

Rapid Response[®] Marijuana (THC) Home Test

Instructions for Use

For professional and self-testing in vitro diagnostic use only.

Please read all instructions first, and to check for and familiarize with the materials before performing a test

Intended Use

A rapid, one step screening test for the simultaneous, qualitative detection of marijuana metabolites in human urine. It is intended for professional and self-testing *in vitro* use.

The Rapid Response® Marijuana (THC) Home Test is a lateral flow chromatographic immunoassay for the qualitative detection of Marijuana and its metabolites in urine at the following cut-off concentrations in urine:¹

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

This test will detect other related compounds, please refer to the Analytical Specificity in the section Performance Characteristics of this product insert. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used 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 test result, particularly when preliminary positive results are used. It is intended for professional and self-testing *in vitro* use.

Summary

THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana occurs in 20-30 minutes and the duration of the effect is typically 90-120. Elevated levels of urinary metabolites are found within 1-3 hours of exposure and remain detectable for 1-7 days after smoking; however, actual clearance rates are dependent on many factors such as frequency of drug use, the amount of drug taken, metabolism rates, and even body fat content. The main metabolite excreted in the urine is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC- COOH).

Principle

The Rapid Response[®] Marijuana (THC) Home Test is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. In absence of marijuana metabolites, or if they are present in the urine specimen below 50 ng/mL, it will not saturate the binding sites of the antibody coated particles on the test strip. The antibody coated particles will then be captured by immobilized marijuana conjugate and a visible coloured line will show up in the test line region. The coloured line will not form in the test line region if the marijuana level is above 50 ng/mL because it will saturate all the binding sites of anti-marijuana

antibodies. A drug-positive urine specimen will not generate a coloured line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

Reagents

• The test contains mouse monoclonal anti-marijuana antibody-coupled particles and marijuana-protein conjugate. A goat antibody is employed in the control line system.

Precautions

- For professional and self-testing *in vitro* use.
- Do not use after the expiration date.
- The Test Dip 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 Dip card should be discarded according to local regulations.

Storage and Stability

- The pouched Test Dip card should be stored at room temperature or refrigerated [2-30°C (35.6-86°F].
- The Test Dip card is stable until the expiration date printed on the sealed pouch.
- The Test Dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture, and heat.
- DO NOT FREEZE.
- Do not use beyond the expiration date.

Specimen Collection and Preparation

When To Collect Urine For The Test?

• The minimum detection time is 2 hours, so you may collect urine samples 2 hours after suspected drug use.

How To Collect Urine?

- Collect a urine sample in a clean dried specimen container.
- Avoid high temperatures and sunlight.

Specimen Storage

 Urine specimens may be stored at 2-8°C (35.6-46.4°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.

Quality Control

The Rapid Response[®] Marijuana (THC) Home Test provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear, regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control line in the control region serves as 1) verification that sufficient volume is added, and 2) that proper flow is obtained.

Limitations

- The Rapid Response[®] Marijuana (THC) Home Test 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) is the preferred confirmatory method.
- 2. There is a possibility that technical or procedural errors, or 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, fresh urine specimen.
- **4.** A positive result does not indicate level of intoxication, route of drug administration or concentration of drug in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when the drug is present but below the cut-off level of the test.
- 6. The test does not distinguish between drugs of abuse and certain medications.
- 7. A positive result might be obtained from certain foods or food supplements.

Questions and Answers

1. What does this urine test do?

This test indicates if marijuana metabolites are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that marijuana metabolites may be present, it is suggested that you send the sample to a laboratory for additional testing to confirm the results.

2. What is "cut-off level" and approximate detection time?

The cut-off level is the specified concentration of a drug in a urine sample that can be detected by the test. Above that concentration the test result is considered positive, and below that concentration it is considered negative.

Drug (Identifier)	THC: 11-nor-Δ ⁹ -THC-9-COOH
Cut-off level	50 ng/mL
Minimum detection time	2 hours
Maximum detection time	7 days

3. How accurate is the test?

The test is 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 or false negatives for those who use drug-testing kits.

4. What does a preliminary positive screen test mean?

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

5. What should I do, if the lab test confirms a positive result?

If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

6. What is a false positive test?

A false positive result is a test result that reads positive when the drug or drug metabolite is not present, or its concentration is less than the detectable cut-off level.

