Unow™ Drug Test Device

AMP 50/BZO 10/BUP 10/COC 30/MET 50/OPI 40/THC 25

The Unow™ Drug Test Device is a rapid, one-step immunoassay for the qualitative detection of Amphetamine, Benzodiazepines, Buprenorphine, Cocaine, Methamphetamine, Opiates, Δ9-Tetrahydrocannabinol(THC) and their metabolites at the following cut-off concentrations in human oral fluid or drug residue on surfaces.

Test	Calibrator	Cutoff (ng/mL)
Amphetamine(AMP)	d-Amphetamine	50
Benzodiazepine(BZO)	Oxazepam	10
Buprenorphine(BUP)	Buprenorphine	10
Cocaine(COC)	Benzoylecgonine	30
Methamphetamine(MET)	d-Methamphetamine	50
Opiates(OPI)	Morphine	40
Marijuana(THC)	Delta-9-Tetrahydrocannabinol	25

This device provides only preliminary drug test results. To obtain a quantitative result or a confirmation of a presumptive positive result, a more specific alternative method must be used. GC/MS/MS or LC/MS/MS is the preferred confirmatory method. Professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated.

Explanation

AMP: A central nervous system stimulant that is used to treat attention deficit hyperactivity disorder (ADHD) and narcolepsy. It increases the release of neurotransmitters like dopamine and norepinephrine, leading to heightened alertness and energy.

BZO: A class of psychoactive drugs known for their sedative, anxiolytic, muscle relaxant, and anticonvulsant properties. They are commonly prescribed for anxiety, insomnia, and seizures.

BUP: A partial opioid agonist used in the treatment of opioid addiction. It helps reduce withdrawal symptoms and cravings without producing the same high as other opioids, making it useful in medication-assisted treatment programs.

COC: Cocaine is a powerful central nervous system stimulant derived from the coca plant. It works by blocking the reuptake of neurotransmitters such as dopamine, norepinephrine, and serotonin, leading to increased levels in the brain. This results in heightened alertness, energy, and euphoria. However, cocaine is highly addictive and can have severe negative effects on the cardiovascular system and mental health.

MET: Methamphetamine is a powerful central nervous system stimulant that affects chemicals in the brain and nerves that contribute to hyperactivity and impulse control. It increases the release of dopamine, leading to increased energy, alertness, and euphoria. Methamphetamine is highly addictive and can cause severe dental problems, skin sores, and significant neurological damage.

OPI/MOR: Opiates are a group of drugs derived from the opium poppy plant, including natural substances like morphine and codeine. They are primarily used for their analgesic (pain-relieving) properties. Opiates work by binding to opioid receptors in the brain, reducing the perception of pain and often producing feelings of euphoria. They carry a high risk of addiction and overdose.

THC: The primary psychoactive component of cannabis, responsible for the "high" associated with marijuana use. It interacts with cannabinoid receptors in the brain, affecting mood, memory, and perception.

Summary

Drugs can be rapidly metabolized in the blood after consumption. Detection of drugs or drug metabolites in body fluids (blood, urine or oral fluid) can reveal recent use of the drugs. Rapid lateral flow immunoassay testing (within 5-10 minutes) of drugs of abuse is superior over other chemical or immunological assay methods for onsite screening, due to its ease of use. It is ideal for quick screening of large population and is non-invasive.

Extensive research has demonstrated the close correlation of drugs and their metabolites concentrations between blood samples and oral fluid samples. Oral fluid testing for the detection of drugs of abuse have also been successful in numerous studies. Oral fluid drug testing in particular, overcomes the limitations of the widely used urine drug testing. Oral fluid drug testing can be performed by "face to face" collection therefore sample adulteration is difficult. Oral fluid collection can be conveniently and repeatedly done under a variety of circumstances to avoid needs for separate urine specimen collection.

