



REF D-1VFH-1 REF D-1VFH-2 REF D-1VFH-3 REF D-1VFH-4 REF D-1VFH-5
REF D-1PH-1 REF D-1PH-2 REF D-1PH-3 REF D-1PH-4 REF D-1PH-5

Rapid Response® Home Drug Test

Instructions for Use

For *in vitro* Diagnostic Use.

Please read all instructions and familiarize yourself with the required testing material before performing the test.

Intended Use

The Rapid Response® Home Drug Test is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of various drugs in human urine to assist in the diagnosis, monitoring, and treatment of substance use disorders. The Rapid Response® Home Drug Test are used in conjunction with a cup and/or panel accessory which allows for the simultaneous detection of multiple drugs in an easy-to-use format. Configurations of the Rapid Response® Home Drug Test can consist of any combination of the below listed drug analytes, up to a total of 16 distinct drug cut-offs. The Rapid Response® Home Drug Test is intended for self-testing or point-of-care in-vitro diagnostic use only.

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	500 ng/mL
Amphetamine (AMP)	1000 ng/mL
Barbiturates (BAR)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Cocaine (COC)	300 ng/mL
Methadone metabolite (EDDP)	300ng/ml
Ecstasy (MDMA)	500 ng/mL
Methamphetamine (MET)	500 ng/mL
Methamphetamine (MET)	1000 ng/mL
Morphine (MOR)	300 ng/mL
Morphine (MOR)	2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL
Fentanyl (FYL)	10 ng/mL

Warning: This test is not designed to test drugs before they are consumed. When used in this way, this test may not detect certain drugs, including fentanyl, even if present.

Summary

The Rapid Response® Home Drug Test is a drug-screening test that will give you a result for the presence of drugs in human urine. During testing, a urine sample moves upward on the test strip. A drug-positive urine sample will not produce a colored line in the specified test line area of the strip. A drug-negative urine sample will produce a colored line in the test line area. A colored line will always show in the control line area.

Precautions

- Do not use after the expiration date.
- The device should remain in the sealed pouch until use.
- Do not re-use the test.

Storage

- Store between 36-86°F; 2-30°C.
- **DO NOT FREEZE.**
- Keep away from direct sunlight, moisture and heat.

Limitation

- This test is for human urine only. Do NOT use this device to test any other fluids.
- Use the test within one hour after opening the sealed pouch.
- Bleach or baking powder, in urine samples may produce incorrect results. If contamination is suspected, repeat the test with another urine sample.
- The test does not distinguish between illicit drugs and certain medications.
- The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

Frequently Asked Questions

1. What does the Rapid Response® Home Drug Test do?

These tests indicate if one or more prescription or illegal drugs 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 drugs may be present, you send the sample to a laboratory for additional testing.

2. What is “cut-off level”?

The cut-off level is the specified concentration of a drug, in a urine sample, at which the test will begin to display positive results. Drug concentrations above the cut-off level are expected to yield positive results, and drug concentrations below the cut-off level are expected to yield negative results.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription medicines 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.

4. Common Street Names for the Drugs to be Detected?

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies, Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkles
Secobarbital (BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, candy, coke, do a line, freeze, girl, happy dust, Mama coca, mojo, monster, nose, pimp, shot, smoking gun, snow, sugar, sweet stuff, and white powder.

Methamphetamine (MET)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methylenedioxyamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Morphine (MOR)	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.
Methadone (MTD)	Amidone, Dolophine, Methadose
Phencyclidine (PCP)	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trunk, white horizon and zoom.
Nortriptyline (TCA)	Pamelor
Marijuana (THC)	420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane, nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker
Propoxyphene (PPX)	Darvon

5. How accurate is the test?

The tests are sensitive and specific to the drugs intended to be detected. These tests, however, are not as accurate as confirmatory 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.

6. If the test results are negative, can the conclusion be that the urine is free of drugs?

If the sample was collected correctly and the test was performed according to the procedure, this means that either the urine samples is free of the drugs tested for, or the drug levels were below the detection limit of this test.

7. Does a preliminary positive screen test mean that you have found drugs?

This means that the test has reacted with something in the sample, typically the target drug or a cross-reacting substance. The test does not distinguish between prescription use or misuse of these drugs. The sample should be sent to a lab for a more accurate, confirmatory test.