7. What is a false negative test?

A false negative test is a test result that reads negative when the drug or drug metabolite is present but isn't detected by the Rapid Response® Marijuana (THC) Home Test. If the sample is diluted, or the sample is adulterated that may cause false negative result.

Assistance

If you have any question regarding to the use of this product, please call our Technical Support Number: 1-888-339-9964 (9am to 5:30 pm EST).

Performance Characteristics

Important

A professional lab operator performed the study test as follows: Accuracy, analytical sensitivity, analytical specificity, Precision, Effect of Urine Specific Gravity, Effect of Urinary pH, Cross-Reactivity and Non-Cross-Reacting Compounds.

Lay users did the Lay User Study.

NOTE: Performance may be negatively impacted if the testing is performed by users with less experience or training.

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the Rapid Response[®] Marijuana (THC) Home Test. Each test was performed by three operators. 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:

Marijuana (Tl	Rapid Response [™] ⁄Iarijuana (THC) Home Test		Low Negative (Less than half the cutoff concentration)	cutoff and the cutoff	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	16	16	1	0
Operator B	Positive	0	0	0	12	24
	Negative	10	16	16	2	0
Operator C	Positive	0	0	0	12	24
	Negative	10	16	16	2	0

% agreement among positives is 95.6% % agreement among negatives is 100%

Analytical Sensitivity

A total of 150 samples, equally distributed at concentrations of -50% Cut-Off, -25% Cut-Off, Cut-Off, +25% Cut-Off, and +50% Cut-Off were tested using three different lots of each test by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for marijuana. The cut-off value 50 ng/mL for the test is verified.

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Rapid Response® Marijuana (THC) Home Test. Rapid Response® Marijuana (THC) Home Test

Drug	Concentration (ng/ml)	% Cross-Reactivity	
Marijuana (THC)	50	100%	
Delta-9- Tetrahydrocannabinol	50,000	0.1%	
11-nor-delta-9-THC- carboxyglucuronide	75	67%	
(-)-11-nor-9-carboxy- delta9-THC	75	67%	
11-Nor-Δ9- Tetrahydrocannabinol	50	100%	
11-Hydroxy-∆9- Tetrahydrocannabinol	5,000	1%	
11-Nor-∆8- Tetrahydrocannabinol	50	100%	
∆8-THC-COOH	50,000	0.1%	

Precision

For the precision study, two runs per day were performed for 25 days for each format with three lots. Three operators, blinded to the sample number participated in the study. Each of the three operators test two aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are shown below:

11-nor-Δ ⁹ -		Lot 1		Lot 2		Lot 3	
THC-9-COOH concentration (ng/mL)	n	-	+	-	+	-	+
0	50	50	0	50	0	50	0
12.5	50	50	0	50	0	50	0
25	50	50	0	50	0	50	0
37.5	50	50	0	50	0	50	0
50	50	20	30	20	30	20	30
62.5	50	0	50	0	50	0	50
75	50	0	50	0	50	0	50
87.5	50	0	50	0	50	0	50
100	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drug at 25% below and 25% above the cut-off levels respectively. The Rapid Response[®] Marijuana (THC) Home Test was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

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The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above cutoff levels. The spiked, pH-adjusted urine was tested with The Rapid Response® Marijuana (THC) Home Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or marijuana positive urine. The following compounds show no cross-reactivity when tested with the Rapid Response® Marijuana (THC) Home Test at a concentration of 100 µg/mL.

