

Rapid Response™

THC Lollipop UltraTrace
(Saliva)

REF THC -2LT156 -25

Product Insert

A rapid test for the qualitative detection of Marijuana in human oral fluid.
For Forensic Use Only.

Intended Use

The Rapid Response™ THC Lollipop UltraTrace is a rapid chromatographic immunoassay for the detection of Δ9-tetrahydrocannabinol (Δ9-THC) in human oral fluid at a cut-off concentration of 1ng/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. LC-MS/MS is the preferred confirmatory method¹. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid shortly after use. Δ9-tetrahydrocannabinol is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The parent THC also known as Δ9-THC is present in oral fluid after use. The Rapid Response™ THC Lollipop UltraTrace yields a positive result when the Δ9-THC concentration in oral fluid exceeds 1 ng/mL.

Principle

The Rapid Response™ THC Lollipop UltraTrace is a rapid chromatographic immunoassay for the qualitative detection of Δ9-THC in oral fluid. The test uses two lines (C,T) to indicate results. The test line (T) is coated with anti-THC antibodies (monoclonal antibodies).The monoclonal antibody is purified agglutinating sera so making the test more reliable and accurate. The control line (C) is coated with antibodies and colloidal gold particles. The assay is conducted by adding oral fluid specimen to the specimen well of the test device and observing the formation of red colored line (s). The specimen migrates via capillary action along the membrane to react with the antibodies at C & T lines. Positive specimens containing Δ9-THC (Antigen) when passes through the membrane, at test line reacts with the anti-THC antibody (Antigen - Antibody reaction). Positive reaction is made visible by colored conjugate. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line should always appear in the control line region(C). It indicates that proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Oral fluid is not classified as biological hazard unless derived from a dental procedure.
- The used collector and cassette should be discarded according to federal, state and local regulations.

Materials

Materials provided

- Test cassettes
- Package insert
- Procedure Card (when applicable)

Materials required but not provided

- Timer

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 cassettes must remain in the

sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

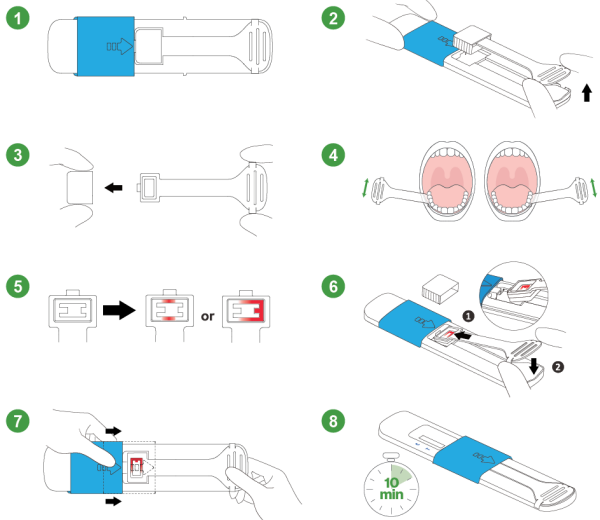
Collection and Storage of Specimens

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection cassettes should be used with this assay. Oral fluid collected at any time of the day may be used.

Test Procedure

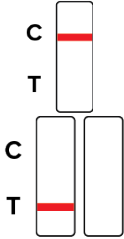
Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Instruct the donor to place the tongue against the roof of the upper or lower jaw and collect saliva in the mouth.
- Remove the swab from the cassette, then remove the cap from the swab.
- Instruct the donor to place the swab between the lower cheek and gum and gently rub back and forth between the left and right cheeks and gums until the sponge is completely saturated with saliva. Do not bite, suck, or chew the sponge as it may break.
- Remove the swab from the mouth, if the saturation indicator has turned red, insert the swab into the cassette. If the saturation indicator has not turned red, place the swab back in the mouth and continue to collect saliva until the saturation indicator turns red.
- Note: When inserting the swab into the cassette, insert the protruding part of the swab head into the hole reserved at the sampling site, and then press down the tail of the swab to secure it.**
- Move the slider in the direction of the arrow until the slider is blocked.
- Place the device on a flat surface while the test is running. Negative results can be read as soon as clear lines form in both the C and T zones of the test. Read presumptive positive results at 10 minutes. Do not read results after 20 minutes.



