absorbant pad	H) Desiccant (in pouch)
I) Plastic cassette	J) Collectors
K) Pouch	L) Collection tubes
M)Security Seal	

1.4 Manufacturing Procedure

1.4.1Coat the gold conjugated Monoclonal THC antibody and Rabbit IgG on the label pad.

1.4.2Use the sprayer to dispense THC antigen and Goat anti rabbit IgG onto the membrane.

1.4.3Assemble the membrane, label pad, absorbent pad and sample pad on the plastic backing.

1.4.4Use the cutter to cut the plastic backing into dipsticks of selected size.

1.4.5For Cassette, lay the dipstick into the plastic cassette, pack the cassette and a desiccant packet into a pouch and seal the pouch.

1.4.6Test the Cassette according to the QC procedure and release the finished product.

1.5 Warning

1.5.1Read the entire user instructions prior to performing test.

1.5.2For self-testing in vitro diagnostic use only.

1.5.3For external use only.

1.5.4Do not use the test after expiration date printed on the package.

1.5.5Do not use the test if its foil pouch is torn or damaged.

1.5.6For single use. Discard after first use

1.5.7The test device should remain in the sealed pouch until use.

1.5.8Contaminated or tainted oral fluid sample may give false results.

1.5.9Keep out of reach of children.

2.PERFORMANCE CHARACTERISTICS

2.1 Specimen Correlation

Assemble each single test into the cassette before testing, and evaluate the cassette with 250 specimens of THC drug type previously collected from subjects presenting for Drug Screen Testing which were confirmed by GC/MS. These specimens were randomized and tested using the THC Rapid Test. Since Sensitivity and Specificity of Strips and Cassettes have been demonstrated to be same and Cassette is a strip embedded in a cassette card, testing with strips reflects the results with cassette also. Specimens were rated as either positive or negative at 5 minutes. The test results are shown in table below.

Table: Specimen Correlation

Method		GC/MS		Total Results
THC Rapid Test Cassette (Oral Fluid)	Results	Positive	Negative	
	Positive	84	4	88
	Negative	2	160	162
Total Results		86	164	250
% Agreement		97.7%	97.6%	97.6%

Conclusion: From the data above, it obtained statistically similar positive agreement, negative agreement and overall agreement rates as GC/MS data.

2.2 Analytical Sensitivity

The analytical sensitivity was determined by spiking negative saliva specimens with intact standard at free saliva (negative), -50% Cut-off, -25% Cut-off, Cut-off, +25% Cut-off, +50% Cut-off and +300% Cut-off. The standards were randomized and coded. The results were confirmed by GC/MS. A total of 10 replicates for each standard were tested. Assemble each single test into the cassette before testing. The specimens were tested with visual interpretations occurring at 5minutes after specimen application. Results are presented in table below:

Table: Analytical Sensitivity Summary

THC3.5 Standard	THC18110010-T										THC18110011-T										THC18110012-T									
0ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1.75ng/ml	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.625ng/ml	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+
3.5ng/ml	-	-	-	-	+	+	+	+	+	+	-	-	-	-	+	+	+	+	+	+	-	-	-	-	+	+	+	+	+	+
4.375ng/ml	-	-	-	+	+	+	+	+	+	+	-	-	+	+	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+
5.25ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10.5ng/ml	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion: The results indicated that each drug in the THC Rapid Test could detect above the cut-off concentration.

2.3 Analytical Specificity

The related compounds of each single drug in cassette will be spiked in drug-free saliva, diluted sequentially to different concentrations and tested until the lowest concentration that has a negative result. The following compounds have negative result at their respective concentrations. And the cutoff concentrations were showed in the tables with "*". The specimens were tested in 5 replicates with visual interpretations occurring at 5 minutes after specimen application. Results are presented in table below.

Table: Interfering Substances

THC3.5 Analytes	Conc. (ng/ml)	THC18110010-T					THC18110011-T					THC18110012-T				
Cannabinol	1,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*2,000	-	-	-	+	+	-	-	-	+	+	-	-	+	+	+
	3,000	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11-nor-Δ^9-THC-9 COOH	1.75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*3.5	-	-	+	+	+	-	-	+	+	+	-	-	+	+	+
	5.25	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Δ^8-THC	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*40	-	-	+	+	+	-	-	-	+	+	-	-	+	+	+
	60	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Δ^9-THC	7.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	*15	-	-	-	-	+	-	-	-	+	+	-	-	+	+	+
	22.5	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion: The cutoff concentrations of each drug related compounds were showed in the tables with "*".

