



Single Drug Screen Test

Easy@Home Single Drug Screen Test offers any 1 of 14 drugs of abuse tests for 14 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxyamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), Buprenorphine (BUP) and Oxycodone (OXY).

This package insert applies to all Single Drug Screen Tests. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level.

For in vitro diagnostic use. It is intended for over-the-counter and for prescription use.

INTENDED USE

Easy@Home Single Drug Screen Test is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

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)	Benzoyllecgonine	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

This assay provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive.

PRINCIPLE

DRUG TESTS

Easy@Home Single Drug Screen Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When testing, the urine is absorbed upward by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

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

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 expiration date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.

STORAGE AND STABILITY

- Store at 4 °C ~ 30 °C up to the expiration date.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Material provided

- One pouch containing a test Panel and a desiccant.
- Package insert

Material Required But Not Provided

- Timer
- Urine cup

SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2 °C -8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).

Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (10°C to 30°C)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. Do not read after 5 minutes.

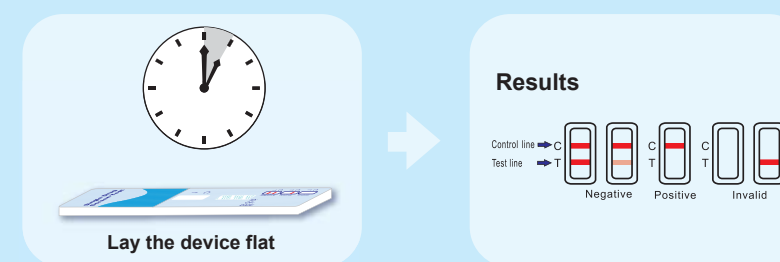
Step 1:

Pull the cap off and immerse the strips into urine for 10 seconds



Step 2:

Read results in 5 minutes. Do not read after 5 minutes.



INTERPRETATION OF RESULTS

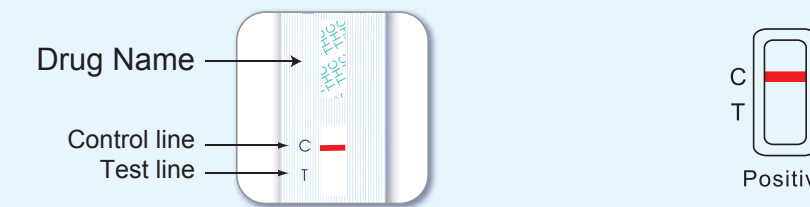
DRUGS

Example:

- 1 Drug Tested: Marijuana(THC)

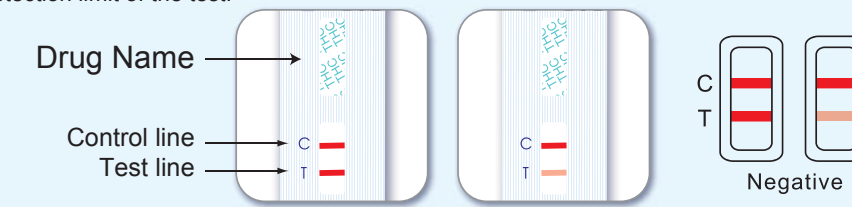
Positive (+)

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.

QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

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	o -Monoacetylmorphine	400
Alphenol	150	Oxycodone	25,000
Aprobarbital	200	Oxymorphone	10,000
Butabarbital	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	o-Monoacetylmorphine	5,000
Benzodiazepine	100	Morphine 3-b-D-glucuronide	2,000
Bromazepam	1,500	s-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

LIMITATIONS


1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen 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. The test result does not distinguish between drugs of abuse and certain medicines.


7. A positive result might be obtained from certain foods or food supplements.

MEANING OF SYMBOLS ON PACKAGE

 Keep away from sunlight

 Store between 4°C and 30°C

 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.

Our professional staff will assist you.

To learn more, please visit us at www.healthcare-manager.com

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?

Any negative result is available to read as long as two lines appeared in the results window. For positive results you have to wait for 5 minutes when only a red or pink colored line appeared next to the letter of C and there is no line appeared next to the letter of T.

Are there any factors that can affect the test result?

Certain over-the-counter medications or prescription drugs may cross-react with the Easy@Home 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 Easy@Home 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 Easy@Home 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 nanograms (ng/ml).

Although Easy@Home 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 Easy@Home Drug Test and how long can a drug be detected in urine?

Most drugs can be detected in urine with a Easy@Home 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 Easy@Home Drug Test, does this guarantee I will test negative on other drug tests administered by a professional?

Many Easy@Home 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.