VacuLid Multi-Drug Urine Test Cup

Catalogue No. See Box label

Please read all instructions first and familiarize with the materials before performing the test.

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VacuLid Multi-Drug Urine Test Cups tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

| Drug(Identifier) | Cut-off level | |
|---|-------------------------|--|
| Amphetamine(AMP) | 1000 ng/mL or 500 ng/mL | |
| Buprenorphine (BUP) | 10 ng/mL | |
| Secobarbital (BAR) | 300 ng/mL | |
| Oxazepam (BZO) | 300 ng/mL | |
| Cocaine (COC) | 300 ng/mL or 150 ng/mL | |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL | |
| Methamphetamine (MET) | 1000 ng/mL or 500 ng/mL | |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL | |
| Morphine (MOP300/OP12000) | 2000 ng/mL or 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 | |
| Cannabinoids (THC) | 50 ng/mL | |

VacuLid Multi-Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only.

The tests 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 applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

WHAT IS VACULID MULTI-DRUG URINE TEST CUP?

VacuLid Multi-Drug Urine Test Cup is an immunochromatographic assay for the qualitative determination of multiple drugs in human urine. It is intended for over-the-counter (OTC) use. For *in vitro* diagnostic use only.

The test is only the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. If you get a "preliminary positive' test result when you use this product, the second step in the process, along with the materials for shipping a portion of the urine sample to the laboratory for confirmation testing of a preliminary positive result, is provided.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

| Drug(ldentifier) | Calibrator | Cut-off level | Minimum detection time | Maximum detection time |
|--|--|---------------|---------------------------|---------------------------|
| Amphetamine (AMP 1000) | d-Amphetamine | 1000 ng/mL | 2-7 hours | 1-2 days |
| Amphetamine (AMP 500) | d-Amphetamine | 500 ng/mL | 2-7 hours | 1-2 days |
| Buprenorphine(BUP) | Buprenorphine | 10 ng/mL | 4 hours | 1-3 days |
| Secobarbital(BAR) | Secobarbital | 300 ng/mL | 2-4 hours | 1-4 days |
| Oxazepam (BZO) | Oxazepam | 300 ng/mL | 2-7 hours | 1-2 days |
| Cocaine (COC 300) | Benzoylecgonine | 300 ng/mL | 1-4 hours | 2-4 days |
| Cocaine (COC 150) | Benzoylecgonine | 150 ng/mL | 1-4 hours | 2-4 days |
| EDDP | 2-ethylidene-1,5- dimethyl-3,3- diphenyl-pyrrolidine | 300 ng/mL | 3-8 hours | 1~3 days |
| Methamphetamine (MET1000) | D(+)- Methamphetamine | 1000 ng/mL | 2-7 hours | 2-4 days |
| Methamphetamine (MET 500) | D(+)- Methamphetamine | 500 ng/mL | 2-7 hours | 2-4 days |
| Methylenedioxymethamph etamine (MDMA) | 3,4- Methylenedioxymeth amphetamine | 500 ng/mL | 2-7 hours | 2-4 days |
| Morphine (OP 12000) | Morphine | 2000 ng/mL | 2 hours | 2-3 days |

| Morphine (MOP300) | Morphine | 300 ng/mL | 2 hours | 2-3 days |
|---------------------|--------------------------|------------|-----------|---------------|
| Methadone (MTD) | Methadone | 300 ng/mL | 3-8 hours | 1-3 days |
| Oxycodone(OXY) | Oxycodone | 100 ng/mL | 4 hours | 1-3 days |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL | 4-6 hours | 7-14days |
| Propoxyphene (PPX) | d-Propoxyphene | 300 ng/mL | 2 hours | 2-3days |
| Nortriptyline (TCA) | Nortriptyline | 1000 ng/mL | 8-12hours | 2-7 days |
| Cannabinoids (THC) | 11-nor-∆9-THC-9- COOH | 50 ng/mL | 2 hours | Up to 5+ days |

WARNINGS AND PRECAUTIONS

- 1. This kit is for external use only. Do not swallow.
- 2. Discard after first use. The test cannot be used more than once.
- 3. Do not use test kits beyond expiry date.
- 4. Do not use the kit if the pouch is punctured or not well sealed.
- 5. Keep out of the reach of children.
- 6. Read the drug test result at 5 minutes. The result can be stable for 30 minutes. Do not read the result after 30 minutes.

CONTENT OF THE KIT

- Test devices, one test in one pouch. One pouch contains a test VacuLid and desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
- Security sealed labels.
- Leaflet with instructions for use. .

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or clock

Evacuated urine collection tube

STORAGE AND STABILITY

Store at 4 °C- 30 °C (39 °F - 86 °F) in the sealed pouch up to the expiration date.

Keep away from direct sunlight, moisture and heat.

DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

You may collect urine samples in minimum detection time later after suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. This is because each drug is cleared by the body at different rates. Please refer to the section "WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?" in this instruction for use for the minimum or maximum detection time of each drug.