Non-Cross-Reacting Compounds

Acebutolol	Menthol
Acetopromazine d6	Meperidine
Acetyl-L-cysteine	Meprobamate
Acetylsalicylic Acid (Aspirin)	Merperidine Metaraminol
Acetaminophen	Methamphetamine
O6-Acetylmorphine	Methadone
Acetazolamide	
N-Acetylprocainamide	D-methamphetamine
Acetone	Methazolamide
Acetophenetidin	Methoxamine
Alprenolol hydrochloride	o-Methoxyanime HCL
Alprazolam	Methoxyphenamine
Allopurinol	Methylene Blue
Alphenal	Methylphenidate
Amcinonide	Methylenedioxymethamphetamine-(+/-)3
Amiloride	Meticrane
Aminophenazoneco	Metoclopromide hydrochloride
Amiodarone	Metronidazole
Hydrochloride	4-Metylumbelliferyl B-D-glucuronide hydrate
Amoxicillin	Mianserin
L-Amphetamine	Midazolam
Ampicinine (Ampicillin)	Milrinone
Amitriptyline	Minaprine
Aminophylline	Morphine hydrochloride
Amantadine	Nabumetone
Hydrochloride	Nadolol
Amphotericin B	Nafcillin
Ammonium Chloride	Nalbuphine
D-Amphetamine	Nalidixic acid
Amobarbital	Nalorphine hydrochloride
Amphetamine sulfate	Naphthol
Amikacin	Naproxen
Amikacin sulfate	Naphazoline hydrochloride
p-Aminobenzoic Acid	1-Naphthylacetic acid1
DL-Aminoglutethimide	Naloxone hydrochloride
Anamycin sulfate	Naltrexone hydrochloride
Aniline	Nalmefene
Antipyrine	Neomycin sulfate
Apomorphine	Nialamide
Aprobarbital	Niacinamide
Aspartame	(+/-) Nicotine
L-Ascorbic Acid	Nimesulidate
L-Aspartic Acid	Nitrazepam
D-Aspartic Acid	Nifedipine
DL-Aspartic Acid	Nicotinic Acid
Atropine	Nitrofurantoin
Baclofen	Norchlordiazepoxide
Benzphetamine	Norclomipramine
Barbituric Acid	Nordiazepam
Betamethasone	Nordoxepin
Berberine	Norfloxacin
Beclometasone dipropionate	Norethindrone
Benzidine	Norpropoxyphene
Benzilic acid	Noscapine
Benzolic acid	Nordazepam
	Nordazepam Nomifensine
Benzyl alcohol	
Benzoylecogonine	Nortriptyline hydrochloride
Bendroflumethiazide	Nylidrin
Benzylamine hydrochloride	Octopamine
Bezoic Acid	Orphenadrine hydrochloride
Bisacodyl	Oxalic Acid

Bromazepam
Bromocriptine Mesylate
Bupivacaine Buprenorphine
Buspirone
Butacaine
Butalbital Butabarbital
Butyrophenone
Butethal
Cannabidiol
Caffeine Carbamazepine
Carisoprodol
Cefaclor
Cefradine Capsules Ceftriaxone
Cefotaxime
Cefoxitin
Cefuroxime Axetil (Zinnat)
Cefadroxil Cephradine
Chlordiazepoxide HCL
Chloroquine
Chlorpheniramine Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlorthalidone
Chlorzoxazone Cholrali Hydras
Cimetidine
Cinchonidine
Cinoxacin
Cicosporin Citric acid
Clenbuterol hydrochloride
Clindamycin
Clobetasone Butyrate Clomipramine
Clorazepate Dipotassium
Clonazepam
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Oxazepam Oxycodone Oxymetazoline Oxyphenbutazone Oxypurinol Pancuronium bromide Papaverine Paracetamol tablets Paclitaxel PCP Morpholine and Pentobarbital Pentylenetetraz Pentoxifylline Perphenazine Phenelzine Penicillin Phenacetin Phencyclidine Phenformin Pheniramine Phenobarbital Phenothiazine Phenol Phenolphthalien Phentermine P-phenylene Phenylephrine-L Phenylbutazone Phenylethylamine Phenylpropanolamine Phenyltoloxamine Pilocarpine Pimozide Pinacidil Pindolo Pipecolic Acid Piroxicam Potassium lodide Prazepam Prazosin Prednisolone acetate Prednisone Prilocaine Primaquine diphosphate Primidone Proadifen Probenecid Procainamide hydrochloride Procaine Prochlorperazine dimaleate salt Procyclidine Promazine Promethazine d-Propoxyphene Propranolol Protriptyline Pseudoephedrine HCL Pyridine-2-Aldoxin Pvridoxine Pyrilamine 2,3-pyridine dicarboxylic acid Quinine Quinidine Quinacrine Sodium chloride Ritodrine Roxithromycin tablets Ranitidine Riboflavin Salbutamol (Albuterol) Salicylic Acid Secobarbital Serotonin Sodium Cromoglicate Sodium Formate Stearic magnesium Sulfamethazine Sulfamethoxazole Sulfisoxazole Sulindac Sulfathiazole Sulfanilamide Tamoxifen Citrate Tannic Acid Temazepam Tenoxicam Terfenadine Terbutaline Tetraethylthiuram disulfide Tetracycline

