

T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel

Catalogue No. See Box Label

SAFElife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Marijuana in human urine with below cutoff concentrations and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level	Minimum Detection Time	Maximum Detection Time
Marijuana (THC 15)	11-nor- Δ^9 -THC-9-COOH	15 ng/mL	2 hours	Up to 5+ days
Marijuana (THC 50)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days
Marijuana (THC 100)	11-nor- Δ^9 -THC-9-COOH	100 ng/mL	2 hours	Up to 5+ days
Marijuana (THC 200)	11-nor- Δ^9 -THC-9-COOH	200 ng/mL	2 hours	Up to 5+ days
Marijuana (THC 300)	11-nor- Δ^9 -THC-9-COOH	300 ng/mL	2 hours	Up to 5+ days

It is intended for forensic use only.

The test is not intended to distinguish between prescription use or abuse of this drug. Professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The test provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 10 minutes.

CONTENTS OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant.
- The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or Clock

STORAGE AND STABILITY

1. Store at 39°F–86°F (4°C–30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time of Marijuana (THC) is 2 hours, urine specimens may be collected 2 hours after the suspected drug use.

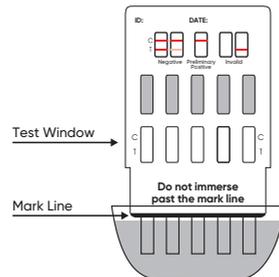
HOW TO COLLECT URINE?

Instruct the donor to void directly into the urine collection cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the urine collection cup with urine specimen.

TEST PROCEDURE

Test should be performed at room temperature 65°F–86°F (18°C–30°C).

1. Remove the test device from the foil pouch by tearing at the notch. Use it as soon as possible.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine specimen close to the Mark Line for at least 15 seconds or the urine migrate up along strip until reach the test window area. **Make sure that the urine level is not above the Mark Line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 10 minutes.**



Note: Results after more than 10 minutes may be not accurate and should not be read.

READING THE RESULTS

Negative (-)

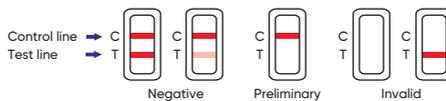
A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of Marijuana (THC) is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result and the concentration of Marijuana (THC) is above the detection limit of the test.

Invalid

If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.



Note: There is no meaning attributed to band color intensity or width.

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests.

What Is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by the SAFElife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by the SAFElife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel. If the specimen is diluted or adulterated, it may cause the false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been

- evaluated. DO NOT use it to test anything other than urine.
2. Adulterated urine specimens may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
 3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
 4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of Marijuana (THC) or the level of intoxication.

SUMMARY

Marijuana refers to the dried leaves, flowers, stems, and seeds from the Cannabis sativa or Cannabis indica plant. Marijuana is a psychoactive drug that contains close to 500 chemicals, including THC, a mind-altering compound that causes harmful health effects. People smoke marijuana in hand-rolled cigarettes, in pipes or water pipes, in blunts, and by using vaporizers that pull THC from the marijuana. Marijuana can also be mixed in food (edibles), such as brownies, cookies, and candy, or brewed as a tea. People also smoke or eat different forms of marijuana extracts, which deliver a large amount of THC and can be potentially more dangerous.

PRINCIPLE

The SAFElife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel is a competitive immunoassay that is used to screen for the presence of Marijuana in urine. It is chromatographic absorbent device in which drugs in a specimen competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band that, regardless of its intensity, which indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result.

To serve as a procedure control, a colored band will appear at the Control Region (C), if the test has been performed properly. This control band should always appear regardless of the presence of drug or metabolite. If the control band does not appear, the test device should be discarded.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control band in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

30 drug-free urine specimens were collected, then used high positive sample (calibrated by GC/MS or LC-MS/MS) and these drug-free urine specimens to produce positive sample with appropriate concentration for each strip as the following table and tested with the SAFElife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel. Each test was read by three viewers. Results were summarized as follows:

Result	THC15			% Agreement with GC/MS or LC/MS
	Drug Free	7.5 ng/ml	25 ng/ml	
Viewer A	+	0	0	100
	-	30	0	100
Viewer B	+	0	30	100
	-	30	0	100
Viewer C	+	0	30	100
	-	30	0	100

