

CDIA™ Marijuana Colloidal Gold Test Cassette (Saliva)

Cat. No.: DTSJZ023

Pkg. Size:

Intended Use

The CDIA™ Marijuana Colloidal Gold Test Cassette (Saliva) is an immunochromatography based one step in vitro test. It is designed for qualitative determination of marijuana metabolites (THC) in human oral fluid specimens. This assay provides only a preliminary analytical test result. 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 Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

General Description

Tetrahydrocannabinol, the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in saliva 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 saliva of up to 14 hours after drug use. The CDIA™ Marijuana Colloidal Gold Test Cassette (Saliva) yields a positive result when the THC-COOH concentration exceeds 12 ng/mL.

Principle of the Test

CDIA™ Marijuana Colloidal Gold Test Cassette (Saliva) 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 portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip

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45-1 Ramsey Road Shirley, NY 11967, USA

Tel: 631-624-4882 Fax: 1-631-938-8221

E-mail: info@creative-diagnostics.com

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because of drug competition, while a drug-negative oral fluid 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.

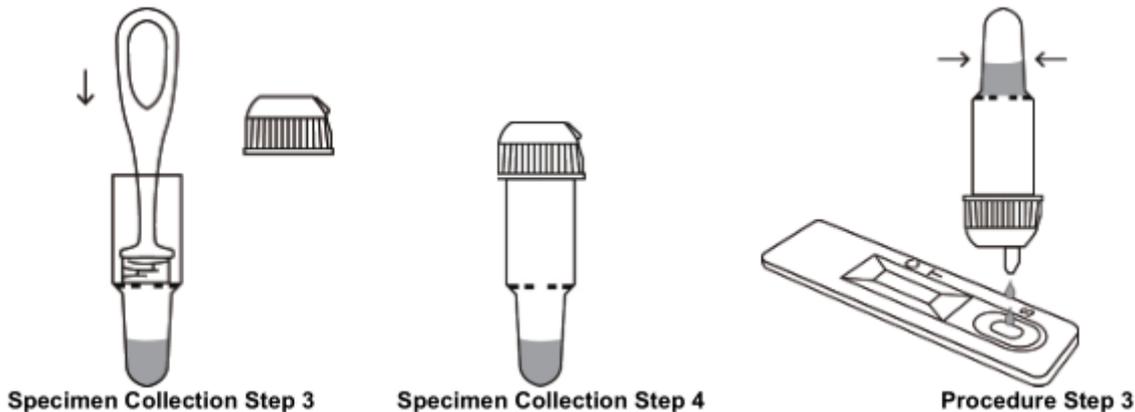
Materials Provides

1. Test Cassette device
2. Oral fluid collection swabs
3. Oral fluid collection tube.
4. Instruction for use.

Specimen Collection and Preparation

Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

1. Remove the oral fluid collection swab from the sealed pouch and insert the sponge end of the oral fluid collection swab into the mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for a total of 3 minutes until the sponge becomes fully saturated. Gentle pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
2. Remove the oral fluid collection swab from the mouth.
3. Place the saturated swab into the collection chamber and press the sponge firmly down on the plastic strainer to release as much liquid as possible.
4. Tightly shut the outer cap of the collection tube.



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Quality Control

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 50% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

Marijuana (THC) Saliva Test Cassette provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Assay Operation

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

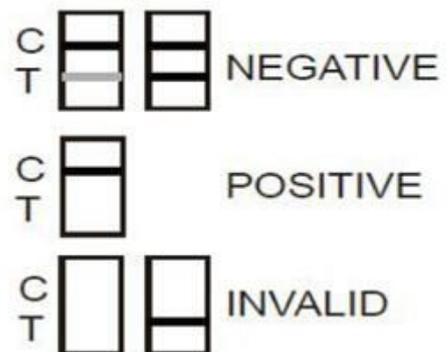
1. Remove the test Cassette from sealed pouch and use it within one hour.
2. Open the dropper tip of the collection tube.
3. Invert the collection tube and transfer 2 drops of oral fluid (approximately 80 uL) in to the specimen well (S) of the test Cassette. Avoid ping air bubbles in the specimen well.
4. Read results at 10 minutes.

Note: Do not interpret the results after 20 minutes.

Results

Negative: Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug and their metabolites in the specimen, it only indicates the level of tested drug and their metabolites in the specimen is less than cut-off level.

Positive: One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug and their metabolites in the specimen is above the cut-off level.



Invalid: If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.