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

If you have received a confirmed positive result, please consult with your physician.

9. How long can drugs be detected in the body with a urine drug test?

Drug	Minimum detection time	Maximum detection time
Amphetamine (AMP)	2-7 hours	1-2 days
Secobarbital (BAR)	2-4 hours	1-4 days
Oxazepam (BZO)	2-7 hours	1-2 days
Cocaine (COC)	1-4 hours	2-4 days
Methamphetamine (MET)	2-7 hours	2-4 days
Methylenedioxyamphetamine (MDMA)	2-7 hours	2-4 days
Buprenorphine (BUP)	4 hours	1-3 days
Morphine (MOP)	2 hours	2-3 days
Methadone (MTD)	3-8 hours	1-3 days
Methadone metabolite (EDDP)	2 hours	2 to 6 days
Phencyclidine (PCP)	4-6 hours	7-14days
Nortriptyline (TCA)	8-12hours	2-7 days
Marijuana (THC)	2 hours	Up to 5+ days
Oxycodone (OXY)	4 hours	1-3 days
Propoxyphene (PPX)	2-4 hours	1-4 days
Fentanyl (FYL)	2-6 hours	3-4 days

Performance Characteristics: Analytical Specificity

Samples containing varying concentrations of the target drug, drug metabolites, and other related compounds were spiked into the negative drug-free human urine and tested for cross-reactivity. The concentrations below represent the lowest concentration at which the defined compound cross-reacts with the specified test strip.

Table 1. Summary of Analytical Specificity Results for AMP500

Compound	Positive Result at (ng/mL)
D-Amphetamine	500
L-Amphetamine	10000
DL-Amphetamine	1200
Phentermine	15000
Hydroxyamphetamine	4000
Methylenedioxyamphetamine (MDA)	500
d-Methamphetamine	>100000
1-Methamphetamine	>100000
Ephedrine	>100000
Methylenedioxyethylamphetamine (MDE)	>100000
3,4-Methylenedioxy-methamphetamine (MDMA)	>100000

Table 2. Summary of Analytical Specificity Results for AMP1000

Compound	Positive Result at (ng/mL)
D-Amphetamine	1000
L-Amphetamine	20000
DL-Amphetamine	3000
Phentermine	30000
Hydroxyamphetamine	8000
Methylenedioxyamphetamine (MDA)	20000
d-Methamphetamine	>100000
1-Methamphetamine	>100000
Ephedrine	>100000
Methylenedioxyethylamphetamine (MDE)	>100000
3,4-Methylenedioxy-methamphetamine (MDMA)	>100000

Table 3. Summary of Analytical Specificity Results for BAR300

Compound	Positive Result at (ng/mL)
Secobarbital	300
Amobarbital	1000
Alphenal	62.5
Aprobarbital	250
Butabarbital	100
Butethal	500
Butalbital	5000
Cyclopentobarbital	500
Pentobarbital	200
Phenobarbital	300

Table 4. Summary of Analytical Specificity Results for BUP10

Compound	Positive Result at (ng/mL)
Buprenorphine	10
Buprenorphine -3-D-Glucuronide	10
Norbuprenorphine	50
Norbuprenorphine-3-D-Glucuronide	100
Morphine	>100000
Oxymorphone	>100000
Hydromorphone	>100000

Table 5. Summary of Analytical Specificity Results for BZO300

Compound	Positive Result at (ng/mL)
Oxazepam	300
Alprazolam	150
alpha-Hydroxyalprazolam	1000
Bromazepam	1000
Chlordiazepoxide	63
Clonazepam HCl	2500
Clobazam	75
Clorazepate dipotassium	100
Desalkylflurazepam	500
Diazepam	500
Estazolam	500
Flunitrazepam	>50000
D,L-Lorazepam	10000
Midazolam	10000
Nitrazepam	75
Norchlordiazepoxide	62.5
Nordiazepam	125
Temazepam	75
Triazolam	1000

Table 6. Summary of Analytical Specificity Results for COC150

Compound	Positive Result at (ng/mL)
Benzoylcegonine	150
Cocaine HCl	500
Cocaethylene	7500
Ecgonine	15000
Norcocaine	50000