THC50					
Result	Drug Free	25 ng/ml	75 ng/ml	% Agreement with GC/MS or LC/MS	
Viewer A	+	0	0	30	100
	-	30	30	0	100
Viewer B	+	0	0	30	100
	-	30	30	0	100
Viewer C	+	0	0	30	100
	-	30	30	0	100
THC100					
Result	Drug Free	75 ng/ml	150 ng/ml	% Agreement with GC/MS or LC/MS	
Viewer A	+	0	0	30	100
	-	30	30	0	100
Viewer B	+	0	0	30	100
	-	30	30	0	100
Viewer C	+	0	0	30	100
	-	30	30	0	100
THC200					
Result	Drug Free	150 ng/ml	300 ng/ml	% Agreement with GC/MS or LC/MS	
Viewer A	+	0	0	30	100
	-	30	30	0	100
Viewer B	+	0	0	30	100
	-	30	30	0	100
Viewer C	+	0	0	30	100
	-	30	30	0	100
THC300					
Result	Drug Free	250 ng/ml	600 ng/ml	% Agreement with GC/MS or LC/MS	
Viewer A	+	0	0	30	100
	-	30	30	0	100
Viewer B	+	0	0	30	100
	-	30	30	0	100
Viewer C	+	0	0	30	100
	-	30	30	0	100

Precision and Sensitivity

To investigate the precision and sensitivity, each strip was analyzed at the following concentrations in the table. The study used three different lots of the SAFELife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel. The data are summarized below:

Drug test	Approximate Concentration of Sample (ng/mL)	Number of determinations per lot	Results (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
THC15	0	10	10/0	10/0	10/0
	7.5	10	10/0	10/0	10/0
	11.25	10	8/2	7/3	8/2
	15	10	4/6	5/5	6/4
	18.75	10	3/7	2/8	1/9
	22.5	10	0/10	0/10	0/10
	30	10	0/10	0/10	0/10
THC50	0	10	10/0	10/0	10/0
	25	10	10/0	10/0	10/0
	37.5	10	8/2	8/2	6/4
	50	10	5/5	5/5	7/3
	62.5	10	3/7	2/8	2/8
	75	10	0/10	0/10	0/10
	100	10	0/10	0/10	0/10
THC100	0	10	10/0	10/0	10/0
	50	10	10/0	10/0	10/0
	75	10	7/3	6/4	8/2
	100	10	4/6	7/3	5/5
	125	10	2/8	3/7	2/8
	150	10	0/10	0/10	0/10
	200	10	0/10	0/10	0/10
THC200	0	10	10/0	10/0	10/0
	100	10	10/0	10/0	10/0
	150	10	8/2	8/2	9/1
	200	10	6/4	7/3	7/3

	250	10	3/7	4/6	2/8
	300	10	0/10	0/10	0/10
	400	10	0/10	0/10	0/10
THC300	0	10	10/0	10/0	10/0
	150	10	10/0	10/0	10/0
	225	10	9/1	9/1	8/2
	300	10	7/3	7/3	6/4
	375	10	3/7	3/7	4/6
	450	10	0/10	0/10	0/10
	600	10	0/10	0/10	0/10

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Substance	Concentration (ng/mL)	Substance	Concentration (ng/mL)
Marijuana (THC15)		Marijuana (THC200)	
11-nor- Δ^9 -THC-9-COOH	15	11-nor- Δ^9 -THC-9-COOH	200
11-hydroxy- Δ^9 -Tetrahydrocannabinol	25,000	11-hydroxy- Δ^9 -Tetrahydrocannabinol	50,000
Δ^8 -Tetrahydrocannabinol	25,000	Δ^8 -Tetrahydrocannabinol	100,000
Δ^9 -Tetrahydrocannabinol	25,000	Δ^9 -Tetrahydrocannabinol	50,000
Cannabinol	25,000	Cannabinol	50,000
Cannabidiol	50,000	Cannabidiol	>100,000
Marijuana (THC50)		Marijuana (THC300)	
11-nor- Δ^9 -THC-9-COOH	50	11-nor- Δ^9 -THC-9-COOH	300
11-hydroxy- Δ^9 -Tetrahydrocannabinol	50,000	11-hydroxy- Δ^9 -Tetrahydrocannabinol	>100,000
Δ^8 -Tetrahydrocannabinol	100,000	Δ^8 -Tetrahydrocannabinol	100,000
Δ^9 -Tetrahydrocannabinol	50,000	Δ^9 -Tetrahydrocannabinol	50,000
Cannabinol	50,000	Cannabinol	50,000
Cannabidiol	>100,000	Cannabidiol	>100,000
Marijuana (THC100)			
11-nor- Δ^9 -THC-9-COOH	100		
11-hydroxy- Δ^9 -Tetrahydrocannabinol	50,000		
Δ^8 -Tetrahydrocannabinol	100,000		
Δ^9 -Tetrahydrocannabinol	50,000		
Cannabinol	50,000		
Cannabidiol	>100,000		

