CLIA WAIVED
One Step Cannabinoids Urine Test
Catalog No. See Pouch Label

The One Step Cannabinoids Urine Test is a rapid test for the qualitative detection of 11-nor-Δ9-THC-9-COOH (major metabolite of Cannabinoids) in human urine at specified cut-off level.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use and it is CLIA WAIVED.

WHAT IS THE ONE STEP CANNABINOIDS URINE TEST?

The One Step Cannabinoids Urine Test is an immunochromatographic assay for the qualitative determination of *11-nor-Δ9-THC-9-COOH (major metabolite of Cannabinoids)* in human urine. It is intended for over-the-counter and for prescription use.

The test is intended for over-the-counter (OTC) use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing - the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is not provided.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug(Identifier)	Cut-off level	Minimum detection time	Maximum detection time
11-nor-Δ9-THC-9-COOH /THC	50 ng/mL	2 hours	Up to 5+ days

WARNINGS AND PRECAUTIONS

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

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is only for storage purposes, and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (40ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

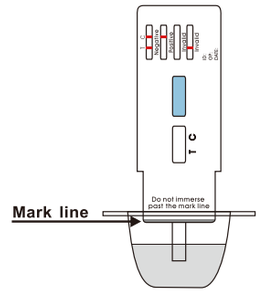
The minimum detection time is 2 hours, urine samples may be collected 2 hours after the suspected drug use.

HOW TO COLLECT URINE?

1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at 2ºC-8°C (36ºF-47ºF) and stored up to forty-eight hours. For longer storage, freeze the samples at -20°C (-4ºF) or below.
2. Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well-mixed before analysis. Cloudy specimens should be centrifuged before analysis.
3. Use only clear aliquots for testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)
1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the 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 sample for about 10 seconds. **Make sure that the urine level is not above the marker line printed on the front of the device.**
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes**.



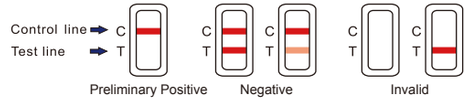
***Note:** Results after more than 5 minutes may be not accurate and should not be read.*

READING THE RESULTS

Preliminary positive (+)
A rose-pink band is visible in the control region. No color band appears in the test region. It indicates a preliminary positive result for the 11-nor-Δ9-THC-9-COOH.

Negative (-)
A rose-pink band is visible in the control region and the test region. It indicates that the concentration of 11-nor-Δ9-THC-9-COOH is zero or below the detection limit of the test.

Invalid
If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.



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

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample should be tested by a laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by the One Step Cannabinoids Urine Test. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial 11-nor-Δ9-THC-9-COOH is present but isn't detected by the One Step Cannabinoids Urine Test. If the sample is diluted, or the sample is adulterated that may cause false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

The test is also intended for prescription use. The below sections are for the reference of prescription users. The above sections of WARNINGS AND PRECAUTIONS, CONTENT OF THE KIT, STORAGE AND STABILITY, TEST PROCEDURE, READING THE RESULTS, and TEST LIMITATIONS also apply to the prescription users.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

SUMMARY

Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

PRINCIPLE

The One Step Cannabinoids Urine Test is a competitive immunoassay that is used to screen for the presence of 11-nor-Δ9-THC-9-COOH in urine. It is chromatographic absorbent device in which 11-nor-Δ9-THC-9-COOH in a sample competitively combined to a limited number of anti-11-nor-Δ9-THC-9-COOH monoclonal antibody (mouse) conjugate binding sites.
When the test is activate, the urine is absorbed into the device by capillary action, mixes with the Cannabinoids monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-11-nor-Δ9-THC-9-COOH monoclonal antibody (mouse) conjugate binds to the Cannabinoids-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.
When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the Cannabinoids monoclonal antibody conjugate preventing the Cannabinoids monoclonal antibody conjugate from binding to the Cannabinoids-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

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 line in the test device in the Control Region, 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.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the One Step Cannabinoids Urine Test dip card. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	Drug-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	18	22
Negative	10	12	17	0	0

% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

Viewer B:

Result	Drug-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	18	22
Negative	10	12	17	0	0

% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

Viewer C:

Result	Drug-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	18	22
Negative	10	12	17	0	0

% agreement among positives is 100% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.5% (95% Confidence Interval 87.12% - 99.56%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 100%
The average negative agreement is 97.5%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: +100%, +75% +50%, +25%, cut off, -25%, -50%, -75% and -100% of cutoff. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots. Totally 3 operators participated in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
12.5	50	50/0
25.0	50	50/0
37.5	50	50/0
50.0	50	4/46
62.5	50	0/50
75.0	50	0/50
87.5	50	0/50
100.0	50	0/50

Lot 2

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
12.5	50	50/0
25.0	50	50/0
37.5	50	50/0
50.0	50	4/46
62.5	50	0/50
75.0	50	0/50
87.5	50	0/50
100.0	50	0/50

Lot 3

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
12.5	50	50/0
25.0	50	50/0
37.5	50	50/0
50.0	50	5/45
62.5	50	0/50
75.0	50	0/50
87.5	50	0/50
100.0	50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test Cannabinoids, 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.

Component	Concentration (ng/ml)
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	30
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500
Δ8- Tetrahydrocannabinol	7,500
Δ9- Tetrahydrocannabinol	10,000
Cannabinol	100,000
Cannabidiol	100,000

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.005-1.025) are collected and spiked with 11-nor-Δ9-THC-9-COOH at 25% below and 25% above cutoff level. Each sample was tested by three batches of the One Step Cannabinoids Urine Test dip card. Three laboratory assistants read the result per batch. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with 11-nor-Δ9-THC-9-COOH at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the One Step Cannabinoids Urine Test dip card. Three laboratory assistants read the result per batch. The result demonstrates that varying range of pH do not interfere with the performance of the test.

Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a 11-nor-Δ9-THC-9-COOH concentration 25% below the cutoff, and urine with a 11-nor-Δ9-THC-9-COOH concentration 25% above the cutoff. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
Ascorbic acid
D,L-Amphetamine
L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
Brompheniramine
Caffeine
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Cre atinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
(-) Y Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meprobamate
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxyamphetamine
(+)3,4-Methylenedioxymethamphetamine
Methylphenidate
Methyprylon
Morphine-3-β-Dglucuronide
Nalorphine
Naloxone
Nalidixic acid
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
p-Hydroxymethamphetamine
Papaverine
Penicillin-G
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethlamine
β-Phenyllethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3 Acetate
Tetrahydrocortisone3 (5-Dglucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D, L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
PrD, L-Tyrosine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY OF SUGGESTED READING

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Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988
Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4ºC - 30ºC (40ºF - 86ºF)


Keep dry


Do not re-use

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