

Test Instruction/ Question & Answer Handbook

5

TOO MUCH URINE WILL FLOOD TEST DEVICE

Online results available 24/7 at www.phamatech.com

Place Red Sticker/ (PIN) Identification Number from Labeled Vial HERE

9150T.5

At Home™ Drug Test

A parenting tool for random screening for the presence of Drugs of Abuse in urine

IMPORTANT

Read entire Test Instruction Handbook before use

WARNINGS AND PRECAUTIONS

This test is only the First Step in a Two Step process for determining the presence of drugs of abuse. You must consult your health care provider or refer all "preliminary" results to the laboratory in order to obtain step two: a confirmed result.

Judgment should be applied to any drug of abuse test result, particularly when initial results are "preliminary." Remember, without proper confirmation testing you cannot accept any result this test gives as being positive.



KIT CONTENTS

Familiarize yourself with the contents of this kit:

TESTING MATERIALS

- 1 Test Instruction/Question & Answer Handbook
- 1 At Home™ Drug Test Device (in a foil pouch)



1 Collection Cup (with a temperature monitoring strip)



CONFIRMATION MATERIALS

 Labeled transport vial (for shipping "preliminary" sample to the laboratory for confirmation, located inside the pre-addressed mailing box)



 Personal Identification Number (on red label located on the transport vial)



1 Plastic transport bag

1 Pre-addressed mailing box



Your Personal Identification Number (PIN) is located on a two part tag which can be found on the labeled vial. Detach the white and red portion and place the red sticker on page 1 of this handbook in the space provided, leaving the white portion attached to the vial.

If any component is missing from this kit you must call our customer service hotline at 877-HOME-TEST (877-466-3837). Please have your Personal ID Number available.

What is the At Home™ Drug Test?

At Home™ Drug Test is a drug screening, and if needed, confirmation service. It provides preliminary urine screening results for the detection/presence of the following drugs of abuse: methamphetamines, amphetamines, marijuana (THC), cocaine and opiates (heroin). It is intended for home use. For assistance in collecting a sample, use of this product or referral, call our Customer Service Hotline at 1-877-HOME-TEST (877-466-3837).

When is the best time to collect a sample?

The sample should be collected as soon as possible after suspected drug use. Timing is very important in detecting any drug of abuse. This is because each drug is cleared by the body and is detected in the urine at different times and rates. Please consult the chart provided in the Question & Answer section for further information.

How much sample do I need?

Fill the Labeled Vial two-thirds (2/3) full and fill the Collection Cup to the 30 ml mark.

Urine Sample Collection

- 1. Have the Collection Cup and Labeled Vial ready.
- Check to make sure that the number on the Labeled Vial matches your Personal Identification Number.
- **3.** Wash your hands with soap and warm water.
- 4. Urinate directly into the Collection Cup (with Temperature Monitoring Strip). Fill the cup to above the 60 ml mark. It is OK to have extra sample. Wipe any splashes or spills that may be on the outside of this cup. <u>DO NOT DIP DEVICE</u> YET!!!
- 5. Immediately check the temperature monitoring strip. The temperature should read between 90°F and 100°F. If the temperature is not in this range, the sample may be altered and another sample should be collected. For more information about tampering, please read the section "A Special Note to Parents About Sample Tampering".
- **6.** Before inserting test device into urine sample, open the Labeled Vial and carefully pour the urine from the Collection Cup INTO the Labeled Vial. Fill the vial to about 2/3 full and tightly close the cap.
- IMPORTANT: The rest of the urine should be enough to reach the 30 ml mark on the Collection Cup. <u>ANY</u> <u>MORE THAN THIS IS TOO MUCH AND MAY FLOOD</u> <u>DEVICE.</u>

- 8. Wash and dry hands.
- **9.** Set the Collection Cup and Labeled Vial aside while you review the test instructions.

A special note to parents about tampering:

A good urine sample is very important to getting an accurate result. It is very important that the sample to be screened has not been altered or tampered with in any way.