Effect of Urinary Specific Gravity

The results demonstrate that the urinary specific gravity range of 1.000-1.021 does not affect the test results.

Effect of Urinary pH

The results demonstrate that the range of urinary pH from 5 to 9 does not interfere with the performance of test.

Interfering Substances

The following compounds were added to drug-free urine, urine with drug concentration 25% below the cutoff, and urine with drug concentration 25% above the cutoff for the corresponding SAFELife™ T-Dip Marijuana (THC) Multi-Level Urine Drug Test Panel. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetaminophen	Bupropion	Cocaine
Acetylcodine	Buspirone	Codeine
Acetylsalicylic Acid	Captopril	Cyclobenzaprine
Acyclovir	Carbamazepine	Dexlansoprazole
Adrenaline	Cefaclor	Dextromethorphan
Alprazolam	Cefradine	Diazepam
Aminophylline	Cephalexin	Diclofenac
Amiodarone	Chlorpheniramine	Dicyclomine
Amitriptyline	Chlorpromazine	Digoxin
Amiodipine	Ciprofloxacin	Diltiazem
Amoxicillin	Citalopram	Diphenhydramine
Ampicillin	Clarithromycin	Diphenoxylate
Aripiprazole	Clomipramine	Dirthromycin
Atorvastatin	Clopidogrel	Domperidone

Dopamine	Metoprolol Tartrate	Pioglitazone
Doxepin	Midomafetamine	Piracetam
D-Proproxyphene	Mifepristone	Pravastatin
Duloxetine	Mirtazapine	Prednisone
Enalapril Maleate	Minocycline	Procaine
Estradiol	Montelukast Sodium	Promethazine
Estroven	Mosapride Citrate	Pranoprolo
Extenze	Naloxone	Propylthiouracil
Fenofibrate	Naltrexone	Pseudoephedrine
Fluoxetine	Nifedipine	Quetiapine
Fluvoxamine	Nimodipine	Ranitidine
Furosemide	Nitrazepam	Rifampicin
Gabapentin	Noscapine	Risperidone
Gibenzamide	O3-Monoacetylmorphine	Secobarbital
Gilclazide	Olanzapine	Sertraline
Glucosamine Chondroitin	Omeprazole	Sildenafil Citrate
Glucose	Ondansetron	Simvastatin
Hydrochlorothiazide	Oxazepam	Sodium Levothyroxine
Hydrocortisone	Papaverine	Sodium Valproate
Isosorbide Dinitrate	Paracetamol	Spirolactone
Ketoconazole	Paroxetine	Tetracycline
Kratom	Perfluridol	Tizanidine
Lactose	Penicillin V Potassium	Topiramate
Lamotrigine	Perphenazine	Tramadol
Lansoprazole	Pethidine	Trazodone
Levofloxacin	Phenelzine	Triamterene
Levonorgestrel	Phenibut	Ursodeoxycholic Acid
Lidocaine	Phenobarbital	Vitamin B1
Lithium Carbonate	Phentolamine	Vitamin B2
Loperamide	Phenylephrine	Vitamin C
Loratadine	Phenytoin	
Methadone	Pholcodine	

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll-Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

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 Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR (ed): Drug Addiction I, New York, Spring - Verlag, 1977.
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 Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
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INDEX OF SYMBOLS

	Keep away from sunlight
	Store between 39°F - 86°F (4°C - 30°C)
	Keep dry
	Do not reuse
	Consult instructions for use

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