Table 7. Summary of Analytical Specificity Results for COC300

Compound	Positive Result at (ng/mL)
Benzoylcegonine	300
Cocaine HCl	750
Cocaethylene	12500
Ecgonine	32000
Norcocaine	100000

Table 8. Summary of Analytical Specificity Results for EDDP300

Compound	Positive Result at (ng/mL)
2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	300
2-Ethyl-5-methyl-3,3-diphenylpyrrolidine (EDMP)	>100000
Disopyramide	75
Methadone	>100000
Levo-alpha-acetylmethadol HCl (LAAM HCl)	>100000
alpha-Methadol	>100000
Doxylamine	>100000

Table 9. Summary of Analytical Specificity Results for MDMA500

Compound	Positive Result at (ng/mL)
Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	5000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
D-Methamphetamine	>50000
D-Amphetamine	>50000
L-Amphetamine	>50000
L-Methamphetamine	>50000

Table 10. Summary of Analytical Specificity Results for MET500

Compound	Positive Result at (ng/mL)
D-Methamphetamine	500
3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	5000
Methamphetamine	500
p-Hydroxymethamphetamine	5000
D-Amphetamine	>100000
L-Amphetamine	>100000
Chloroquine	40000
Ephedrine	2000
L-Methamphetamine	5000
3,4-Methylenedioxyamphetamine (MDA)	>100000
3,4-methylenedioxyamphetamine (MDMA)	5000
β-Phenylethylamine	4000
Trimethobenzamide	10000

Table 11. Summary of Analytical Specificity Results for MET1000

Compound	Positive Result at (ng/mL)
D-Methamphetamine	1000
3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10000
Methamphetamine	1000
p-Hydroxymethamphetamine	10000
D-Amphetamine	>100000
L-Amphetamine	>100000
Chloroquine	50000
Ephedrine	4000
L-Methamphetamine	10000
3,4-Methylenedioxyamphetamine (MDA)	>100000
3,4-methylenedioxyamphetamine (MDMA)	500
β-Phenylethylamine	7500
Trimethobenzamide	20000

Table 12. Summary of Analytical Specificity Results for MOR300

Compound	Positive Result at (ng/mL)
Morphine	300
Codeine	300
Ethylmorphine	310
Hydrocodone	25000
Hydromorphone	10000
Levorphanol	>100000
6-Acetylmorphine	250
Morphine-3-β-D-glucuronide	10000
Normorphine	100000
Oxycodone	>10000
Oxymorphone	>10000
Procaine	>10000
Thebaine	>10000
Heroin	500

Table 13. Summary of Analytical Specificity Results for MOR2000

Compound	Positive Result at (ng/mL)
Morphine	2000
Acetylmorphine	2500
Codeine	1000
Ethyl Morphine	250
Heroin	5000
Hydromorphone	2500
Hydrocodone	5000
Thebaine	13000
Morphine-3-β-glucuronide	>200000
Procaine	>400000
Levorphanol	>400000
Oxycodone	>400000
Oxymorphone	>400000

Table 14. Summary of Analytical Specificity Results for MTD300

Compound	Positive Result at (ng/mL)
Methadone	300
Doxylamine	5000
Levo-alpha-acetylmethadol HCl (LAAM HCl)	10000
alpha-Methadol	2000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	>100000
2-Ethyl-5-methyl-3,3-diphenylpyrrolidine (EDMP)	>100000

Table 15. Summary of Analytical Specificity Results for OXY100

Compound	Positive Result at (ng/mL)
Oxycodone	100
Dihydrocodeine	>100000
Codeine	>100000
Hydromorphone	>100000

Morphine	>100000
Buprenorphine	>100000
Ethylmorphine	>100000
Oxymorphone	250
Hydrocodone	3125
2-Ethyl-5-methyl-3,3-diphenylpyrrolidine (EDMP)	>100000