The following steps are things you can do to minimize or reduce the possibility that the sample has been tampered with:

Make sure the faucets in the bathroom basin and shower are turned off tightly and the child should be instructed not to turn them on. Place blue coloring into the toilet. This will help to discourage the use of any water sources to dilute the specimen. Tape medicine cabinet door closed. Check the child's clothing to ensure that they do not have access to or anything in their possession that would be used to tamper with the specimen.

Whether or not you as a parent makes a decision to use any of these options is your choice. This decision is best made after careful consideration based upon your knowledge of the child. Preferably, the child should be tested randomly.

Performing the At Home™ Screening Test:

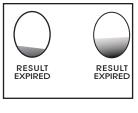
- 1. Begin in a well-lit place. Have a watch or timer ready.
- **2.** Make sure the sample and test components are at room temperature before testing.
- 3. Open the foil pouch at the notch and remove the At Home™ Drug Test Device. Take care not to touch the test area of the device.
- 4. Insert the test device directly into the Collection Cup DO NOT insert the device any deeper into the sample than shown by the "Max Urine Level" line.
- **5.** Allow device to remain in the urine sample for 10 minutes.
- Read the result at ten (10) minutes. You will see a red color appear in the "Result Ready" window on the right.
- 7. As you watch the test develop you may notice that the urine sample moves up the test device. In most cases the control line "C" will become visible before the test line "T" does. This is normal and means the test is developing properly.
- Read test results immediately after 10 minutes have elapsed.

IMPORTANT: After 15 minutes or when the "Result Expired" window turns red results are no longer valid and should not be read.

Reading the Results: Using the Timer



When the "RESULT READY" window is completely filled with red color, or almost completely covered with red color that reaches the top of the window, test results are ready to read.

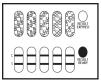


When the red color becomes clearly visible at the bottom of the "RESULT EXPIRED" window, test results should no longer be read. Results must now be considered invalid.

Reading the Results

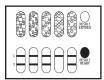
NEGATIVE RESULTS for all drugs tested

Negative: A negative result is indicated by two (2) rose pink color bands (of any intensity),



one in the control region AND one in the test region. This result means that the urine screened negative.

REMEMBER - EVEN A VERY FAINT LINE IS A NEGATIVE RESULT

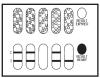


PRELIMINARY RESULT for Cocaine (example)

Preliminary: A single rose pink color band which appears in the control region, and NO line in the test region means the urine screen is considered to be

PRELIMINARY POSITIVE. The urine sample must be sent to the laboratory for further testing. More than one test may be "preliminary".

NO RESULT for THC and Opiates (example) No Result: A test must be considered No Result if no bands appear or if a band appears in the test region "T"



without a band in the control region "C". The presence of a control band is necessary to confirm assay performance and must always appear.

Understanding the Result

Each At Home™ Drug Test is made to detect the presence of the following drugs: ecstasy and methamphetamines, amphetamines, THC (marijuana), cocaine and opiates. The test detects any or all of these drugs when they are above the detection limit of the test.

What does a negative test result mean?

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

However, if drug use is still suspected, you may wish to re-screen at a later time.

What does a preliminary test result mean?

This means that the test has reacted with something in the sample and must be sent to the lab for a more accurate test. Please review the Test Limitations following this section.

First, and most important: BE PATIENT. The result you obtained is called "preliminary" for a reason. The sample MUST be tested by our clinical laboratory in order to determine if a drug of abuse is actually present. You will never know for sure without taking the second step.

Remember, screening is the first step in a two part system:

- Step 1: Screen out (eliminate) the negative samples.
- Step 2: Send any sample which does not give a negative result to a laboratory for further testing.

Test Limitations:

- Failure to use this kit as directed may result in an insufficient sample or an inaccurate screening result.
- This test can be used on urine samples only. No other fluids have been evaluated. Do not use this device to test anything but urine.
- Our laboratory must receive an adequate amount of sample to perform confirmation testing.
- The urine sample is perishable. Old urine samples may not be suitable for testing.

- You cannot retrieve your confirmed result without knowing your Personal Identification Number (PIN).
- Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.
- The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g. technical or procedural error).
- Adulterated urine samples may produce erroneous results.
- Strong oxidizing agents such as bleach can oxidize drug analytes. If a sample is suspected of being tampered with, a new sample must be obtained.
- This test provides a screening result. It is not designed to determine the actual concentration of a drug or the level of intoxication.
- Liability is limited to the purchase price of the kit.