HOW TO COLLECT URINE?

- 1. Remove a test cup from the foil pouch by tearing at the notch and use it as soon as possible. Open the cap of the test cup and urinate directly into the test cup to reach the minimum urine level. Wipe off any splashes or spills that may be on the outside of this cup.
- 2. You may observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is added to the cup. The temperature range from 32°C to 38°C (90 °F-100°F) indicates a fresh uncontaminated sample.
- 3. Peel back the protective seal label on the cap to expose the integrated transfer device.
- 4. Place evacuated tube into cavity on cap, stopper down. Advance the tube over puncture point to pierce stopper.
- 5. Hold the tube in position. The urine will be filled into the tube automatically.
- 6. Remove the tube after collection. Re-attach the protective seal label for safety.
- 7. Label the evacuated tube for transport to laboratory. Make sure the number on the evacuated tube matches your Personal Identification Number.



HOW TO DO THE TEST?

Test should be at room temperature 18°C - 30°C $~(65^{o}\,\text{F}$ -86°F) .

- 1. After the urine has been collected, re-cap the test cup and place it on a flat surface.
- 2. Peel the label from right to left. Read the result at 5 minutes. The result can be stable for 30 minutes. Do not read the result after 30 minutes.



Note: Results after more than 30 minutes may be not accurate and should not be read.

READING THE RESULTS

Preliminary positive (+)

A colored band is visible in each control region. No colored band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

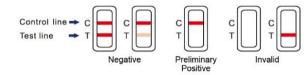
Negative (-)

A colored band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid

If a color band is not visible in each of the control region, the test is invalid. Another test should be run to reevaluate the specimen. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



A preliminary positive test result does not always mean that a person took illegal drugs. A negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect 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 laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by VacuLid Multi-Drug Urine Test Cup. 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?

The definition of a false negative test is that the initial drug is present but isn't detected by VacuLid Multi-Drug

Urine Test Cup. If the sample is diluted or adulterated that may cause false negative result.

If you get a negative test result but you still suspect someone is taking drugs you should test again at another time ,or test for different drugs.

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 anything but urine.
- 2. Adulterated urine samples may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
- 3. It is possible that technical or procedural errors, as well as other interfering substances in the urine sample may cause false results.
- 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. You can't retrieve your confirmed results without knowing your Personal Identification Number.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test do?

These tests indicate if one or more prescription or illegal drugs are present in urine. These tests detect the presence of drugs such as amphetamine, secobarbital, buprenorphine, oxazepam, benzoylecgonine, EDDP, MDMA, methamphetamine, morphine, methadone, oxycodone, phencyclidine, propoxyphene, nortriptyline and marijuana.

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 result is called positive, and below that concentration it is called negative.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription drugs (for example, Oxycodone or Valium) 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. What are the 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 |
| Buprenorphine(BUP) | Bupe, Subbies, Temmies |
| 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 |
| Morphine (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) | mixture, meth, linctus, green |
| Oxycodone (OXY) | OC, Ocycotton, OX, and Kicker |
| Phencyclidine (PCP) | Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trank, white horizon and zoom. |
| Nortriptyline (TCA) | |
| Cannabinoids (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. |

5. Howaccurate 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 person is free of drugs?

This means that if the sample was collected properly and if the test was performed according to direction, then none of the drug screened were present in the sample.

7. Does a preliminary positive screen test mean that drugs of abuse have been found?

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. What is the principle of VacuLid Multi-Drug Urine Test Cup?

VacuLid Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine.

When the test is activated, the urine is absorbed into the device by capillary action. Then flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates.

If concentrations of sample drugs are below corresponding detected drugs' cutoff, respective drug antibody conjugates bind to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. This produces a colored line in test region that indicates a negative result.

On the contrary, if concentrations of sample drugs are at or above corresponding detected drugs' cutoff, the free drugs of sample bind to the respective drug antibody conjugates. It prevents the respective drug antibody conjugates from binding to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. Therefore, there is no colored line in the test region that indicates a preliminary positive result.

To serve as a procedure control, if the test has been performed properly, a colored line will appear at the Control Region (C).

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIDENTIAL CONFIRMATION TESTING

- 1. Ensure that the labeled evacuated tube is about two thirds (2/3) full and that the cap is tightly closed.
- 2. Check the label identifying the drug that was a preliminary positive result.
- 3. Place the labeled evacuated tube in the plastic bag and seal the plastic bag.
- 4. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address is already on the mailing box.
- 5. Drop the mailing box and pay the postage at any US Postal Service Office.

IMPORTANT: You may call or send an email for the confirmed test results along with the Personal Identification Number. The phone number and email address are already inside the mailing box. Please remember to mark down the phone number and email address.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

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.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

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

INDEX OF SYMBOLS



Keep away from sunlight



Store between 4°C and 30°C



Keep dry



Do not re-use

Rev. A1

Distributed by: Sober Scientific LLC support@soberscientific.com www.soberscientific.com

Rel: 2019/05/08