GENACHECK

RAPID SELF-TEST KIT FOR **CANNABIS**

5 MINS

- Highly Sensitive (Detection Limit ~50ng/ml)
- FDA Cleared for At-Home Use
- Highly Specific (No Cross-Reactive With 92 drugs)
- Rapid One Step Test (5 Minutes)

Website: www.genabio.com | Email: info@genabio.com | Phone: 1-800-614-3365

ACCURACY

A comprehensive analysis of 80 clinical urine specimens was conducted by using GC/MS in conjunction with the GenaCheck™ Rapid Self-Test Kit for Cannabis. Each test was administered by three skilled operators.

The samples were categorized based on their concentration into five distinct groups: drug-free, below half the cut-off point, near cut-off negative, near cut-off positive, and high positive. The results were exceptionally consistent, demonstrating an impressive 95.8% agreement among positive results and a perfect 100% agreement among negative results.

GenaCheck™ Rapid Self-Test Kit For Cannabis		Drug-free	Low Negative (Less than half the cut-off concentration)	Near Cut-Off Negative (Between 50% below the cut-off and the cut-off concentration)	Near Cut-Off Positive (Between the cut-off and 50% above the cut-off concentration)	High Positive (greater than 50% above the cut-off concentration
Operator A	Positive	0	0	0	13	26
	Negative	10	16	16	1	0
Operator B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

ANALYTICAL SENSITIVITY

We conducted testing on a total of 150 samples, thoughtfully distributed into five concentration categories: -50% Cut-Off, -25% Cut-Off, Cut-Off, +25% Cut-Off, and +50% Cut-Off. This rigorous testing was carried out using three separate lots of each device and managed by three distinct operators.

The results were consistent and reassuring. All samples at and above +25% Cut-Off displayed positive results for Cannabis, affirming the device's reliability in detecting concentrations above the verified cut-off value of 50 ng/mL. Similarly, all samples at and below -25% Cut-Off yielded negative results, showcasing the device's precision in detecting concentrations below this threshold.

INCLUSIVITY

The following table lists compounds that are positively detected in urine by the GenaCheck™ Rapid Self-Test Kit for Cannabis Dip Card Device.

Drug	Concentration (ng/ml)
MARIJUANA (THC)	50
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
Δ^8-THC-COOH	50,000

PRECISION

This study was conducted over a course of 25 days for each format, with two runs performed daily. The study involved three different lots and engaged three operators, each of whom was unaware of the sample number system. Every operator conducted two runs per day, testing two aliquots at each concentration for each lot. This resulted in a total of 50 determinations made by each operator at each concentration.

11-nor-Δ⁹-THC-9-COOH concentration (ng/mL)	N	Lot 1		Lot 2		Lot 3	
		negative	positive	negative	negative	negative	positive
0	0	50	0	50	50	50	0
12.5	12.5	50	0	50	50	50	0
25	25	50	0	50	50	50	0
37.5	37.5	50	0	50	50	50	0
50	50	20	30	20	20	20	30
62.5	62.5	0	50	0	0	0	50
75	75	0	50	0	0	0	50
87.5	87.5	0	50	0	0	0	50
100	100	0	50	0	0	0	50

EFFECT OF URINARY SPECIFIC GRAVITY

We examined the impact of urinary specific gravity using fifteen (15) urine samples with varying specific gravity values, ranging from 1.000 to 1.035. These samples included normal, high, and low specific gravity. Drugs were spiked into these samples at levels 25% below and 25% above the cut-off thresholds. The GenaCheck™ Rapid Self-Test Kit for Cannabis Dip card was tested in duplicate, with ten drug-free urine samples and ten spiked urine samples. The results conclusively demonstrate that a wide range of urinary specific gravity values does not influence the test results.

EFFECT OF URINARY pH

In another study, we assessed the effect of urinary pH on test performance. We adjusted the pH of a negative urine pool within the range of 4.00 to 9.00 in 1 pH unit increments. The urine was spiked with the target drug at levels 25% below and 25% above the cut-off values. The GenaCheck™ Rapid Self-Test Kit for Cannabis Dip card was employed for testing. The results unequivocally indicate that variations in pH within this range do not interfere with the test's accuracy.

CROSS-REACTIVITY

When tested with the GenaCheck™ Rapid Self-Test Kit for Cannabis Dip card at a concentration of 100 µg/mL, the following compounds exhibited no cross-reactivity with the test.