Results Interpretation

POSITIVE: Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test line region (T).
NOTE: The intensity of the color in the test line region (T) may vary depending on the concentration of THC present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.



NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Control

A procedural control is included in the test. A color 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

- The Rapid Response™ THC Lollipop UltraTrace provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. LC-MS/MS is the preferred confirmatory method.¹
- 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.
- 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.

Performance Characteristics

Analytical Sensitivity

Drug-free oral fluid was spiked with drugs to target concentrations of ±50% cut-off, and +300% cut-off and tested with the Rapid Response™ THC Lollipop UltraTrace. The results are summarized below.

Δ9-THC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
0.5	-50%	30	30	0
1	Cut-off	30	12	18
1.5	+50%	30	0	30
3	3X	30	0	30

Analytical Specificity

The following table lists compounds and their respective concentrations in oral fluid that yield a positive result in Rapid Response™ THC Lollipop UltraTrace at 10 minutes.

Compound	Concentration (ng/mL)
Δ9 -THC	1
11-nor-Δ9-THC-9 COOH	>100,000
11-nor-Δ9-THC-8 COOH	>100,000
Cannabinol	5
(±)-11-Hydroxy-Δ9-THC	5
Cannabidiol	200
9(R)-Hexahydrocannabinol	10
9(S)-Hexahydrocannabinol	20
(-)-Δ8 -THC	10

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free oral fluid or Marijuana positive oral fluid. The following compounds show no cross-reactivity when tested with THC Rapid Test Cassette (Oral Fluid) at a concentration of 10µg/mL

Non Cross-Reacting Compounds

4-Acetamidophenol	Estrone-3-sulfate	Penicillin-G
Acetophenetidin	Ethyl-p-aminobenzoate	Pentazocine
N-Acetylprocainamide	Fenoprofen	Pentobarbital
Acetylsalicylic acid	Furosemide	Perphenazine
Aminopyrine	Gentisic acid	Phencyclidine
Amitypyline	Hemoglobin	Phenelzine

Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
L-Ascorbic acid	Hydrocortisone	β-Phenylethylamine
D,L-Amphetamine	O-Hydroxyhippuric acid	Phenylpropanolamine
L-Amphetamine	3-Hydroxytyramine	Prednisolone
Apomorphine	Ibuprofen	Papaverine
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Procaine
Benzilic acid	(±) - Isoproterenol	Promazine
Benzoic acid	Isoxsuprine	Promethazine
Benzoylcegonine	Ketamine	D,L-Propanolol
Benzphetamine	Ketoprofen	D-Propoxyphene
Bilirubin	Labetalol	D-Pseudoephedrine
(±)-Brompheniramine	Levorphanol	Quinidine
Caffeine	Loperamide	Quinine
Chloralhydrate	Maprotiline	Ranitidine
Chloramphenicol	Meprobamate	Salicylic acid
Chlordiazepoxide	Methadone	Secobarbital
Chlorothiazide	Methoxyphenamine	Serotonin (5-Hydroxytyramine)
		Sulfamethazine

(±) Chlorpheniramine	(+) 3,4-Methylenedioxyamphetamine	
Chlorpromazine	(+) 3,4-Methylenedioxymethamphetamine	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methypyrrolon	Tetracycline
Clomipramine	Morphine-3-β-D-glucuronide	Tetrahydrocortisone, 3-Acetate
Clonidine	Nalidixic acid	Tetrahydrocortisone 3 (β-D-glucuronide)

Cocaine hydrochloride	Nalorphine	Tetrahydrozoline
Codeine	Naloxone	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	D, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-)-ψ-Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac
β-Estradiol		

Bibliography

- Lendoiro, E., et al. "Molecularly imprinted polymer for selective determination of Δ9-tetrahydrocannabinol and 11-nor-Δ9-tetrahydrocannabinol carboxylic acid using LC-MS/MS in urine and oral fluid." Analytical & Bioanalytical Chemistry (2014).

Glossary of Symbols

	Consult instructions for use		Tests per Kit		Unique device identifier
	Store between 35.6°F to 86°F (2-30°C)		Use by		Do Not Reuse
	Lot Number		Manufacturer		Catalogue #

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