

Areta®

Drug Test Cup

Areta® Drug Test Cup offers a variety of solutions for fast, accurate and easy drug testing. Depending on the test you have purchased, Areta® Drug Test Cup can detect up to 15 different drugs from any combination of following commonly abused drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepine (BZO), Buprenorphine(BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxyamphetamine (MDMA), Morphine (MOP), Opiate (OPI2000), Oxycodone(OXY), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), and Propoxyphene (PPX).

The multi-drug device may be combined with the adulteration control (Creatinine (CR), Glutaraldehyde (GLU), Nitrite (NI), pH, Specific Gravity (S.G.), Oxidants (OXI), and/or Pyridium Chlorochromate (PCC)) for the determination of diluted or adulterated urine specimens. The adulteration control is an important pre-screening test for drug-testing. (The adulteration tests are optional).

This package insert applies to both multi-drug cups with and without the adulteration. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the pouch and the prints on the test cup to identify which drugs are included in your test.

For in vitro diagnostic use only. For over-the-counter use only.

WHAT IS Areta® DRUG TEST CUP?

Areta® Drug Test Cup is an immunochromatographic assay for the qualitative determination of multiple drugs in human urine.

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

Drug(Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP)	d-Amphetamine	1000ng/mL	2-7 hours	1-2 days
Barbiturates (BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Benzodiazepine (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days

Buprenorphine(BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Cocaine (COC)	Benzoylcegonine	300 ng/mL	1-4 hours	2-4 days
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Methamphetamine (MET)	D(+)-Methamphetamine	1000ng/mL	2-7 hours	2-4 days
Methylenedioxyamphetamine (MDMA)	3,4-Methylenedioxyamphetamine HCl (MDMA)	500 ng/mL	2-7 hours	2-4 days
Morphine (MOP)	Morphine	300 ng/mL	2 hours	2-3 days
Opiate (OPI2000)	Morphine	2000ng/mL	2 hours	2-3 days
Oxycodone(OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Tricyclic Antidepressants (TCA)	Notriptyline	1000ng/mL	8-12hours	2-7 days
Propoxyphene (PPX)	Propoxyphene	300 ng/mL	8-12hours	5-10 days

WARNINGS AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiry date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Do not read after 5 minutes

CONTENT OF THE KIT

- Test devices, one test in one pouch. One pouch contains a test cup with test card and a desic cant. The desiccant is for storage purposes only, and is not used in the test procedures.
- Leaflet with instructions for use.
- Adulterant color chart (Optional).

STORAGE AND STABILITY

Store at 4°C ~ 30°C (40°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 within detection time after suspected drug use. Collection time is crucial to detecting any drug of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the section "WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?" in this instruction for use for the minimum/ maximum detection time for 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. The sample volume should be higher than the minimum urine level. Re-cap the cup. Wipe of 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 to see if the urine is diluted by water or liquid other than urine. The temperature range from 32°C to 38°C (90 °F-100°F) is acceptable.
3. IMPORTANT: The urine sample should meet or exceed the minimum urine level required for proper testing. The minimum urine level is located on the side of the cup label.

HOW TO DO THE TEST?

Test must be in room temperature 10°C ~ 30°C (50°F ~ 86°F).

For drugs test:

1. After the urine has been collected, re-cap the cup and place the test cup on a flat surface.
2. Peel the label from right to left and read the result at 5 minutes. Do not read results after 5 minutes.

For drugs and adulteration test:

1. After the urine has been collected, re-cap the cup and place the test cup on a flat surface.
2. Start the timer. Peel the label from right to left and read the result.
3. For the adulteration strip(s), compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results. Note: All reagent areas may be read between 1 - 2 minutes. Changes in color after 2 minutes are of no diagnostic value.
4. For the drug of abuse tests, read the results for the drugs at 5 minutes. Do not read after 5 minutes.

Note: Results after more than 5 minutes may be not accurate and should not be read.

Instructions:

Step 1: Collect Urine.



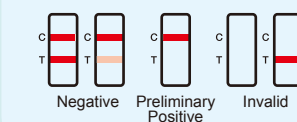
Step 2: Peel off label to view results.



Step 3: Wait 5 minutes and read results.



Results



READING THE RESULTS

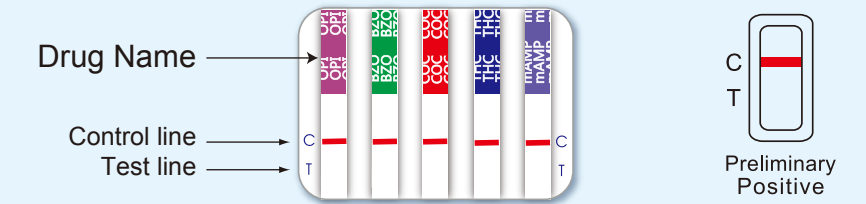
ADULTERATION CONTROL:

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding color blocks on the enclosed color chart.