NON CROSS-REACTING COMPOUNDS

Acetophenetidin	Cotinine(-)	Cortisone	Pseudoephedrine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinidine
Acetylsalicylic acid	Dexamethasone	Labetalol	Quinine
Amiloride	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Desipramine	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Droperidol	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrozoline
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide

p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α -Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

LAY USER STUDY

We conducted a comprehensive lay user study across three intended user sites, involving 140 lay individuals. For the GenaCheck™ Rapid Self-Test Kit for Cannabis device study specifically, 65 females and 75 males participated in testing the Cannabis sample. Our diverse group of participants possessed a wide range of educational and professional backgrounds and spanned in age from 21 to over 50 years.

Urine samples were meticulously prepared, covering a spectrum of concentrations, including negative, +/-75%, +/-50%, and +/-25% of the established cut-off values. This was achieved by introducing drug(s) into drug-free pooled urine specimens, and the concentration levels were rigorously confirmed through GC/MS analysis. Each sample was individually aliquoted and labeled in a blinded fashion.

Every participant was equipped with a package insert, one blind-labeled sample, and the testing device. The summarized results from this study are outlined below."

% of Cut-Off	Number of samples	THC concentration by GC/MS (ng/ml)	No. of Positive	No. of Negative	The % agreement
-100%Cut-Off	20	0	0	20	100%
-75%Cut-Off	20	12.5	0	20	100%
-50% Cut-Off	20	25	0	20	100%
-25% Cut-Off	20	37.5	2	18	90%
+25% Cut-Off	20	62.5	19	1	95%
+50% Cut-Off	20	75	20	0	100%
+75% Cut-Off	20	87.5	20	0	100%

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	GenaCheck Rapid Self-Test Kit for Cannabis
Classification Name:	ENZYME IMMUNOASSAY, CANNABINOIDS
Product Code:	LDJ
Device Class:	2
Regulation Number:	862.3870
Medical Specialty:	Toxicology
Registered Establishment Name:	GENABIO DIAGNOSTICS INC
Registered Establishment Number:	3016609999
Premarket Submission Number:	K140546
Owner/Operator:	Genabio Diagnostics Inc.
Owner/Operator Number:	10063095
Establishment Operations:	Repackager/Relabeler; Complaint File Establishment

Page Last Updated: 02/26/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

EN

GENABIO

GenaCheck™ Rapid Self-Test Kit For Cannabis

Instructions For Use

For in vitro diagnostic Use Only
For Over-The-Counter Use Only

Instructions for Use for testing of any combination of the following drugs: Cannabis.

A rapid, one step screening test for the simultaneous, qualitative detection of Cannabis metabolites in human urine. For in vitro diagnostic use only. It is intended for Over-The-Counter use.

Preparation

HOW TO COLLECT URINE?

• Urinate directly into a self prepared urine collection cup.

• Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.

• The residual urine sample in the urine collection cup is for your self-testing.

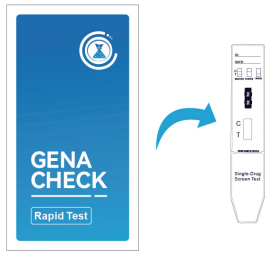
Specimen Storage

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). Frozen specimens should be thawed and mixed well before testing.

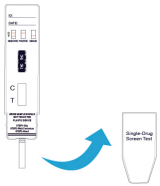
Test Procedure

Allow the test card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

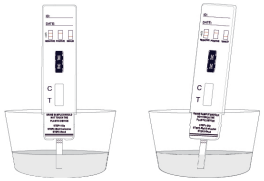
Remove the test card from the foil pouch.



Remove the cap from the test card.



Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic cassette.



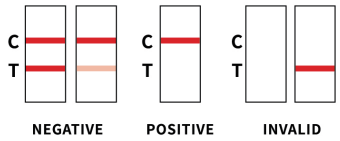
Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.

Read results at 5 minutes.

Note:

Do not interpret result after 5-minute timepoint has passed.

Result Interpretation



(Please refer to the illustration above)

NEGATIVE: Two lines appear. One red line should be in the control region (C), and another apparent red or pink 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 red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (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.

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 must be tested by 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 GenaCheck™ Rapid Self-Test Kit for Cannabis. 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 GenaCheck™ Rapid Self-Test Kit for Cannabis. If the sample is diluted, or the sample is adulterated that may cause false negative result.

Intended Use

Urine based tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The GenaCheck™ Rapid Self-Test Kit for Cannabis is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:

Test	Calibrator	Cut-off (ng/mL)
Cannabis (THC)	11-nor-Δ⁹-THC-9 COOH	50

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary

The GenaCheck™ Rapid Self-Test Kit for Cannabis is a rapid urine screening test that can be performed without the use of an instrument. 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 provided.

