

Clinical Use
Please read all instructions before use.

Quick Cup Tests

Catalogue No.: See Box Label

Intended Use

The Precision Quick Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, EDDP, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

| Drug (Identifier) | Cut-off level |
|----------------------------|---------------|
| Amphetamine(AMP) | 1000 ng/mL |
| Barbiturates (BAR) | 300 ng/mL |
| Buprenorphine(BUP) | 10 ng/mL |
| Benzodiazepines(BZO) | 300 ng/mL |
| Cocaine(COC) | 300 ng/mL |
| Methadone metabolite(EDDP) | 300ng/ml |
| Ecstasy(MDMA) | 500 ng/mL |
| Methamphetamine(MET) | 1000 ng/mL |
| Morphine(MOR) | 300 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 |

Configuration of the Precision Panel Dip Tests and the Precision Quick Cup Tests 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 Precision Quick Cup Tests?

The Precision Quick Cup Tests are drug-screening tests that will give you a result for the presence 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 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.

Contents of the Kit

- One Test Device
 - Shipping bag
 - Labeled Tube for shipping sample
- Instructions for Use
 - Mailing box (Prepaid)
 - Urine collection cup

Not included in package

- Watch, timer or clock

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

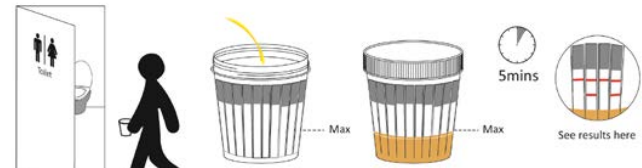
- Store between 39.2°F and 86°F.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.

URINE COLLECTION

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

PROCEDURE

- Remove the Quick Cup from the sealed pouch and use it within the first hour after opening
- Collect urine specimen in the provided cup.
- Screw the cap onto the cup and immediately start the timer



Reading Result:
4. The result should be read at 5 minutes.

INTERPRETATION OF RESULTS

PRELIMINARY POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

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).

INVALID: NO line appears in the C – Control region, then the result is Invalid.

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. Refer to the Confirmation Testing part of this insert.

- 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.

- 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 contaminated that may cause a false negative result.

LIMITATIONS

- This test is for human urine only. Do NOT use this device to test any other fluids.
- 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 drugs of abuse and certain medications.
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FREQUENTLY ASKED QUESTIONS

- What does the Precision Quick Cup 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.
- 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.
- 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.
- 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 |
| Methylenedioxy-methamphetamine (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, heroína, 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 |

- 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.

- 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.

- 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.

- 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.

- 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 |
| Methylenedioxy-methamphetamine (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 |
| 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 |
| Methadone metabolite (EDDP) | 2 hours | 2 to 6 days |

CONFIRMATION TESTING

- Write Identification Number on the label.
- 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.
- Please fill out name, return address, and cell phone number on Mailing Box.
- Place labeled vial in shipping bag and seal the bag.
- Place the sealed Shipping bag in the Mailing Box.
- Mail the box using any US Postal Service.
- Contact the lab if you do not get the result in 5 days.

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.ade.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









PERFORMANCE CHARACTERISTICS

A lay user study was performed at three intended user sites. There were 310 lay persons for the drug test. They had different educational and professional backgrounds. Their age range was from 21 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 GC/MS. It demonstrated that lay users understood the device’s instructions and could use the device accurately.

LITERATURE REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982
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3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's the Pharmacological Basis of Therapeutics. 6th Ed. New York: Macmillan; 1980

GLOSSARY OF SYMBOLS

| | | | |
|--|---|---|------------------------|
|  | Catalog number |  | Temperature limitation |
|  | Consult instructions for use |  | Batch code |
|  | <i>In vitro</i> diagnostic medical device |  | Use by |
|  | Manufacturer |  | Do not reuse |

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