Unow™ Drug Test Device is uniquely designed for user-friendly onsite rapid drug testing using oral fluid specimen (5-10 minutes). As shown in the instructions, the oral fluid can be quickly collected and tested.

In addition to the aforementioned advantages of detecting drugs of abuse in oral specimen, **Unow™ Drug Test Device** can also detect drug residues on any contaminated solid surfaces as well as their other forms such as powder. Sample collection and testing don't require testers to handle any liquids for the whole sample collection and testing processes. No sample treatment such as dissolving powders or residue in a solution is needed.

Test Principle

Unow™ Drug Test Device is based on competitive lateral flow immunoassay to qualitatively detect illicit drugs and their metabolites. Drug antibodies were conjugated to colloidal gold nanoparticles. After samples are applied, the nanoparticle-antibody conjugate will flow and bind to the drug conjugate line located on the nitrocellulose membrane of the test strip forming a red color line for each drug target. If the sample contains drug, the drug molecule will competitively bind to the antibody on the gold nanoparticles. The antibody-gold conjugate nanoparticles will not bind the drug conjugate on the membrane and therefore no colored line will be formed (positive).

Precautions

- For Forensic Use only
- The test device is for single use and should remain in its original sealed pouch until ready for use.
- Do not use after the expiration date indicated on the kit.
- Handle all oral specimens as potentially infectious. The used device should be discarded according to federal, state and local regulation.

Materials Provided

1. 1 Package Insert
2. Test device with desiccant packaged individually in a foil pouch.

Storage and Stability

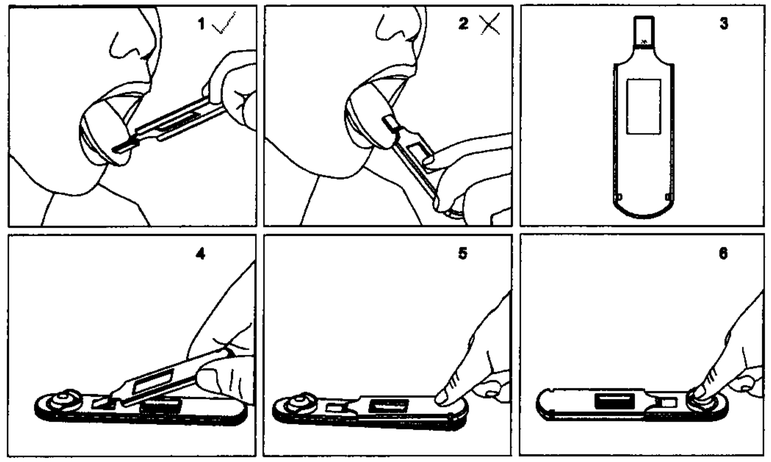
1. Store at 2°C-30°C. Do not open pouch until ready to perform the assay.
2. Keep away from direct sunlight, moisture and heat.

Test Procedure

For Oral Fluid:

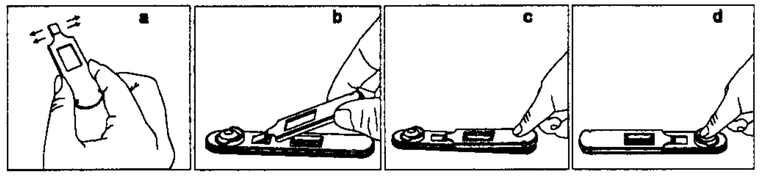
Allow the test device to reach room temperature 15 - 30°C, and instruct the donor not to eat, drink, smoke or chew tobacco products for at least 15 minutes prior to collection of fluid specimen.

1. Remove the test device and the flocked pad from the sealed pouch and use the device as soon as possible.
2. Wipe saliva on the tongue with the pad tip (Picture 1). Do not rub the whole pad against tongue, this may not collect enough saliva sample (Picture 2). The collection is finished when a pink spot indicator appears (Picture 3). About 80uLsaliva is collected.
3. Insert the flocked pad in the device (Picture 4).
4. Press until click to lock (Picture 5).
5. Lay the device on a flat surface and press the reagent blister by thumb until the blister collapses completely to release all the buffer (Picture 6).
6. When the liquid sample front is initially observed on both strips, start the timer. Read results at 5 minutes. The results are invalid after 10 minutes.