2.4 Cross Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free saliva or drug positive saliva containing, ∆9-THC-COOH. The following compounds show no cross-reactivity when tested with the THC Rapid Test Cassette (Oral Fluid) at a concentration of 100µg/mL. Visual interpretations occurred at 5 minutes after specimen application. Results are presented in table below.

Table: Cross Reactivity

4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+) 3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diflunisal	Methylphenidate	Promethazine
Amitryptyline	Digoxin	Methyprylon	D,L-Propanolol
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphene
Amoxicillin	Doxylamine	β-D-glucuronide	D-Pseudoephedrine
Ampicillin	Ecgonine hydrochloride	Nalidixic acid	Quinidine
L-Ascorbic acid	Ecgonine methylester	Nalorphine	Quinine
D,L-Amphetamine	(-)-ψ-Ephedrine	Naloxone	Ranitidine
L-Amphetamine	Erythromycin	Naltrexone	Salicylic acid
Apomorphine	β-Estradiol	Naproxen	Secobarbital
Aspartame	Estrone-3-sulfate	Niacinamide	Serotonin (5-Hydroxytyramine)
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Benzilic acid	Fenoprofen	Norcodein	Sulindac
Benzoic acid	Furosemide	Norethindrone	Temazepam
Benzoylecgonine	Gentisic acid	D-Norpropoxyphene	Tetracycline
Benzphetamine	Hemoglobin	Noscapine	Tetrahydrocortisone,
Bilirubin	Hydralazine	D,L-Octopamine	3-Acetate
(±)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	Tetrahydrocortisone
Caffeine	Hydrocodone	Oxazepam	3 (β-D-glucuronide)
Cannabidiol	Hydrocortisone	Oxolinic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chlordiazepoxide	Ibuprofen	p-Hydroxy-	Thioridazine
Chlorothiazide	Imipramine	methamphetamine	D, L-Thyroxine

(±) Chlorpheniramine	Iproniazid	Papaverine	Tolbutamine
Chlorpromazine	(±) - Isoproterenol	Penicillin-G	Triamterene
Chlorquine	Isoxsuprine	Pentazocine	Trifluoperazine
Cholesterol	Ketamine	Pentobarbital	Trimethoprim
Clomipramine	Ketoprofen	Perphenazine	Trimipramine
Clonidine	Labetalol	Phencyclidine	Tryptamine
Cocaine hydrochloride	Levorphanol	Phenelzine	D, L-Tryptophan
Codeine	Loperamide	Phenobarbital	Tyramine
Cortisone	Maprotiline	Phentermine	D, L-Tyrosine
(-) Cotinine	Meprobamate	L-Phenylephrine	Uric acid
Creatinine	Methadone	β-Phenylethylamine	Verapamil
	Methoxyphenamine	Phenylpropanolamine	Zomepirac

Conclusion: The compounds listed in above table show no cross-reactivity when tested at a concentration of 100 μg/ml in 5 minutes.

2.5 Between Day Reproducibility

The concentration of all tests in the cassette at 0ng/ml, -50%Cut-off, +50%Cut-off and 300% cut off specimens were run on ten separate days using the same lot of reagents. The specimens were tested in triplicate in lot1 of test Cassette. Results were read visually at 5 minutes after specimen application. Results are presented in table below.

Table: Between Day Results

THC18110010-T

Day		1			2			3			4			5			6			7			8			9			10		
0ng/ml THC	5min	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1.75ng/ml THC	5min	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5.25ng/ml THC	5min	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10.5ng/ml THC	5min	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion: Test results were consistent over the ten days period.

2.6 Between Lot Reproducibility (lot to lot variability)

THC concentration at Drug free saliva, -50% Cut-off, +50% Cut-off and 300% cut off saliva specimens were run in replicates of ten in three separate lots of products. Results were read visually at 5 after specimen application. The test results are shown in table below.

