

Accurate[®]

Multi Panel Drug Urine Test Cup

Package Insert

Package insert for testing of any combination of the following drugs: Methamphetamine, Cocaine, Morphine, Amphetamine, Oxycodone, Ecstasy, EDDP, Buprenorphine, Phencyclidine, Secobarbital, Methadone, Marijuana, Oxazepam, Propoxyphene and Tricyclic Antidepressants.

INTENDED USE

Accurate[®] Multi Panel Drug Urine Test Cups (CLIA WAIVED) 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 Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1,000 ng/mL
Buprenorphine (BUP)	10ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	300 ng/mL or 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)	1,000 ng/mL
Marijuana (THC 50)	50 ng/mL

Accurate[®] Multi Panel 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.

STORAGE

Store as packaged in the sealed pouch at 39-86°F (4-30°C). The Test Cup is stable through the expiration date printed on the label. The Test Cup must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SAMPLE COLLECTION

The urine sample must be collected in a clean and dry container provided. Urine collected at any time of the day may be used.

What is included inside the package?

- User Instruction
- Collection Cup
- Test Cup (inside foil pouch)
- Pre-addressed and pre-paid mailing box for shipping samples for confirmation testing.

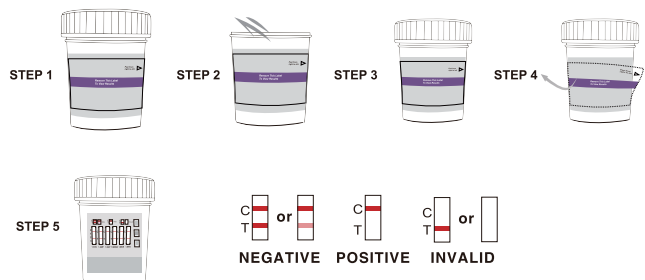
Not included in package:

- Watch, timer, or clock

DIRECTIONS FOR USE

Allow the test cup to come to room temperature [15-30°C (59-86°F)] prior to test.

- Tear the foil bag open, remove test cup and disposable gloves provided for donor. Label the device with donor information.
- Open test cup lid. Urinary directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30ml to maximum 110ml (marked on the cup).
- After urine specimen has been collected, close the lid securely and place the urine test cup on a flat surface.
- Peel off label to reveal test result. Read test result at 5 minutes. **DO NOT INTERPRET RESULT AFTER 30 MINUTES.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Negative: If a line shows in both the C - control and the T - test area, it means a Negative result for the test drug, regardless of how dark or light the line may appear.

Positive: If a line appears in the C – Control area, but no line shows in the T - Test area, it means a Preliminary Positive result for the test drug.

Invalid: NO line shows in the C – Control area, then the result is Invalid. In such case, retest with a new device.

NOTE: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

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

What Is a False Positive Test?

The test result from the device is positive, but the target drug is not in the sample. The most common causes are interfering substances. 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?

The target drug is present but isn't detected by the device. If the sample is diluted, or the sample is tainted or polluted with certain substances, this could cause a false negative result.

LIMITATIONS

- The device is for urine test only.
- Substances, such as bleach and/or alum, in urine samples may produce wrong results.
- A positive result does not indicate drug route or drug concentration.
- The test does not tell differences between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

How do I mail a positive urine sample to the laboratory for confidential confirmation testing?

- Label the collection cup.
- Place collection cup in pre-addressed and pre-paid mailing box (included). Make sure the cup lid is securely fastened then place it in the plastic bag (included). Seal the bag and place into the mailing box.
- Close the pre-addressed and pre-paid mailing box and secure it with packing tape. Samples do not need to be shipped refrigerated. Samples may also be stored at room temperature for up to 24 hours before mailing.

Performance Characteristics

A lay user study was performed at three intended user sites. There were 310 lay persons for each 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. Results demonstrated that lay users understood the device's instructions and could use the device accurately.

Additional Information and References

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 <https://www.addiction.com> 1-844-768-0189

Center for Substance Abuse Treatment <https://www.samhsa.gov/> 1-800-662-HELP

National Institute on Drug Abuse www.drugabuse.gov 1-301-443-1124

American Council for Drug Education www.freetreatmentcenters.com 1-800-607-2263

INDEX OF SYMBOLS



Keep away from sunlight



Store between 4–30°C



Keep dry



Do not re-use



Do not freeze

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