Rapid Detect Dip Drug Test

Rapid Detect Dip Drug Test is an immunochromatographic assay for the qualitative detection of Synthetic Cannabinoid (K2) in human urine at a cutoff concentration indicated in the table below.

The test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription use and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine. The test provides only preliminary test results. A more specific alternative 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For forensic use only.

WHAT IS RAPID DETECT DIP DRUG TEST?

Rapid Detect Dip Drug Test is a rapid test for qualitative detection of Synthetic Cannabinoid (K2) in human urine. The **Rapid Detect Dip Drug Test** yields a positive result when drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

WHAT IS THE CUT-OFF VALUE?

Drug Test	Drug (Identifier)	Cutoff Level
Synthetic Cannabinoid (K2)	JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid	20 ng/mL

PRINCIPLE

The **Rapid Detect Dip Drug Test** is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of specimen has been added.

WARNINGS AND PRECAUTIONS

1. For forensic use only.
2. For external use only.
3. For single use. Discard after first use.
4. Do not use the test if the pouch is punctured or not well sealed.
5. Do not use after expiration date.
6. Keep out of the reach of children.
7. The used dip test and urine specimen should be discarded according to federal, state and local regulations.

CONTENT OF THE PACKAGE

Included in package:

- User Instruction
- Dip Test (inside foil pouch)

Not included in package:

- Watch, Timer or Clock
- Collection Cup

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 39°F - 86°F (4°C - 30°C). The test is stable through the expiration date printed on the sealed pouch. The dip test 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.

WHEN TO COLLECT URINE FOR THE TEST?

You can use urine from any time of the day. The minimum detection time varies for different drugs.

HOW TO COLLECT URINE?

1. When you are ready to begin, remove the dip test from the sealed foil pouch.
2. Notice the colored tape on each strip indicates the name of the drug you are testing for.
3. Fill the collection cup with a fresh urine sample. Do not over-fill.

HOW TO DO THE TEST?

1. Remove cap for single dip cassette. Insert the test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the plastic device on the single dip cassette or the conjugate pad on the single strip, this could cause inconclusive drug test results. Place the test on a flat surface (with the cap on for single dip cassette).
2. Wait for 5 minutes (start timing immediately after dip is taken out of the urine sample).
3. Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

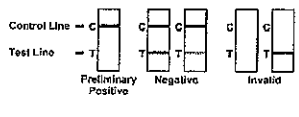
Note: Results after more than 5 minutes may be not accurate and should not be read.

READING THE RESULTS

<u>Preliminary Positive (+)</u>: If a line appears in the C - Control area but NO line appears in the T - Test area, then it indicates a Preliminary Positive result for the corresponding drug.

<u>Negative (-)</u>: If a line appears in both the C - Control and T - Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or light the line may appear.

<u>Invalid</u>: If at 5 minutes, NO line appears in the C - Control area, then the results are invalid. In such case, retest with a new dip test.



Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

A 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 a laboratory in order to determine if a drug of abuse is actually present.

WHAT IS A FALSE POSITIVE TEST?

The definition of a false positive test would be an instance where the test result from the **Rapid Detect Dip Drug Test** is positive, even though the initial target drug is not present in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also 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 target drug is present but is not detected by the **Rapid Detect Dip Drug Test**. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

TEST LIMITATIONS

1. The **Rapid Detect Dip Drug 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 interfering substances in the urine specimen may cause erroneous results.
3. Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
4. A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be done with each new lot and each new shipment. It should be done every thirty days to check storage. Please contact our Technical Support at 507-526-3951 for controls that work with the dip test.

PERFORMANCE CHARACTERISTICS

<u>Accuracy</u>

In the comparison study, the **Rapid Detect Dip Drug Test** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid. Clinical specimens were quantified by GC/MS analysis before testing. The following results are tabulated from these clinical studies:

% Agreement with GC/MS Synthetic Cannabinoid (K2) 20 ng/mL		
	Positive	Negative
Negative Samples	1	22
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]		
Near Cut-off Positive Samples [between cut-off and 150% of cut-off]	37	0
Positive Samples [>150% of cut-off]		
Agreement with GC/MS	>97%	>99%

Overall Agreement with GC/MS is 98%.

<u>Reproducibility</u>

Reproducibility studies were carried out using commercially available stock solutions of the drug analytes listed. Dilutions were made from the stock solution of each drug to the concentrations specified in the following table. The results are listed in the following table.

JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid Concentration (ng/mL)	Total Number of Determinations	Result	Precision
No Drug Present	60	60 negative	>99%
10	60	60 negative	>99%
30	60	60 positive	>99%

<u>Analytical Specificity</u>

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the **Rapid Detect Dip Drug Test** at a read time of 5 minutes.

Synthetic Cannabinoid (K2)	Result
JWH-018 5-pentanoic acid metabolite	20
JWH-073 4-butanoic acid metabolite	20
MAM2201 N-pentanoic acid metabolite	200
JWH-398 N-pentanoic acid metabolite	400
JWH-210 N-(5-carboxypentyl) metabolite	2,500
JWH-073 3-hydroxybutyl metabolite	2,500
JWH-018 N-4-hydroxypentyl	8,000
JWH-073 4-hydroxybutyl metabolite	40,000
JWH-019 5-hydroxyhexyl metabolite	40,000
JWH-018 5-hydroxypentyl metabolite	45,000
JWH-122 5-hydroxypentyl metabolite	50,000
JWH-122 4-hydroxypentyl metabolite	50,000
JWH-019 6-hydroxyhexyl metabolite	50,000
RCS-4 N-(5-carboxypentyl) metabolite	50,000
Trifluoperazine dihydrochloride	50,000
Trifluoperazine hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000

<u>Analytical Sensitivity</u>

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	K2	
		-	+
0% Cut-off	10	10	0
-50% Cut-off	10	10	0
-25% Cut-off	10	10	0
Cut-off	10	0	10
+25% Cut-off	10	0	10
+50% Cut-off	10	0	10

EFFECT OF URINARY SPECIFIC GRAVITY

Urine samples of normal, high, and low specific gravity ranges (1.000-1.035) were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **Rapid Detect Dip Drug Test** was tested using twelve drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY PH

The pH of an aliquot of negative urine pool was adjusted to pH ranges of 4.0 - 9.0 and spiked with drugs at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Rapid Detect Dip Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Synthetic Cannabinoid (K2). The following compounds show no cross-reactivity when tested with the **Rapid Detect Dip Drug Test** at concentrations of 100 µg/mL.

