

Rapid Response®

Marijuana (THC) Saliva Test Stick

REF THC-2L157-25
REF THC-2L156-25
REF THC-2L11-25
REF THC-2L5-25

Product Insert

For forensic use only.

Intended Use

The Rapid Response® Marijuana (THC) Saliva Test Stick is a rapid visual immunoassay for the qualitative, presumptive detection of THC parent (Δ^9 -THC) in human saliva specimens. The test system consists of a membrane strip mounted in a plastic cassette.

Test	Calibrator	Cut-off (ng/mL)
Marijuana (THC)	Δ^9 -THC	1/6/10/25

Principle

The Rapid Response® Marijuana (THC) Saliva Test Stick has been designed to detect the THC parent through visual interpretation of color development in the Device. The membrane was immobilized with THC parent antibodies on the test region, and the sample pad was pre-coated with colored anti-THC parent antibodies colloidal gold conjugates. During testing, the specimen reacts with anti-THC antibodies conjugated to colored particles and precoated onto the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient THC in the specimen, a colored line will form at the test region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result. The appearance of a colored line at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For forensic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local

regulations.

Materials

Materials provided

- Individually packed test devices
- Product insert
- Quick reference card

Materials required but not provided

- Timer
- Pipette
- Positive and negative controls
- Centrifuge

Storage and Stability

- The kit should be stored at 2-30°C (35.6-86°F) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

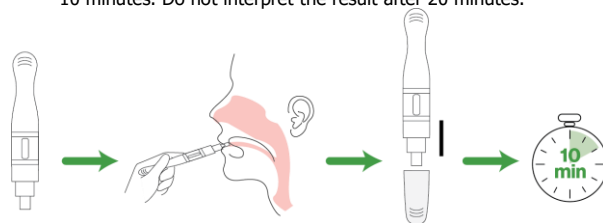
Collection and Storage of Specimens

- The Rapid Response® Marijuana (THC) Saliva Test Stick is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

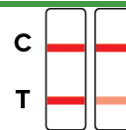
Test Procedure

Bring tests, specimens, and/or controls to room temperature (15-30°C; 59-86°F) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

- Remove the cap by holding the sides and pulling gently. This will expose the collection pad.
- Place the collection pad underneath the tongue to collect saliva. Instruct the donor to hold the device in place with hand.
- Remove from mouth as soon as color move in the test window. Re-cap the device.
As the test begins to work, color will migrate across the membrane.
- Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



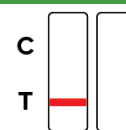
Results Interpretation



POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.



NEGATIVE: Only one colored line appears, in the control region (C). No colored line appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.



INVALID: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Control

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response® Marijuana (THC) Saliva Test Stick is for forensic use only, and should be only used for the qualitative detection of drugs in oral fluid.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
- A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.

- A negative result does not at any time rule out the presence of drugs/metabolites in saliva, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs and certain medications.

Performance Characteristics

Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of \pm 50% cut-off and \pm 25% cut-off and tested with Rapid Response® Marijuana (THC) Saliva Test Stick. The results are summarized below:

Drug Conc. (Cut-off range)	n	THC1		THC6		THC10		THC25	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	26	4	12	18	10	20	14	16
-25% Cut-off	30	19	11	10	20	7	23	0	30
Cut-off	30	0	30	0	30	0	30	0	30
+25% Cut-off	30	0	30	0	30	0	30	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30

Specificity

The following table lists the concentrations of compounds (ng/mL) above which the Rapid Response® Marijuana (THC) Saliva Test Stick identified positive results at 10 minutes.

THC 1-Related Compounds	
Δ^9 -Tetrahydrocannabinol	1
Cannabidiol	12000
Cannabinol	800
Methaqualone	20000
Isoxsuprine hydrochloride	30000
Omeprazole	40000
Δ^8 -Tetrahydrocannabinol	2000
(\pm)-11-Hydroxy- Δ^9 -THC	80
11-nor- Δ^9 -THC-9 COOH	>2000

THC 6 Related Compounds	
Δ^9 -Tetrahydrocannabinol	6
Cannabidiol	15000
Cannabinol	900
Methaqualone	20000
Isoxsuprine hydrochloride	30000
Omeprazole	40000
Δ^8 -Tetrahydrocannabinol	2000
(\pm)-11-Hydroxy- Δ^9 -THC	100
11-nor- Δ^9 -THC-9 COOH	>2000

THC 10-Related Compounds	
Δ^9 -Tetrahydrocannabinol	10
Cannabidiol	15000
Cannabinol	1000
Methaqualone	20000
Isoxsuprine hydrochloride	30000
Omeprazole	40000
Δ^8 -Tetrahydrocannabinol	2500
(\pm)-11-Hydroxy- Δ^9 -THC	150

11-nor- Δ 9 -THC-9 COOH	>2000
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THC 25 -Related Compounds	
Δ 9-Tetrahydrocannabinol	25
Cannabidiol	15000
Cannabinol	800
Methaqualone	20000
Isoxsuprine hydrochloride	30000
Omeprazole	40000
Δ 8-Tetrahydrocannabinol	2500
(\pm)-11-Hydroxy- Δ 9-THC	100
11-nor- Δ 9 -THC-9 COOH	>2000










A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Rapid Response[®] Marijuana (THC) Saliva Test Stick when tested at concentrations up to 100 μ g/mL.

(-)-Ephedrine	(+)-Naproxen
(+/-)-Ephedrine	4-Dimethylaminoantipyrine
Acetaminophen	Acetone
Albumin	Amitriptyline
Ampicillin	Aspartame
Aspirin	Benzocaine
Bilirubin	b-Phenylethyl-amine
Caffeine	Chloroquine
Chlorpheniramine	Creatine
Dextromethorphan	Dextrophan tartrate
Dopamine	Erythromycin
Ethanol	Furosemide
Glucose	Guaiacol Glyceryl Ether
Hemoglobin	Ibuprofen
Imipramine	Isoproterenol
Lidocaine	Methadone
Oxalic Acid	Penicillin-G
Pheniramine	Phenothiazine
Procaine	Protonix
Pseudoephedrine	Quinidine
Ranitidine	Sertraline
Tyramine	Vitamin C (Ascorbic Acid)
Trimeprazine	Venlafaxine

Bibliography

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
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4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

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	 Catalogue #	 Manufacturer

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