Table: Between Lot Results

Lot1#: THC18110010-T

Specimens / Days	0 ng/ml THC	1.75ng/ml THC	5.25ng/ml THC	10.5ng/ml THC
1	-	-	+	+
2	-	-	+	+
3	-	-	+	+
4	-	-	+	+
5	-	-	+	+
6	-	-	+	+
7	-	-	+	+
8	-	-	+	+
9	-	-	+	+
10	-	-	+	+

Lot2#: THC18110011-T

Specimens / Days	0 ng/ml THC	1.75ng/ml THC	5.25ng/ml THC	10.5ng/ml THC
1	-	-	+	+
2	-	-	+	+
3	-	-	+	+

4	-	-	+	+
5	-	-	+	+
6	-	-	+	+
7	-	-	+	+
8	-	-	+	+
9	-	-	+	+
10	-	-	+	+

Lot3#: THC18110012-T

Specimens / Days	0 ng/ml THC	1.75ng/ml THC	5.25ng/ml THC	10.5ng/ml THC
1	-	-	+	+
2	-	-	+	+
3	-	-	+	+
4	-	-	+	+
5	-	-	+	+
6	-	-	+	+
7	-	-	+	+
8	-	-	+	+
9	-	-	+	+
10	-	-	+	+

Conclusion: Test results were consistent among the three lots of each test in THC Rapid Test Cassette (Oral Fluid).

2.7 Accelerated Stability

Accelerated Stability of the THC Rapid Test (Oral Fluid) was evaluated using samples from three lots of format. These were placed in an incubator with the temperature calibrated at 45℃ and 55℃. If the 55°C result is not accepted, 45°C accelerated study result would be used to extrapolate estimated shelf life of the test.

According to Arrhennius Equation, a series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 91,105,112,119,126 and 133 days at 45℃, and same performance study would be tested at 0, 7, 14, 21, 28, 35, 42, 49 and 56 days at 55℃. Test products were assayed using 0, -50% cutoff, +50%cutoff and 300% cut off specimens. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert.

Time line for Accelerate Stability Study

Day / Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	49 days	56 days	60 days	77 days	91 days	105 days	112 days	119 days	126 days	133 days
45^0C.	√	√	√	√	√	√	√		√		√	√	√	√	√	√	√
55^0C.	√	√	√	√	√	√	√	√	√	√							

*DAY 0: Run 3 test products each with four testing specimen.

Table: Accelerated Stability Summary

THC3.5：

Accelerated Stability Study Results at 45℃																	
Day	**Specimen**	**Batch No.**															
		Lot 1					**Lot 2**					**Lot 3**					
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

7	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
91	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
105	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
112	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
119	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
126	Negative	-	-	-	-	-	-	-	-	-
	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+
133	Negative	-	-	-	-	-	-	-	-	-

	-50%cutoff	-	-	-	-	-	-	-	-	-
	+50%cutoff	+	+	+	+	+	+	+	+	+
	3X cutoff	+	+	+	+	+	+	+	+	+

Accelerated Stability Study Results at 55℃

Day	Specimen	Batch No.															
		Lot 1					Lot 2					Lot 3					
0	Negative	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	-50%cutoff	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	+50%cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	3X cutoff	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
7	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
14	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
21	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
28	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
35	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
42	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
49	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
56	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	
60	Negative	-		-		-		-		-		-		-		-	
	-50%cutoff	-		-		-		-		-		-		-		-	
	+50%cutoff	+		+		+		+		+		+		+		+	
	3X cutoff	+		+		+		+		+		+		+		+	

Conclusion: THC Rapid Test Cassette (Oral Fluid) is stable at 45℃ for 84 days or 55℃ for 42 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 27 months from the data of manufacture.

2.8 Precision

A study was conducted at three hospitals by untrained operators using three different lots of product which assemble in cassette to demonstrate the within run, between run and between operator precision. An identical cassette of coded specimens, containing drug free saliva, -50% Cut-off, -25% Cut-off, +25% Cut-off and +50% Cut-off to each site.

Results:

THC18110007-T

THC3.5 Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1.75	10	10	0	10	0	10	0
2.625	10	9	1	9	1	9	1
4.375	10	3	7	3	7	2	8
5.25	10	0	10	0	10	0	10

Conclusion: Specimens determined to be negative, -50% cutoff, -25% cutoff, +25% cutoff and +50%cutoff values demonstrate high precision for THC Rapid Test Cassette (Oral Fluid).

Document History Summary

Version No.	Date	Description	Remark
01	2021.01.18	New Document	N/A

Certificate of Analysis

Product Name:	THC Rapid Test Cassette (Oral Fluid)			**Catalog No.:**	DTH-P802H
Batch No.:	THC25020017	**Date of Sampling:**	2025.03.03	**Quantity:**	1000PCS
Expiry Date:	2027-01	**Date of Analysis:**	2025.03.03	**Specification:**	3.5ng/ml
Other information:/					

QC Item		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	3X Cut Off	Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others：	/

Final QC Conclusion：	This batch of product met the QC Criteria.

QC supervisor: Freeman.zheng

Date: 2025.03.03

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