DRUGS-OF-ABUSE TESTS:

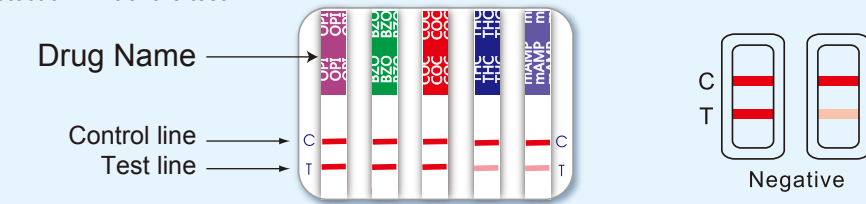
Positive (+)

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



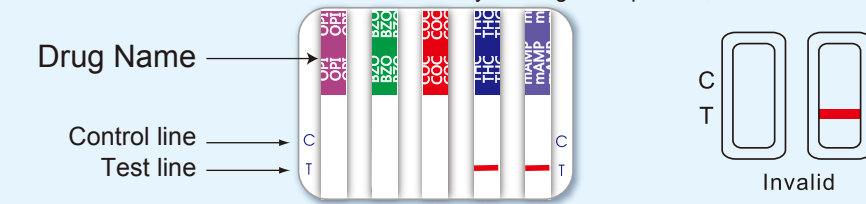
Negative (-)

A rose-pink 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 zero or below the detection limit of the test.



Invalid

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. 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 a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence 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 Areta® Drug 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 Areta® Drug Test Cup . If the sample is diluted, or the sample is adulterated that may cause false negative result.

SPECIFICITY AND CROSS REACTIVITY

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Amphetamine (AMP)	Concentration (ng/ml)	Methylenedioxyamphetamine (MDMA)	Concentration (ng/ml)
d-Amphetamin	1,000	3,4-Methylenedioxyamphetamine HCl (MDMA)	500
d,l-Amphetamine	3,000	3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
l-Amphetamine	50,000	3,4-Methylenedioxyethylamphetamine (MDE)	300
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	Morphine (MOP)	
Phentermine	3,000	Morphine	300
d-methamphetamine	>100,000	Codeine	300
l-methamphetamine	>100,000	Ethyl Morphine	300
3,4-Methylenedioxyethylamphetamine(MDE)	100,000	Heroin	300
(+/-)3,4-methylenedioxymethamphetamine (MDMA)	100,000	Hydrocodone	5,000
Barbiturates (BAR)		Hydromorphone	5,000
Secobarbital	300	Morphine-3-β-d-glucuronide	1,000
Amobarbital	300	σ -Monoacetylmorphine	400
Alphenol	150	Oxycodone	25,000
Aprobarbital	200	Oxymorphone	10,000
Butobarbital	75	Thebaine	30,000
Butathal	100	Opiate (OPI 2000)	
Butalbital	5,000	Morphine	2,000
Cyclopentobarbital	600	Codeine	2,000
Pentobarbital	5,000	Ethylmorphine	5,000
Phenobarbital	10,000	Heroin	2,000
Benzodiazepine (BZO)		Hydrocodone	12,500
Oxazepam	300	Hydromorphone	5,000
Alprazolam	200	Levorphanol	75,000
a-Hydroxyalprazolam	1,500	σ-Monoacetylmorphine	5,000
Benzodiazepine	100	Morphine 3-b-D-glucuronide	2,000
Bromazepam	1,500	σ-Monoacetylmorphine	5,000
Chlordiazepam	10,000	Norcodeine	12,500
Chlordiazepoxide	1,500	Normorphone	50,000
Clonazepam HCl	800	Oxycodone	25,000
Clobazam	100	Oxymorphone	25,000
Clonazepam	5,000	Procaine	150,000
Clorazepate dipotassium	200	Thebaine	100,000
Delorazepam	1,500	Oxycodone(OXY)	