For Drug Residue :

1. Remove the test device and the flocked pad from the sealed pouch and use the device as soon as possible.
2. Wipe the suspected surfaces (about 10cm * 10cm, sample loading should be less than 500ug) or swab on different areas with the flocked pad back and forth (Picture a).
3. Insert the flocked pad in the device (Picture b).
4. Press until click to lock (Picture c).
5. Lay the device on a flat surface and press the reagent blister by thumb until the blister collapses completely to release all the buffer (Picture d).
6. When the liquid sample front is initially observed on both strips, start the timer. Read results at 5 minutes. The results are invalid after 10 minutes.



Interpreting Test Results

Negative Results

A red colored band should be observed in control region (C), and specific drug test region.

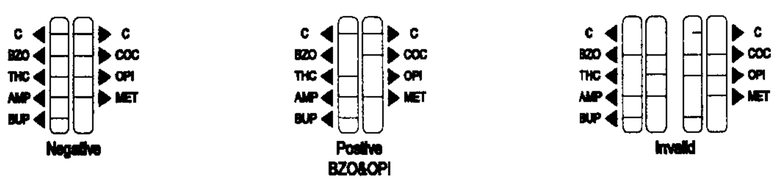
The color and density of the test band may vary for control and drug test region.

Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band appears at the specific test region, the result is a **presumptive positive** for that particular drug.

Invalid

When **no** band appears in the control (C) region, **the test is invalid** regardless of the results in the test region. If the test is invalid, check testing procedures. **Repeat the test using a new device.**



Important: Do not compare color intensity of one test band to another. Read each test independently.
Any darker or light red band for a specific test is observed in the test region along with the presence of the control line (C), the sample should be considered negative. For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS/MS or LC/MS/MS) must be used.

Quality Control

Although all **Unow™ Drug Test Device** lots undergo strict quality surveillance and control, it is recommended that the product user perform quality control with known negative and positive samples at a regular basis. Quality control test is also recommended when a new lot is going to be used or the product has been stored outside of the recommended storage conditions. Negative and positive controls should give the expected results when tested by pipetting 80uL of the controls onto the flocked pad.

Limitations of Procedure

1. Rare false positive or false negative results may occur due to non-specific cross reaction between the test reagent in the test strip and certain component in the oral fluid. The cause of the false results could be from a food component that contains compounds with similar or identical structure for binding to the test reagent. Other conditions such as physiological or pathological conditions, or the donor taking medicine, could also produce false results. If the test result is suspicious, further confirmation testing using GC/MS/MS or LC/MS/MS method is recommended.

2. Under certain physiological or pathological conditions, such as waking up from sleep in the early morning, dry mouth syndrome, oral fluid collection time may be prolonged. The donor must not eat or drink within 15 minutes before testing.

3. The assay is designed for detection of nano scale drug residues. Positive results only indicate the presumptive presence of drugs. It is not intended to test 'anything and everything' (beverages/sodas/alcohols, food products, household products, phytosanitary products, cosmetics), which may contain chemical or biological compounds that could interfere with the proper functioning of the test.

Bibliography of Suggested Reading

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2. Caplan, Y. and Goldberger, B., Alternative Specimens for Workplace Drug Testing, J. Analytical Toxicology, vol. 25, p. 396-399, 2001.
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4. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
5. Heltsley, R, et al, "Oral Fluid Drug Testing of Chronic Pain Patients. II Comparison of Paired Oral Fluid and Urine Specimens", J. Analytical. Toxicology, 2012 March.; 36 (2), pp 75-80.

Glossary of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	n	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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