Tetrahydrozoline

Erythromycir Eserine Estazolam Estradiol,17B Estriol Estrone Estrone-3-sulfate Etoposide Ethacrvnic Acid Ethambutol Ethopropazine Ethyl-p-aminobenzoate Ethylenediamine Tetraacetic Etodolac EthylMorphine Famotidine Fenfluramine Ferrous Sulfate Fenoprofen Flufenamic Acid Flunitrazepam Flunisolide Flurandrenolide Flurazeparr Furosemide Gemfibrozil Gentamicin Sulfate Gentisic acid Glutathione reduc Glybenclamide Glucose Griseofulvin Halcinonide Heroin Hexachloropher Hexobarbital Hippuric Acid Histamine Hydralazine (1R,9S)-(-)-β-Hydrastine Hydroflumethiazide Hydromorphone Hydrocodone Hydroxocobalamin α-Hydroxyhippuric acid Hydroxyzine dihydrochloride α-Hydroxyalprazolam 21-Hydroxy Progesterone Hydroxyprogesterone p-Hydroxymethamphetamine Hydrocortisone Hydrochlorothiazide Hypoxanthine Ibuprofen Imipramine Imidazole Indapamide Indomethacin Ipratropium bromid Isonicotinic Acid Isopropamide Isoxsuprine Isoproterenol-(+/-Ketamine Kynurenic Acid Labetalol Lactose Levorphanol Lidocaine Lithium Carbonate Lisinopril Loperamide Lorazepam (±) Mannitol Maprotiline Mebendazole Meclofenamic Acid Medazepam Mefenamic Acid Melanin

Thebaine Theobromine Thioridazine hydrochloride Thiamine Theophylline Tobramycin Tolazamide Tolbutamide Tolmetin Triprolidine Tramadol Trazodone 2,4,6-trmethylbezamide Tropic Acid Tropine D/L-Tvrosine Triamterene Triflupromazine hydrochloride Trichloroacetic acid Trimipramine Tryptamine Trifluoperazine DL-Tryptophan Triazolam Trans-2-phenylcyclopropylamine hydrochloride Tyramine Uric Acid Urea Vancomycin HCL Venlafaxine hydrochloride Verapamil **Xylometazoline** Yohimbine Zearalenone Zomepirac Zopiclone Albumin, Human recombinant Atenolol Benzthiazide **Beclomethasone** Bilirubin Bupropion hydrochloride Chlorothiazide Chlorotrianisene Camphor Clonidine hydrochloride Canrenoic acid Captopril Desoximetasone Dipyridamole Clozapine Chloramphenicol Cortisone R(-)-Epinephrine Emetine dihydro-chloride hydrate Ethyl acetate Fluphenazine dihydrochloride (+/-)-4-Hydroxyamphetamine HCL Norcocaine Pargyline Hvdroxvurea Melphalan, minimum Methoxyamine hydrochloride Metaproterenol hemisulfate salt Oxymorphone Ofloxacin Picrotoxin Potassium chloride Propionylpromazine Methyl salicylate Trichlormethiazide Trimethoprim L-Thyroxine Vincamine Vanillic acid diethylamine Chlordiazepoxide Norbuprenorphine Trimethobenzamide 4-Hydroxy Phencyclidine

Lay User Study

A lay user study was performed at three intended user sites with 140 lay persons. For the test study, 65 female and 75 male participants tested the marijuana sample. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations: negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the product insert, 1 blind labeled sample and a test. The typical results are summarized below.

			Lay perso		
% of Cutoff	Number of samples	THC Concentration by GC/MS (ng/ mL)	No. of Positive	No. of Negative	Percent agreement (%)
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	12.5	0	20	100%
-50% Cutoff	20	25	0	20	100%
-25% Cutoff	20	37.5	2	18	90%
+25% Cutoff	20	62.5	19	1	95%
+50% Cutoff	20	75	20	0	100%
+75% Cutoff	20	87.5	20	0	100%

Bibliography

- 1. "Marijuana". Oxford English Dictionary. June 2013.
- Mahmoud A. ElSohly (2007). Marijuana and the Cannabinoids. Springer 2. Science. p. 151. ISBN 978-1- 59259-947-9.
- 3. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

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.