Table 16. Summary of Analytical Specificity Results for PCP25

Compound	Positive Result at (ng/mL)
Phencyclidine	25
4-Hydroxyphencyclidine	75

Table 17. Summary of Analytical Specificity Results for PPX300

Compound	Positive Result at (ng/mL)
d-Propoxyphene	300
Norpropoxyphene	333

Table 18. Summary of Analytical Specificity Results for TCA1000

Compound	Positive Result at (ng/mL)
Nortriptyline	1000
Amitriptyline	750
Clomipramine	10000
Desipramine	200
Doxepin	1250
Imipramine	625
Maprotiline	2000
Nordoxepin	1000
Promazine	1500
Promethazine	25000
Trimipramine	3000
Cyclobenzaprine Hydrochloride	5000
Norclomipramine	3000

Table 19. Summary of Analytical Specificity Results for THC50

Compound	Positive Result at (ng/mL)
11-Nor-Δ9-Tetrahydrocannabinol-9-COOH	50
11-Hydroxy-Δ9-Tetrahydrocannabinol	50
11-Nor-Δ8-Tetrahydrocannabinol-9-COOH	50
Cannabinol	20000
Δ8-Tetrahydrocannabinol	15000
Δ9-Tetrahydrocannabinol	15000
Cannabidiol	>100000
11-Nor-Δ9-THC-carboxy glucuronide	75
(-)-11-nor-9-carboxy-Δ 9-THC	50

Table 20. Summary of Analytical Specificity Results for FYL10

Compound	Positive Result at (ng/mL)
Methylenedioxymethamphetamine (MDMA)	100000
Methamphetamine	5000000
Cocaine	2000000
Methadone	4000000

Lidocaine	20000000
Diphenhydramine	2500000
Furanyl Fentanyl	1000
Valeryl Fentanyl	1000
Butyryl Fentanyl	300
P-Fluoro Fentanyl	200
Ocfentanil	10000
Carfentanil	10000
Sufentanil	10000
Norfentanyl	10000
Fentanyl	10










More Information and Resources


You can contact your health care provider, or any of the following organizations listed below for additional information and/or counseling regarding substance misuse prevention and treatment:

- **The Center for Addiction and Mental Health (CAMH)**
1-800-463-2338 / www.camh.ca
- **Health Canada**
1-866-225-0709 / www.canada.ca
- **Canadian Centre on Substance Use and Addiction (CCSA)**
1-833-235-4048 / www.ccsa.ca
- **Canadian Centre for Addiction**
1-855-499-9446 / www.canadiancentreforaddictions.org

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

Glossary of Symbols

 Consult instructions for use	 Test per Kit	 Do Not Reuse
 Store between 39.2°F and 86°F (4°C and 30°C)	 Use by	 Catalogue #
 Lot Number	 For <i>in vitro</i> diagnostic use only	 Manufacturer

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



Rapid Response® Home Drug Test

Allow the test to reach room temperature [59-86°F (15-30°C)] before testing.

Materials Provided

Unpack the test components from the kit and make sure that all the packaging is intact.

For each test you will need:



Test Cup or Test Panel
(with Test Strips)



Instructions for Use
(This Document)



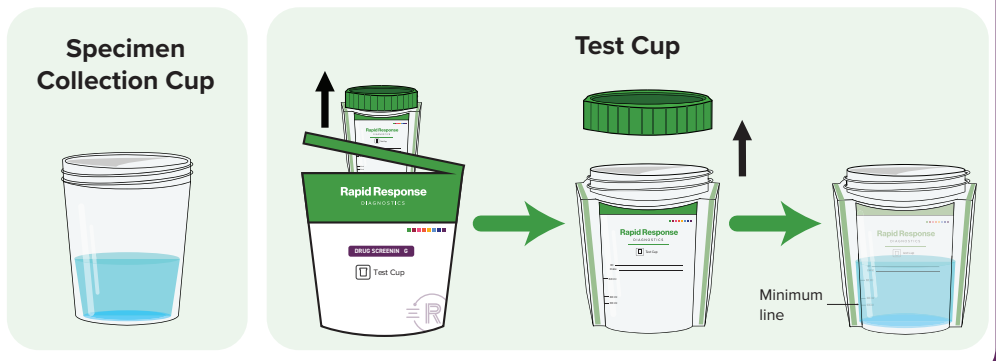
Watch, Timer or Clock
(Not provided)



Specimen Collection Cup
(Optional)