Non Cross-Reacting Compounds - Synthetic Cannabinoid (K2)		
(-)-11-nor-9-carboxy-delta-9-THC	Cefotaxime	Estrone
(-)-delta-9-THC	Cefoxitin	Estrone-3-Sulfate
(+/-) Nicotine	Cefradine Capsules	Ethacrynic Acid
(+/-)-11-nor-9-carboxy-delta-9-THC	Ceftriaxone	Ethambutol
(+/-)-4-Hydroxyamphetamine HCL	Cefuroxime Axetil (Zinnat)	Ethyl Acetate
(1R,9S)-(-)-β-Hydrastine	Cephradine	Ethylenediamine Tetraacetic Acid
11-Hydroxy-delta-9-THC	Cetirizine Hydrochloride	Ethyl Morphine
1-Naphthylacetic Acid1	Chloral Hydrate	Ethyl-p-aminobenzoate
2,3-Pyridine Dicarboxylic Acid	Chloramphenicol	Etodolac
4-Metylumbelliferyl β-D-Glucuronide Hydrate	Chlordiazepoxide HCL	Etoposide
5,5-Diphenylhydantoin	Chloroquine	Famotidine
Acebutolol	Chlorothiazide	Fenfluramine
Acetaminophen	Chlorotrianisene	Fenoprofen
Acetazolamide	Chlorpheniramine	Fentanyl Citrate Salt
Acetone	Chlorpromazine	Ferrous Sulfate
Acetophenetidin	Chlorpropamide	Flufenamic Acid
Acetopromazine – d6	Chlorthalidone	Flunisolide
Acetyl-L-Cysteine	Chlorzoxazone	Fluphenazine Dihydrochloride
Acetylsalicylic Acid (Aspirin)	Cholesterol	Flurandrenolide
a-Chymotrypsin	Cicosporin	Flurazepam
a-Hydroxyalprazolam	Cimetidine	Furosemide
a-Hydroxyhippuric Acid	Cinchonidine	Gemfibrozil
Albumin, Human Recombinant	Cinoxacin	Gentamicin Sulfate
Allopurinol	Citric Acid	Gentisic Acid
Alphenal	Clenbuterol Hydrochloride	Glucose
Alprazolam	Clindamycin	Glutathione Reduced
Alprenolol Hydrochloride	Clobazam	Glybenclamide
Amantadine Hydrochloride	Clobetasone Butyrate	Griseofulvin
Amikacin	Clomipramine	Halcinonide
Amikacin Sulfate	Clonazepam	Haloperidol
Amiloride	Clonidine Hydrochloride	Hemoglobin
Aminophenazon	Clorazepate Dipotassium	Heroin
Aminophylline	Cloxacillin	Hexachlorophene
Amiodarone Hydrochloride	Clozapine	Hippuric Acid
Amitriptyline	Cocaethylene	Histamine
Ammonium Chloride	Cocaine Hydrochloride	Hydralazine
Amobarbital	Codeine	Hydrochlorothiazide
Amoxicillin	Colchicine	Hydrocodone
Amphetamine Sulfate	Compound Zinc Undec	Hydrocortisone
Amphotericin B	Cortisone	Hydroflumethiazide
Ampicilnine (Ampicillin)	Cotinine	Hydromorphone
Anamycin Sulfate	Creatinine	Hydroxocobalamin
Aniline	Cyclobenzaprine Hydrochloride	Hydroxyprogesterone
Antipyrine	Cyclopentobarbital	Hydroxyurea
Apomorphine	Cyclophosphamide	Hydroxyzine Dihydrochloride
Aprobarbital	Cyproheptadine Hydrochloride	Hypnoval (Cyclobarbital)
Aspartame	D/L-Tyrosine	Hypoxanthine
Atenolol	Dantrolene Sodium	Ibuprofen
Atropine	D-Aspartic Acid	Imidazole
Baclofen	Deferoxamine Mesylate	Imipramine
Barbituric Acid	Delta-8-THC	Indapamide
Beclometasone Dipropionate	Deoxyepinephrine	Indomethacin
Beclomethasone	Desipramine	Ipratropium Bromide
Bendroflumethiazide	Desoximetasone	Isonicotinic Acid
Benzalkonium Bromide	Dexamethasone	Isoproterenol-(+/-)
Benzilic Acid	Dextromethorphan Hydrobromide	Isoxsuprine
Benzocaine	Diazepam	JWH-210 4-hydroxypentyl metabolite
Benzoic Acid	Diazoxide	
Benzoylecogonine	Dieldrin	Ketamine
Benzphetamine	Diflorasone Diacetate	Kynurenic Acid
Benzthiazide	Diflunisal	Labetalol
Benzyl Alcohol	Digoxin	Lactose
Benzylamine Hydrochloride	Dihydralazine	L-Aspartic Acid
Berberine	Dimethyl Isosorbide	L-Cystine
Betamethasone	Dimethyl Sulfoxide	Levorphenol
Bilirubin	Dipyridamole	Lidocaine
Bisacodyl	Dipyrone	Lisinopril
Bromazepam	Disopyramide	Lithium Carbonate
Bromocriptine Mesylate	DL-3,4-Dihydroxymandelic Acid	Loperamide
Bupivacaine	DL-Aminoglutethimide	Lorazepam (±) /Lorazepam Glucuronide
Buprenorphine	DL-Aspartic Acid	
Bupropion Hydrochloride	DL-Tryptophan	L-Thyroxine
Buspirone	D-Methamphetamine	Mannitol
Butabarbital	Dobutamine	Maprotiline
Butacaine	Dopamine	Mebendazole
Butalbital	Doxepin	Meclofenamic Acid
Butethal	Doxycycline Hyclate	Medazepam
Butyrophenone	Doxylamine	Mefenamic Acid
Caffeine	Droperidol	Melanin
Camphor	Ecgonine Methylester	Menthol
Cannabidiol	Emetine Dihydro-Chloride Hydrate	Meperidine
Canrenoic Acid	Ephedrine-(+/-)	Meprobamate
Captopril	Erythromycin	Merperidine
Carbamazepine	Eserine	Metaproterenol Hemisulfate Salt
Carisoprodol	Estazolam	Metaraminol
Cefaclor	Estradiol, 17B-	Methadone
Cefadroxil	Estriol	Methamphetamine