Mailing a Urine Sample to the Laboratory for Confidential Confirmation Testing:

- □ 1. Remove red tag from the labeled transport vial and place on the front of this handbook. Save the handbook for retrieval of results in 3 to 10 days. The labeled transport vial must be two thirds full (2/3). **2.** Place the labeled trasport vial into the plastic transport bag. □ **3.** Seal the plastic transport bag. **4.** Place the sealed plastic transport bag into the pre-addressed mailing box, secure with tape. **5.** Record the date the urine sample was collected on the outside of the box. ☐ **6.** The mailing box is not pre-paid. Applicable shipping charges must be paid to the carrier
- **7.** Place the mailing box in any USPS mailbox.

to ensure delivery.

IT IS IMPORTANT TO MAIL IT RIGHT AWAY! Old urine samples may not be suitable for testing.

Getting the Laboratory Results

- Get the identification number from the red sticker on page 1 of this booklet before you call for your results. You must have this number to obtain your laboratory test result. Have a piece of paper and a pencil ready.
- Dial 1-877-HOME-TEST (877-466-3837), Monday through Friday, between 7:00 am and 5:00 pm Pacific Standard Time.
- Identify yourself by your personal identification number (PIN) only.
- You will be given the laboratory result for those tests identified as preliminary positive.
- Your result should be available 7 to 10 business days after you ship your sample, but it may take longer depending upon your location.

- Results are also available on the internet at www.phamatech.com. You must have your identification number (PIN) to access your results.
- Remember to have your identification number handy when you call. Results will not be disclosed without an ID number.
- Please call Customer Service at 1-877-HOME-TEST (877-466-3837) for assistance.



Questions & Answers

Drug Test Identification Code:			
MET	Methamphetamine and Ecstasy (MDMA)		
AMP	Amphetamine and methylenedioxyamphetamine (MDA)		
THC	Marijuana		
COC	Cocaine		
OPI	Opiates		

Remember:

You are not alone in the struggle against drugs.

No one is immune to these problems.

COMMUNICATE

The number one way to help your loved one is to communicate your concern to them.

Frequent knowledgeable communication about the facts of drug abuse can strengthen the will of your child to stay away from drugs.

Some commonly abused drugs

Amphetamine

Amphetamines are central nervous stimulants whose effects include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well being. Large doses and long term usage can result in higher tolerance levels and dependency.

MDA, the parent drug of MDMA (ecstasy), is an amphetamine-like drug that has also been abused and is similar in chemical structure to MDMA. Research shows that MDA destroys serotonin-producing neurons in the brain, which play a direct role in regulating aggression, mood, sexual activity, sleep and sensitivity to pain. It is probably this action on the serotonin system that gives MDA its purported properties of heightened sexual experience, tranquility and sociability.

Cocaine

Cocaine is made from coca leaves. Its effects include alertness, wakefulness, increased energy and an overall feeling of euphoria. Cocaine can be smoked, inhaled ("snorted") or injected. Cocaine can be a very addictive drug.

Methamphetamine

Methamphetamine is a stimulant drug. It is used in pill form, or in powdered form by snorting or injecting. Crystallized methamphetamine is a smokable and more powerful form of the drug. Some of the effects of methamphetamine use include: increased heart rate, wakefulness, physical activity and decreased appetite. Methamphetamine use can cause irreversible damage to the brain, producing strokes and convulsions, which can lead to death.

Ecstasy

Ecstasy is the street name for 3,4 methylenedioxymethamphetamine (MDMA). It combines the stimulating effects of methamphetamine with a hallucinogen. Some of the effects of use include: increased heart rate, wakefulness, increased body temperature and rapid dehydration in certain settings. Psychological effects include confusion, depression, anxiety and paranoia. Use can lead to brain damage, heart and kidney failure.

Opiates

Opiates are any of the addictive narcotic drugs. The opiates include drugs such as morphine, heroin and codeine. Opiates can reduce attention, sensory and motor abilities. **Phencyclidine (PCP)** (available in #9149 only) Phencyclidine hydrochloride (or PCP), also known as "angel dust", is an hallucinogen. PCP is commonly taken orally, by inhalation, by "snorting" or by injection. The effects of this drug are unpredictable and variable. Users may exhibit signs of euphoria, anxiety, relaxation, increased strength, time/space distortions, panic or hallucination.