Collection of Specimens

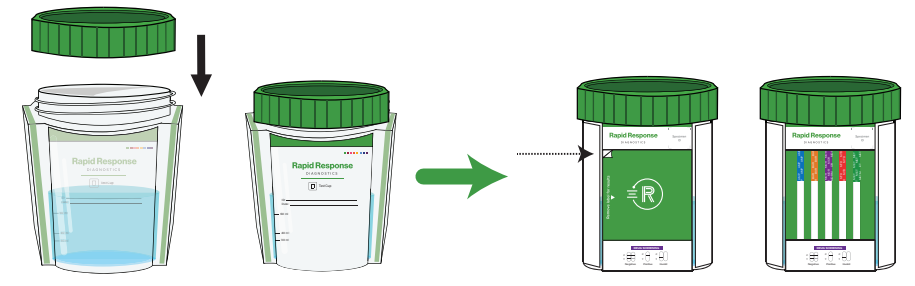
Remove the provided cup from the package and collect the urine specimen with the cup.
Urine volume must exceed the minimum line mark. Urine from any time of the day may be used.



Test Procedure

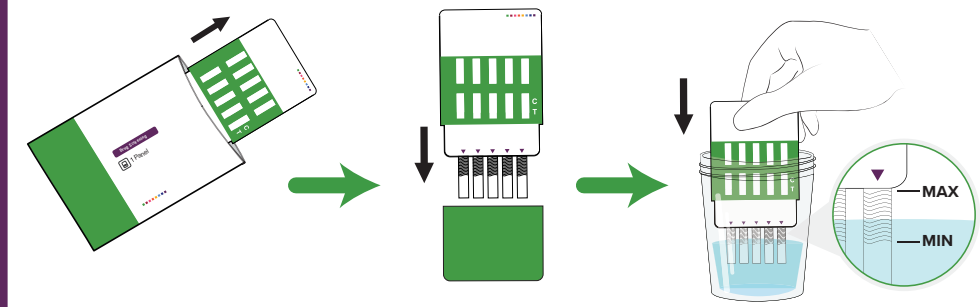
Rapid Response® Home Drug Test with Test Cup:

1. Screw the cap onto the cup and immediately start the timer.
2. Remove the peel-off label.

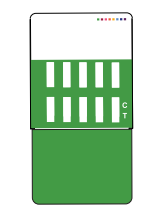


Rapid Response® Home Drug Test with Test Panel:

1. Remove the Test Panel from the sealed pouch.
2. Remove the cap from the Test Panel.
3. Dip the absorbent tip of the Test Panel into the urine sample for 10-15 seconds. Ensure the urine level is below the maximum line (MAX) on the strip. The urine sample should not touch the plastic device.



4. Replace the cap over the absorbent tip and lay the device flat on a non-absorbent clean surface. Set a timer.



Reading the Result

5 minutes after specimen collection or after dipping the test panel:
Read the result at 5 minutes. Do not interpret the result after 10 minutes.



	<p>PRELIMINARY POSITIVE: Only one coloured line appears, in the control region (C). No apparent coloured line appears in the test region (T).</p>
	<p>NEGATIVE: Two coloured lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T). Any shade of color in the test region (T) should be considered negative.</p>
	<p>INVALID: No line appears in the control region (C), then the result is Invalid.</p>

Understanding The Test Results

A positive result does not mean a person took illegal drugs. A negative result does not mean a person did not take illegal drugs. There are many factors that affect the test. Certain drug tests are more accurate than others.

IMPORTANT: The results from the test are preliminary. The sample must be tested by a lab to confirm the result.

1. **What is a false positive test?**
A false positive test result means the drug is not present but shows as detected by the device. The most common causes for a false positive test are cross reactants. Certain food and medicines, diet plan drugs and nutritional supplements may cause a false positive result with this product.
2. **What is a false negative test?**
A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is adulterated, that may cause a false negative result.

Assistance

If you have questions, reach out to our Technical Support:
support@btnx.com
1-888-339-9964
Monday-Friday 9:00AM-5:30PM EST.

BTNX Inc.
Tel: +1-888-339-9964
Fax: +1-905-944-0406
Email: support@btnx.com
www.btnx.com