Non Cross-Reacting Compounds - Synthetic Cannabinoid (K2)		
Methoxamine	Pancuronium Bromide	Ritodrine
Methoxyamine Hydrochloride	Papaverine	Roxithromycin Tablets
Methoxyphenamine	Paracetamol Tablets	Salbutamol (Albuterol)
Methyl Salicylate	Pargyline	Salicylic Acid
Methylene Blue	PCP Morpholine Analog	Secobarbital
Methylenedioxymethamphetamine-(+/-) 3/4 (MDMA)	Penicillin	Serotonin
	Pentobarbital	Sertraline
Methylphenidate	Pentoxifylline	Sodium Chloride
Metkrane	Pentylenetetrazole	Sodium Cromoglicate
Metoclopromide Hydrochloride	Perphenazine	Sodium Formate
Metronidazole	Phenacetin	Stearic Magnesium
Mianserin	Phencyclidine (PCP)	Sulfamethazine
Midazolam	Phenelzine	Sulfamethoxazole
Milrinone	Phenformin	Sulfanilamide
Minaprine	Pheniramine	Sulfathiazole
Morphine	Phenobarbital	Sulindac
Nabumetone	Phenol	Tamoxifen Citrate
N-Acetylprocainamide	Phenolphthalein	Tannic Acid
Nadolol	Phenothiazine	Temazepam
Nafcillin	Phentermine	Tenoxicam
Nalbuphine	Phenylbutazone	Terbutaline
Nalidixic Acid	Phenylephrine-L	Terfenadine
Nalmefene	Phenylethylamine	Tetracycline
Nalorphine Hydrochloride	Phenylpropanolamine	Tetraethylthiuram Disulfide
Naloxone Hydrochloride	Phenylpropanolamine	Tetrahydrocannabinol, Delta-9-
Naltrexone Hydrochloride	p-Hyrdoxymethamphetamine	Tetrahydrozoline
Naphazoline Hydrochloride	Picrotoxin	Thebaine
Naphthol	Pilocarpine	Theobromine
Naproxen	Pimozide	Theophylline
Neomycin Sulfate	Pipecolic Acid	Thiamine
Niacinamide	Piroxicam	Thioridazine Hydrochloride
Nialamide	Potassium Chloride	Tobramycin
Nicotinic Acid	Potassium Iodide	Tolazamide
Nifedipine	p-Phenylene	Tolbutamide
Nimesulide	Prazepam	Tolmetin
Nitrazepam	Prazosin	Tramadol
Nitrofurantoin	Prednisolone Acetate	Trans-2-Phenylcyclo-Propylamine Hydrochloride
Nomifensine	Prednisone	
Norchlordiazepoxide	Prilocaine	Trazodone
Norclomipramine	Primaquine diphosphate	Triazolam
Norcocaine	Primidone	Trichlormethiazide
Nordiazepam	Proadifen	Trichloroacetic Acid
Nordoxepin	Probenecid	Trimethoprim
Norethindrone	Procainamide Hydrochloride	Trimipramine
Norfloxacin	Procaine	Triprolidine
Norfludiazepam	Prochlorperazine Dimaleate Salt	Tropic Acid
Norpropoxyphene	Procyclidine	Tropine
Nortriptyline Hydrochloride	Promazine	Tryptamine
Noscapine	Promethazine	Tyramine
Nylidrin	Propionylpromazine	Urea
O6-Acetylmorphine	Propoxyphene,d-	Uric Acid
Octopamine	Propranolol	Vancomycin HCL
Ofloxacin	Protriptyline	Vanillic acid Diethylamine
Orphenadrine Hydrochloride	Pseudoephedrine HCL	VB2
Oxalic Acid	Pyridine-2-Aldoxime	Venlafaxine Hydrochloride
Oxazepam	Pyridoxine	Verapamil
Oxycodone	Pyrilamine	Vincamine
Oxymetazoline	Quinacrine	Xylometazoline
Oxymorphone	Quinidine	Yohimbine
Oxyphenbutazone	Quinine	Zearalenone
Oxypurinol	R(-)-Epinephrine	Zomepirac
Paclitaxel	Ranitidine	Zopiclone
p-Aminobenzoic Acid	Riboflavin	

BIBLIOGRAPHY OF SUGGESTED READING

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

ADDITIONAL INFORMATION AND REFERENCES

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 1-800-729-6686

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

	Use-By Date		Temperature Limit
REF	Catalogue Number		Do Not Re-Use
	Do Not Use if Package is Damaged		Consult Instructions for Use
	Keep Away from Sunlight		Caution
	Keep Dry	Σ	Contains Sufficient for <n> Tests
LOT	Batch Code		

Distributed by:
Rapid Detect, Inc.
301 Turman Street
Poteau, OK 74953
Toll Free: 888-404-0020
www.rapiddetect.com

RDI4351-FUO, Rev A 05/2019