Desalkylflurazepam	400	Oxycodone	100
Diazepam	200	Dihydrocodeine	20,000
Estazolam	2,500	Codeine	100,000
Flunitrazepam	400	Hydromorphone	100,000
D,L-Lorazepam	1,500	Morphine	> 100,000
Midazolam	12,500	Acetylmorphine	> 100,000
Nitrazepam	100	Buprenorphine	> 100,000
Norchlordiazepoxide	200	Ethylmorphine	> 100,000
Nordiazepam	400	Phencyclidine (PCP)	
Temazepam	100	Phencyclidine	25
Triazolam	1,000	4-Hydroxyphencyclidine	12500
Buprenorphine(BUP)		Tricyclic Antidepressants (TCA)	
Buprenorphine	10	Notriptyline	1,000
Buprenorphine -3-D-Glucuronide	15	Nordoxepine	1,000
Norbuprenorphine	20	Trimipramine	3,000
Norbuprenorphine 3-D-Glucuronide	200	Amitriptyline	1,500
Cocaine (COC)		Promazine	1,500
Benzoylcegonine	300	Desipramine	200
Cocaine HCl	750	Imipramine	400
Cocaethylene	12,500	Clomipramine	12,500
Ecgonine	32,000	Doxepine	2,000
Marijuana (THC)		Maprotiline	2,000
11-nor-Δ9-THC-9-COOH	50	Promethazine	25,000
11-nor-Δ8-THC-9-COOH	30	Methamphetamine (MET)	
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	D(+)-Methamphetamine	1,000
Δ8- Tetrahydrocannabinol	7,500	D-Amphetamine	50,000
Δ9- Tetrahydrocannabinol	10,000	Chloroquine	50,000
Cannabinol	100,000	(+/-)-Ephedrine	50,000
Cannabidiol	100,000	(-)-Methamphetamine	25,000
Methadone (MTD)		(+/-)3,4-methylenedioxymethamphetamine(MDMA)	2,000
Methadone	300	β-Phenylethylamine	50,000
Doxylamine	50,000	Trimethobenzamide	10,000
Propoxyphene (PPX)			
d-Norpropoxyphene	300		

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. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. There is a possibility that technical or procedural errors may cause erroneous results.
5. 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.

6. Test does not distinguish between drugs of abuse and certain medications.

7. The adulteration assays are for screening purposes only; all abnormal results should be confirmed by an alternative methodology.

MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between 4°C-30°C (40°F-86°F)



Keep dry



Do not re-use

Questions?

Any questions, please call us toll-free at

1-855-822-6999.

Monday – Friday 9:00 a.m.-5:00 p.m. Central Time.

To learn more, please visit us at

www.healthcare-manager.com

Manufactured for **Easy Healthcare Corporation**

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QUESTIONS AND ANSWERS

The Drug Line is lighter than the Control Line. Does this mean some drug is present?

No. Any line next to the word Drug or the drug abbreviation (depending on the test you have purchased), no matter how dark or light, is considered a Negative Result and no further testing is required. It is possible that the intensity of the lines will vary among the drugs being tested for due to a variety of reasons such as; how diluted the urine is, the pH or protein level of the urine, or interference from a metabolite in the urine that closely resembles the drug.

How soon can I read my results?

Negative result is available to read whenever the Test line which representing the specific drug appears and Control lines shall always appears if test is valid. For positive results you have to wait until 5 minutes when the specific Test line doesn't show up at all while Control lines shall always appears if test is valid.

Are there any factors that can affect the test result?

Certain over-the-counter medications or prescription drugs may cross-react with the Areta® Drug Test and cause a Preliminary Positive Result.

The test will only give accurate results on fresh human urine samples. Old or diluted urine samples may not be suitable for testing.

If you are testing someone else, keep in mind that Areta® Drug Tests are only as accurate as the urine sample being tested. Samples can easily be “adulterated” (i.e., contaminated or tampered) with common household products such as bleach and other liquids if you're not closely supervising the entire process.

This test provides a screening result only. It is not designed to determine the actual concentration of a drug, the level of intoxication nor is it to be used for legal purposes.

What cut-off levels do Areta® Drug Tests use for detecting drugs in urine?

The cut-off level for each drug varies (depending on the type of drug) and is measured in nanogras(ng/ml).

Although Areta® Drug Tests are designed to detect a very small amount of a drug in urine, if the amount is below the established cut-off level, you may test negative for that drug even though you may have taken the drug.

How soon after taking a drug can you detect it in urine with a Areta® Drug Test and how long can a drug be detected in urine?

Most drugs can be detected in urine with a Areta® Drug Test within a few hours after taking the drug; however this can vary depending on the type of drug taken, the amount taken, the frequency of use, and the metabolism of the person being tested.

Each drug is cleared by the body at different rates. Some drugs, for example marijuana, can stay in the body for up to several weeks after use.

If I test negative with a Areta® Drug Test, does this guarantee I will test negative on other drug tests administered by a professional?

Many Areta® Drug testing products are more than 99 percent accurate in detecting specific drugs according to the designated cut-off levels. However, if a more sensitive test is administered, there is a chance of testing positive if drugs are present in urine.