THC (marijuana)

Tetrahydrocannabinol (THC) is an active component in marijuana. Marijuana is commonly taken by smoking, but it may also be eaten. Marijuana may impair learning and coordination abilities. Low concentrations of THC persists in urine at a detectable concentration for many days after smoking.

Common street names for drugs:

Amphetamines and MDA	speed, amp, bennie, chalk, black beauties	
Cocaine	Big C, coke, snow, flake, candy, crack, blow, rock	
Methamphetamines	crystal, meth, ice, glass	
Methylenedioxy- methamphetamine (MDMA)	Ecstasy, E, Adam, XTC, X	
Opiates	heroin, H, hairy hombre, horse, jones, scag	
PCP	angel dust, magic dust, sherms, star dust	
Marijuana (THC)	pot, weed, herb, bud, MJ, doobie, reefer, grass joint, homegrown, spliff	

What is the At Home™ Drug Test?

- At Home™ Drug Test is a qualitative test for the detection of five (5) drug families or metabolites in urine; Amphetamines, Methamphetamines, Marijuana (THC), Cocaine, and Opiates.
- At Home™ Drug Test allows the detection to be done confidentially, with the name of the person tested unknown.
- At Home™ Drug Test hot line is a source of referrals to healthcare services.
- At Home™ Drug Test hot line is a source of educational information.

How long after using drugs can they be detected in urine?

Each drug is cleared by the body at different rates. The amount of a drug (the concentration) in the body, how often the drug is taken, how the drug was taken (swallowed, inhaled, smoked or injected) as well as user age, weight, diet and metabolic rate all play a part in detection times. A general guideline for drug detection periods is as follows:

Drug	Approximate Detection Times	
	Minimum	Maximum
Amphetamine and MDA	2 to 7 hours	2 to 4 days
Cocaine metabolite	1.25 to 4 hours	2 to 3 days
Methamphetamine and MDMA	2 to 7 hours	2 to 4 days
Opiates	2.5 hours	2 to 3 days
Phencyclidine (PCP)	7 hours	3 to 5 days
Marijuana (THC)	6 to 18 hours	up to 28 days

What the laboratory results mean

- You will be told if the laboratory test result for your urine sample was positive or negative according to confirmation testing.
- The results you receive will come from tests performed by laboratory professionals. These tests are run on very accurate and reliable equipment.
- **3.** Positive results are released only when the sample is confirmed to be positive using sophisticated techniques and equipment such as gas chromatography/mass spectrometry.
- 4. Samples which are screened as negative do not require the second (confirmation) test. This can mean several things:
 - a. These drugs were not used in the past few days prior to providing the urine sample. Therefore, they either don't do drugs or had not done them just prior to testing.
 - **b.** The person may only use a small amount of a drug, an amount too small to be detected by the test.

- c. A person may be taking a drug not tested for with the At Home™ Drug Test. Only six (6) drugs are tested for and so if any other drugs were in use the test result would be negative. Substances such as LSD, alcohol, inhalants, benzodiazepines and antidepressants will not be identified with this test.
- **d.** The sample may have been tampered with or be unsuitable due to some rare technical interference
- Certain foods and medicines such as cough syrup, inhalers, anti-diarrhea medicines, diet plan drugs, poppy seeds may cause a positive test result.
 - a. Both codeine and heroin break down to morphine in the body so a positive result for morphine may be from a person taking either morphine, heroin or codeine (in cough syrup).
 - b. People can test positive for THC (or marijuana) because they have been repeatedly around heavy marijuana smoke even though they did not eat or smoke marijuana themselves.

- **c.** Certain diet plan drugs may give a positive result for amphetamine.
- **d.** Eating enough poppy seeds may cause a positive opiate result.
- 6. Remember, when a drug is found in the urine, testing:
 - does not tell us how the drug got there (eaten, inhaled, smoked or injected).
 - b. does not distinguish a prescription medicine from a drug of abuse.
 - does not tell if the positive result is from a food that someone ate.
- 7. In the event a positive result for a drug was confirmed, please consult with our staff on a proper course of action. We will help you identify counselors who will help you. It is important that you remain calm and do not react in a negative way to the situation.
- **8.** If you have received a positive result and you do not believe the test, 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.