Note: A borderline (\pm) in test line zone should be considered negative result.

Expected Results

Marijuana(THC) Saliva Test Cassette is a qualitative assay. It identifies the drug in human saliva at its cut-off concentration or higher. The concentration of the drug can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

Expected Results

A. Sensitivity

The cut-off concentration (sensitivity level) of the Marijuana (THC) Saliva Test Cassette is determined to be: THC 25 ng/ml. 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 the Marijuana (THC) Saliva Test Cassette. The results are summarized below.

Drug Conc.(Cut-off range)	n	THC	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	29	1
Cut-off	30	8	22
+25% Cut-off	30	2	28
+50% Cut-off	30	0	30

B. Precision

The precision of Marijuana (THC) Saliva Test Cassette was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 30 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

C. Specificity

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

Tests	Compounds	Concentration (ng/ml)
THC	11-nor- Δ 9 -THC-9 COOH	25
	Δ 8-Tetrahydrocannabinol	2,000
	Δ 9-Tetrahydrocannabinol	4,000
	11-hydroxy- Δ 9 -THC	300

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 Marijuana (THC) Saliva Test Cassette when tested at concentrations up to 100 ug/mL.

Acetamidophenol	Acetaminophen	Acetylsalicylic acid	6-Acetylmorphine
Alfentanil HCL	7-Aminoflunitrazepam	7-Aminoclonazepam	Alprazolam
7-Aminonitrazepam	Amitriptyline Hydrochloride	Amobarbital Sodium	(\pm)Amphetamine
Ascorbic acid	Atenolol	Atropine	Benzoylcegonine
Bromazepam	Buprenorphine	Butalbital	Caffeine
Cannabidiol	Cannabinal	Chlordiazepoxide	Chloroquine
Chlorpheniramine	Cis-Tramadol	Citalopram HBr	Clobazam
Clonazepam	Cocaine Hydrochloride	Codeine	Cortisone
Cotinine	(-)- Δ 8-THC	(-)- Δ 9-THC	Desipramine
Dextromethorphan	Doxylamine succinate	Digitoxin	Digoxin
Dihydrocodeine	Diphenhydramine	Doxepin	Diazepam
d-Pseudoephedrine	EDDP Perchlorate	EMDP	Estazolam
Ethylmorphine	(-)-Ephedrine Hydrochloride	Fentanyl	Flunitrazepam
Fluoxetine	Guaiacol glycer ester	Gentisic acid	Flurazepam
Heroin	Hydrochlorothiazine	Hydrocodone	Hydromorphone
Hydroxyzine	(\pm)-11-Hydroxy- Δ 9-THC	Ibuprofen	Ketamine
Isoproterenol	Imipramine Hydrochloride	Lidocaine	Lorazepam
Lormetazepam	(\pm)-MBDB	(\pm)-MDA	(\pm)MDEA
(\pm)-MDMA	(\pm)Methamphetamine	(\pm)Methadone	Meperidine
Methaqualone	(+)-Methamphetamine	Methylphenidate	Midazolam
Morphine	Morphine-3- β -glucuronide	Nalbuphine	Nalorphine
Naloxone	N-Desmethyl-cis tramadol	Natrexone	Neomycin
Niacinamide	(-)-11-nor-9-Carboxy- Δ 9-THC	Norbuprenorphine	Nitrazepam
Norcodeine	Nordiazepam	(\pm)-Norketamine	Normorphine
Norsertaline	Norpropoxyphene	Nortriptyline	Oxazepam
Orphenadine	O-Desmethyl-cis tramadol	Oxcarbazepine	Oxycodone
Oxymorphone	Pentobarbital	Perphenazine	Phencyclidine
Phenobarbital	β - Phenylethylamine	Phenylpropanolamine	Prazepam
Promethazine	Propoxyphene	(\pm)-Propranolol	Protriptyline
Quetiapine fumarate	R(-)-Epinephrine	R(-)-Methamphetamine	Ranitidine
Ritalinic acid	S(-)-Nicotine	Salicylic acid	Secobarbital
Sertraline	Temazepam	Tetracycline	Tetrahydrozoline
Theophylline	Theophylline	Triazolam	Trimipramine
Tyramine	Venlafaxine	Verapamil	

Storage and Stability

The test device should be stored at 4 to 30°C and will be effective until the expiration date stated on the package. The product is humidity -sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

Limitation

1. The Marijuana (THC) Saliva Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

Precautions

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Saliva is not classified as biological hazard unless derived from a dental procedure.