

U-NOW Drug Test Cup

Instruction of use for testing of any combination of the following drugs:
AMP/BAR/BZO/BUP/COC/THC/MET/MTD/MDMA/MOP/OXY/PCP/PPX/TCA

Please read all instructions before use.

INTENDED USE

U-NOW Drug Test Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detections of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 ng/mL
Barbiturates (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Buprenorphine (BUP)	10 ng/mL
Cocaine (COC)	300 ng/mL
Marijuana (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methadone (MTD)	300 ng/mL
Methylenedioxymethamphetamine-ecstasy (MDMA)	500 ng/mL
Morphine (MOP300/OPI2000)	300 ng/mL or 2000 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Tri-cyclic Antidepressants (TCA)	1000 ng/mL

Configuration of the U-NOW Drug Test Cup test can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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.

For in vitro diagnostic use only.

What are the U-NOW Drug Test Cup?

The U-NOW Drug Test Cup is drug-screening tests that will give you a result for the presence of drugs of abuse 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 (T) area of the strip. A drug-negative urine sample will produce a colored line in the test line (T) area. A colored line will always show in the control line (C) area.

WARNINGS AND PRECAUTIONS

- Immunoassay for in vitro diagnostic use only.
- Do not use after expiration date.
- The Test Cup should remain in the sealed pouch until use.
- Do not re-use the test.
- The used Test Cup should be discarded according to local regulations.

CONTENTS OF THE KIT

- Drug Test Cup
- Desiccant
- Instruction for use
- Drug Screen Procedure Card
- Adulterated strips standard colorimetric chart (optional)
- Pre-addressed and mailing box for shipping samples for confirmation testing (optional)

NOT INCLUDED IN PACKAGE

- Watch, timer or clock

STORAGE

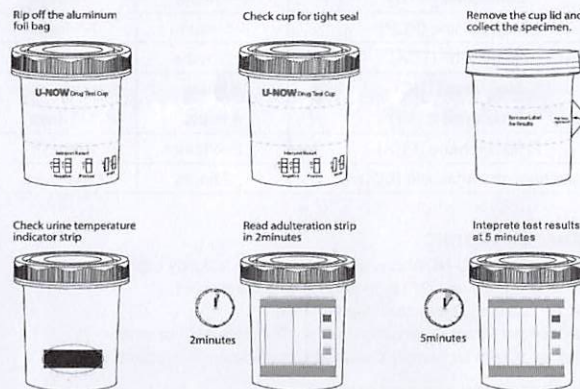
- Store at 39 ~ 86 °F (4 ~ 30 °C) in the sealed pouch up to the expiration date.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.

URINE COLLECTION AND PREPARATION

- Collect urine sample in the provided cup. Urine collected at any time of the day may be used.

HOW TO PERFORM THE TEST?

1. Remove the U-NOW Drug Test Cup from the sealed pouch and use it within the first hour after opening.
2. Peel off label and collect urine specimen in the provided cup.
3. Screw the cap onto the cup and immediately start the timer.
4. Read the results. The drug test results should be read at 5 minutes. The drug test results remain stable for up to thirty minutes.



Note: If the urine cup contains adulterated strips, please refer to the accompanying adulterated strips standard colorimetric chart for result interpretation. If the color development of the adulterated strips meets the requirements of the color card, follow the operation steps to interpret the results of the test items. If the color of the adulterated bar does not meet the requirements of the color card, considering the possibility of adulteration of urine, whether it is necessary to re-sample and test again, it needs to be analyzed and judged according to the actual situation on the spot.

INTERPRETATION OF TEST RESULTS

Preliminary positive (+)

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T), a preliminary positive result is indicated for the corresponding drug of that specific test zone.

Negative (-)

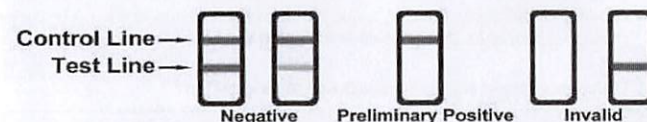
Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T), it indicates that the

concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

NO line appears in the "C" region, then the result is Invalid. Another test should be opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.

Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.



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: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS/MS is the preferred confirmatory method.

What Is A False Positive Test?

A false positive test result means the drug is not present but shows a positive result by the device. 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?

A false negative test means the drug is present but is not detected by the device. Diluted or contaminated urine specimens may cause a 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 substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause incorrect results.
3. Contaminated urine samples may produce incorrect results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of contamination, repeat the test with another urine sample.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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.

PERFORMANCE CHARACTERISTICS

A lay user study was performed at three intended user sites. There were 300 lay persons for the drug test. They had different educational and professional backgrounds. Their age range was from 18 to >50. Urine samples were prepared at the various concentrations. These concentrations were prepared by adding drug(s) into drug-free pooled urine samples. The concentrations of the samples were confirmed. Lay user results were compared to results obtained by LC/MS/MS. It demonstrated that lay users understood the device's instructions and could use the device accurately.

FREQUENTLY ASKED QUESTIONS

1. What does the U-NOW Drug Test Cup 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 screening test using the Test Cup. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional confirmation testing.

2. What is "cut-off level"?

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.

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
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Morphine (MOP/OPI)	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.
Notriptyline (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 to drugs and accurate. These tests, however, 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.

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

This means that if the sample was collected properly and the test was performed according to the directions, either the urine sample 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 of

abuse?

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.

8. 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.

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
Methylenedioxymethamphetamine (MDMA)	2-7 hours	2-4 days
Buprenorphine (BUP)	4 hours	1-3 days
Morphine (MOP/OPI)	2 hours	2-3 days
Methadone (MTD)	3-8 hours	1-3 days
Phencyclidine (PCP)	4-6 hours	7-14days
Notriptyline (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
Methadone metabolite (EDDP)	2 hours	2 to 6 days

CONFIRMATION TESTING

1. Please ensure the U-NOW cup with urine sample is tightly capped.
2. Write NAME, DOB and DATE on the cup where indicated.
3. Place the cup in the biohazard bag provided.
4. Please contact Virant Diagnostics Lab at (877) 888-2973 or email toxlab@virantdx.com for sample pickup and/or shipment instructions.

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 abuse prevention and treatment:

- American Council for Drug Education (ACDE)
1-800-DRUGHELP / www.acde.org
- Center for Substance Abuse Treatment (CSAT)
1-877-SAMHSA-7 / www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD)
1-800-NCA-CALL / www.ncadd.org
- Pride Youth Program formerly Parent's Resource Institute for Drug Education, Inc. (PRIDE)
1-800-668-9277 / www.prideyouthprogram.org
- The Treatment Center
1-877-409-9043 / www.thetreatmentcenter.org

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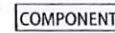
Add: Bioeasy Building 101 (whole building), 1st Liuxian Street, Xingdong Community, Xin'an Road, Bao'an, 518101 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA



Consult Instructions
For Use



In Vitro Diagnostic
Medical Device



Materials Included



Instruction for Use



Manufacturer



Date of Manufacture



Keep Dry



Do Not Reuse



Store at 4°C-30°C



Catalogue Number



Expiration Date



Keep away from
Sunlight



Lot Number

IFU VER: TS-IU-C196 A0

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