What about False Positive Results?

A screening test can give a false positive result. Certain cross reactive substances are known to occur. These can be present due to diet, prescription or over the counter medications, etc. This is why it is important to send any sample not giving a negative result to the laboratory for further evaluation.

An analysis by the laboratory, which involves confirmation testing, will determine whether or not a drug is present in the urine. If the laboratory reports a positive result you may be assured that the drug was indeed present. However, it would be incorrect to assume the urine sample came from a drug abuser just because the result is positive. It is necessary to determine how contact with the drug occurred.

Can False Negative Results occur?

If you have observed behavioral changes which you feel could be caused by drug abuse don't discard the thought just because the test result is reported negative. A false negative result can occur for a number of reasons. Certain products are being marketed as a means of defeating drug testing. These interfere with various methods used in either the screening or confirmation tests. Drugs other than those tested for with this device may be involved. More often, the concentration of the drug in the urine sample is below cut-off, or sensitivity, of the screening assay. When this occurs the test is reported negative. Drug test cut-off concentrations are listed below:

Drug Class	Cut-off Concentrations (ng/ml)	
	Immunoassay	GC/MS
Amphetamines and MDA	1000	500
Cocaine	300	150
Methamphetamine and MDMA	500	500
Opiates-morphine	300	300
Marijuana (THC)	50	15
Phencyclidine (PCP)	25	25

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 1-800-729-6686

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

See our website for additional information at: www.phamatech.com

Listed below is a glossary of definitions appropriate to drugs of abuse testing.

Cannabinoids - A family of compounds, some of which are psychoactive, found in the common hemp plant, or Cannabis sativa. Most of the pharmacological effects are produced by delta-9-tetrahydrocannabinol. In urine drug testing, the prior use of marijuana is established by the detection of metabolites of cannabinoids. These metabolites are generally inactive, but are often present in significant quantities. The most abundant metabolite is 11-nordelta-9-tetrahydrocannabinol-9-carboxylic acid, sometimes referred to as 9-carboxy-THC. Most immunoassays and confirmation procedures are directed toward this metabolite.

Confirmation - The process of using a second analytical procedure to verify the presence of a specific drug or metabolite, which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test to ensure reliability and accuracy.

Cross Reactivity - The degree to which an antibody interacts with antigens other than the one used to produce the antibody. This is a property of nearly all naturally derived antibodies. **Cutoff** - The concentration of a target drug in a specimen at or above which the test is called positive and below which it is called negative.

False Negative - A test result which states that no drug is present when, in fact, a tested drug or metabolite is present in an amount greater the threshold or cutoff amount.

False Positive - A test result which states that a drug or metabolite is present when, in fact, the drug or metabolite is not present, or is present in an amount less than the threshold or cutoff value.

GC/MS - An abbreviation for the instrumental technique which couples the powerful separation potential of gas chromatography with the specific characterization ability of mass spectroscopy.

Mass Spectrometry - Analysis using an analytical instrument that provides accurate information about the molecular mass and structure of complex molecules. This technique can identify extremely small amounts of drugs or metabolites by their mass-fragmented spectrum.

Metabolite - Drug breakdown products.

Passive Inhalation - The exposure of nonsmoking subjects, through inhalation, to sidestream smoke from active smokers, thereby raising the possibility that a non-user of marijuana may test positive for metabolites of delta-9tetrahydro-cannabinol.

Screening Test - The initial test used to identify those specimens which are negative or positive for the presence of drugs or their metabolites. Negative specimens need no further examination and need not undergo confirmation testing.

THC - Delta-9-tetrahydrocannabinol, the most pharmacologically active of the cannabinoids (See Cannabinoids).

Manufactured by: Phamatech, Inc. San Diego, CA

Confirmation Test Results are available at 1- 877-HOME-TEST (1-877-466-3837) or online at www.phamatech.com.

Be sure to have your personal identification number (PIN) to access results.