Reagents

The test card contains mouse monoclonal anti-Cannabis antibody- coupled particles and Cannabis-protein conjugate. A goat antibody is employed in the Control Line system.

Warnings And Precautions

• For Over-The-Counter use only. For in vitro diagnostic use only.

• Do not use after the expiration date.

• The Test Card should remain in the sealed pouch until use.

• All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

• The used Test Card should be discarded according to local regulations.

Storage And Stability

Store as packaged in the foil pouch either at room temperature or refrigerated 2-30°C (36-86°F). The Test Card is stable through the expiration date printed on the box and the foil pouch.

The Test Card must remain in the foil pouch until use.

Keep away from direct sunlight, moisture and heat.

DO NOT FREEZE.

Do not use the Test Card beyond the expiration date.

Materials

Materials Provided:

5 x Test Card(s)
1 x Instructions for Use

Materials Required But Not Provided:

Urine Collection Cup, Labeled Vials*, Clock, Disposable Gloves, Mailing Box*, Plastic Sealed Bag*, Identification Label*
* For Laboratory Confirmatory Test (See Confirmation Testing Section)

Limitations

• The GenaCheck™ Rapid Self-Test Kit for Cannabis provides only a qualitative, preliminary analytical result. A secondary analytical substances in the urine specimen may cause erroneous results.

• There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

• Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.

• A positive result does not indicate level of intoxication, administration route or concentration in urine.

• A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

• The test does not distinguish between drugs of abuse and certain medications.

• A positive result might be obtained from certain foods or food supplements.

Frequently Asked Questions

Q. What does the GenaCheck™ Rapid Self-Test Kit for Cannabis do?

A: This test indicates if cannabis (THC) is present in urine above a certain cut-off level. The testing is done in two steps. First, a quick at-home test is performed. Second, if the test suggests that drugs may be present, send the sample to a laboratory for confirmation testing.

Q. What is "cut-off level"?

A: The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

Q. What are drugs of abuse?

A: Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

Q. How accurate is the test?

A: The tests are sensitive to the presence of drugs in urine sample. These tests are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.

Q. Does a preliminary positive test mean the drug of abuse is present in the sample?

A: This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

Additional Information And Resources

A health care provider, or any of the following organizations listed below can be contacted for additional information and/or counseling regarding substance abuse prevention and treatment:

Center for Substance Abuse Treatment (CSAT) 1-877-SAMHSA-7 /www.samhsa.gov

The National Council on Alcoholism and Drug Dependence (NCADD): www.ncadd.org

CONFIRMATORY TESTING: MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

• Ensure that the Labeled Vial is about two third (2/3) full and that the cap is tightly closed.

• Check the label identifying the drug that was a preliminary positive result.

• Be sure to write your Cell Phone Number on the mailing box that the laboratory can send you the message with the confirmed results along with the Personal Identification Number.

• Place the Labeled Vial in the plastic bag and seal the plastic bag.

• Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.

• Place the mailing box in any US Postal Service Office.

Index Of Symbols

	Do Not Re-use		Consult Instructions For Use
Σ	Test Per Kit		Store At 2-30°C (36-86°F)
LOT	Batch Number	REF	Catalog #
UDI	Unique Device Identifier	IVD	For *in vitro diagnostic* Use Only
	Expiration Date		Keep Away From Sunlight
	Keep Dry		

Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00-17:00 EST).

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COMPANY INTRODUCTION

Genabio is a global leader in the production of over-the-counter self-testing products, with an impressive sales record of over $100 million in the past three years. Our extensive customer base spans across the USA, Canada, the UK, Japan and India.

A significant aspect of our product range is the FDA approval, including the COVID-19 Rapid Self-Test Kit. These sought-after products can be found in thousands of locations, including renowned pharmacy chains like Walgreens, leading hospitals such a NYU Langone Health, accredited laboratories like SV Diagnostics Labs and Molecular Testing Labs, and various government departments.

In 2023, Genabio marked a pivotal moment in initiating our listing and financing efforts in Hong Kong. Simultaneously, we are focused on enhancing our brand identity and emphasizing clinical research within the United States. This commitment to research and development aligns with our expansion plans, which encompass increasing our production capacity in both the United States and China.

Our overarching vision is to be the world's foremost provider of self-testing solutions, offering precise, user-friendly, and cost-effective health diagnostics for individuals worldwide.

Our mission is to enhance global health awareness and accessibility, by delivering quality, FDA-approved self-test kits, by driving innovation, and by expanding our reach to ensure individual scan monitor their health with precision and convenience.

CONTACT US

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