Delta-9 THC Saliva Tracer Test
Package Insert
English

For employment and Insurance Only (Not FDA Cleared)

A rapid test for the qualitative detection of Marijuana in human oral fluid. For healthcare professionals including professionals at point of care sites. Immunoassay for invitro diagnostic use only.

【INTENDED USE】

The Delta-9 THC Saliva Tracer Test is a rapid chromatographic immunoassay for the detection of ∆9 -THC (THC parent) in human oral fluid at a cut-off concentration of 40ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method should be used to confirm a preliminary positive analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse screen test result, particularly when preliminary positive results are indicated.

【SUMMARY】

THC (∆9-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 slow 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 ∆9-THC is present in oral fluid 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 thesubsequent sequestering of the drug in the buccal cavity3. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use3.

The Delta-9 THC Saliva Tracer Test yields a positive result when the ∆9 -THC concentration in oral fluid exceeds 40 ng/mL.

【ASSAY PRINCIPLE】

Delta-9 THC Saliva Tracer Test 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. Marijuana, if present in the oral fluid specimen below 40ng/mL, will not saturate the binding sites of the antibody coated particles in the cassette. 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 Marijuana level is above 40ng/mL because it will saturate all the binding sites of anti-Marijuana 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 THC antibody-coupled particles and THC-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 ∆9-THC.

【PRECAUTIONS】

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Saliva 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.

【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.

【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 cassettes should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

- Test cassettes
- Package insert
- Procedure Card

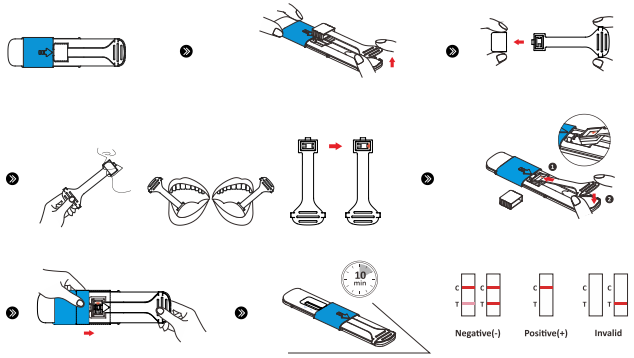
Materials Required but Not Provided

- Timer

【DIRECTIONS FOR USE】

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.

1. Bring the pouch to room temperature before opening. Remove the test from the sealed pouch and use within one hour of opening.
2. Instruct the donor to place the tongue against the root of the upper or lower jaw and collect saliva in the mouth.
3. Remove the swab from the cassette, then remove the cap from the swab.
4. 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.
5. Remove the sponge from the mouth when a clear red/pink color appears on the right side of the back of the sponge,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.
6. Move the slider in the direction of the arrow until the slider is blocked.
7. 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.



【INTERPRETATION OF RESULTS】

(Please refer to the previous illustration)

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 panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

【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.Delta-9 THC Saliva Tracer Test 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. [1,2]

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.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Delta-9 THC Saliva Tracer Test and GC/MS at the cut-off of 40ng/mL. Testing was performed on 99 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
Delta-9 THC Saliva Tracer Test	Results	Positive	Negative	
	Positive	45	0	45
	Negative	2	52	54
Total Results		47	52	99
% Agreement		95.7%	＞99%	98.0%

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off, ± 25% cut-off and +300% cut-off and tested with the Delta-9 THC Saliva Tracer Test. The results are summarized below.

∆9 -THC Concentration (ng/mL)	Percent of Cut-of	n	Visual Result	
			Negative	Positive
0	0	30	30	0
20	-50%	30	30	0
30	-25%	30	26	4
40	Cut-off	30	12	18
50	+25%	30	5	25
60	+50%	30	0	30
120	3X	30	0	30

Analytical Specificity

The following table lists compounds and their respective concentrations in oral fluid that yield a positive result in the Delta-9 THC Saliva Tracer Test at 10 minutes.

Compound	Concentration (ng/mL)
∆9 -THC	40
Cannabinol	40,000
(±)-11-Hydroxy- ∆9-THC	800
11- nor -∆9-THC-9 COOH	32
(-) ∆8 -THC	250
(±) ∆8 -THC	80

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 Delta-9 THC Saliva Tracer Test at a concentration of 100μg/ml.

Acetaminophen	Dextromethorphan	Isoxsuprine	β-Phenylethylamine
Acetone	Diclofenac	Kanamycin	Procaine
Acetophenetidin	Dicyclomine	Ketoprofen	Promethazine
Aspirin	Diflunisal	Labetalol	Quinacrine
Albumin	Digoxin	Lidocaine	Quinidine
Amoxapine	4-Dimethylaminoantipyrine	Lindane	Ranitidine
Amoxicillin	Diphenhydramine	Loperamide	Riboflavin
Ampicillin	5,5-Diphenylhydantoin	Meperidine	Sodium chloride
Ascorbic acid	Disopyramide	Methoxyphenamine	Sulfamethazine
Aspartame	Doxylamine	Metoprolol	Sulindac
Atropine	Dopamine	Nalidixic acid	Temazepam
Benzoic acid	(1R, 2S) - (-)-Ephedrine	(+)-Naproxen	Tetracycline
Bilirubin	Erythromycin	Nimesulide	Tetrahydrozoline
(+/-) Brompheniramine	Ethanol (Except ALC)	Norethindrone	Thebaine
Benzocaine	Etodolac	Noscapine	Theophylline
Buspirone	Famprofazone	Niacinamide	Thiamine
Caffeine	Fenoprofen	Norephedrine	Thioridazine
Chloramphenicol	Fluoxetine Hydrochloride	Orphenadrine	Tolbutamide
Chloroquine	Furosemide	Oxalic acid	Trazodone
(+/-)-Chlorpheniramine	Gentisic acid	Oxolinic acid	Triamterene
S- (+)-Chlorpheniramine maleate salt	D (+) Glucose	Oxymetazoline	Trifluoperazine
Chlorpromazine	Guaiacol Glyceryl Ether	Papaverine	Trimethoprim
Chlorprothixene	Hemoglobin	Pemoline	Trimipramine
Cimetidine	Hydralazine	Penicillin-G	Tryptamine
Clomipramine	Hydrochlorothiazide	Perphenazine	Tyramine
Clonidine	Hydroxyzine	Phenelzine	Uric acid
Creatine	Imipramine	Pheniramine	Verapamil
Cyclobenzaprine	Isoproterenol hydrochloride	Phenothiazine	Zomepirac

【BIBLIOGRAPHY】

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