The Canadian Centre on Substance Use and Addiction

http://www.ccsa.ca 1-833-235-4048

Canadian Centre for Addiction

https://canadiancentreforaddictions.org 1-855-499-9446

Public Safety Canada

https://www.publicsafety.gc.ca 1-800-830-3118

Glossary of Symbols



Store between 2°C to 30°C



Test per Kit Use by date



REF Catalogue number

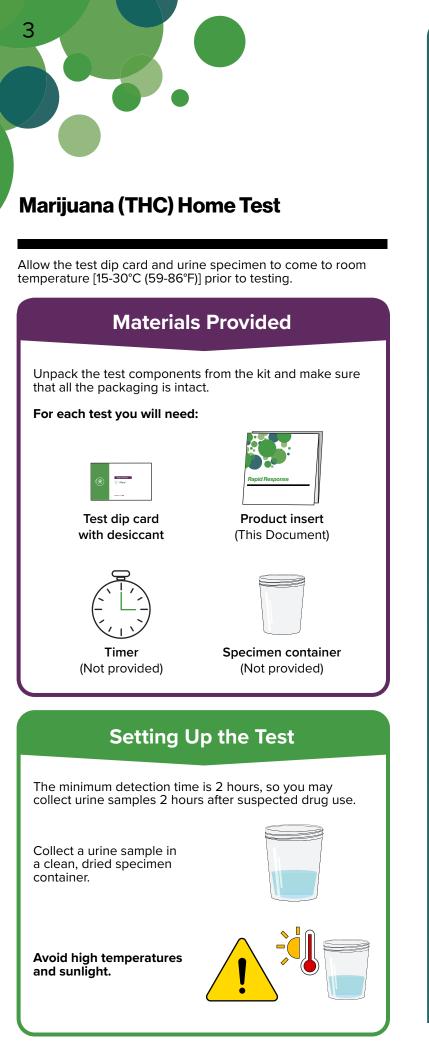
Do Not Reuse



IVD For *in vitro* diagnostic use only LOT Lot Number

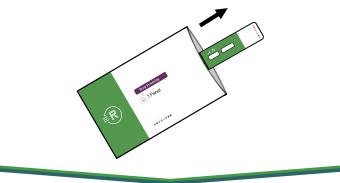
BTNX, Inc. 722 Rosebank Road Pickering, ON, L1W 4B2, Canada Technical Support: 1-888-339-9964 ext.803



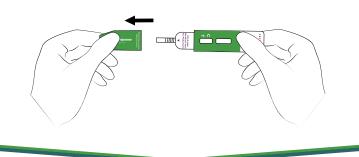


Instructions

Remove the test dip card from the foil pouch.

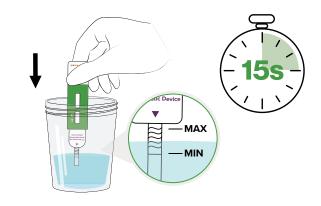


Remove the cap from the test dip card.

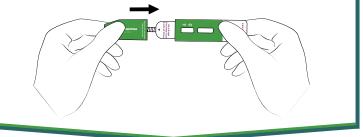


Immerse the absorbent tip into the urine sample for 10-15 seconds.

Urine sample should not touch the plastic holder of the test dip card.



Replace the cap over the absorbent tip and lay the test dip card flat on a non-absorptive, clean surface.

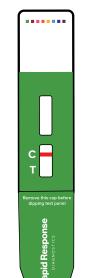


Read the results after 5 minutes.

Do not interpret the results after 5 minutes.

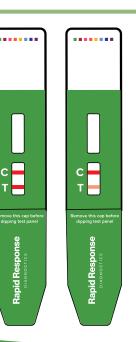


Reading the Results



POSITIVE:

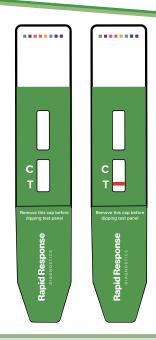
One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.



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.



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 colour intensity or width.

A preliminary positive test result does not always mean a person used marijuana and a negative test result does not always mean a person did not used marijuana. There are several factors that influence the reliability of drug tests. Certain drug tests are more accurate than others.

Important Information

The Rapid Response[™] Marijuana (THC) Home Test is only the first step in a two-step process for determining the presence of drugs of abuse. If you get a "preliminary positive" test result when you use this product, we recommend that you send the urine to a certified laboratory, which can test the urine again with a more accurate and reliable test. The second test is called confirmation testing, which is most often done using a test method called gas chromatography/ mass spectrometry. We recommend that you consult with your doctor or another qualified professional to help you understand test results and to address problems such as drug use.

