

# NOBLE 1 Step Cup™

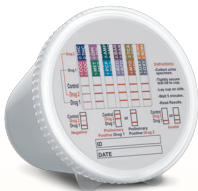
## Drug Test

*Urine Screening Test for between two to twelve drugs, depending on the test purchased*

*Results in 5 minutes*

### Instruction Booklet

*For in vitro diagnostic use*



NOBLE 1 Step Cup™ Pictured

**Before You Begin:** Read all the information in this pamphlet before performing the test. First, make sure you are familiar it contents shown on the following page. Store at room temperature, or refrigerated, 40-86° F (4-30° C) in the sealed pouch, away from direct sunlight. Do not use after the expiration date stamped on the package and foil pouch containing the NOBLE 1 Step Cup™.

## **Materials Provided**

- One (1) NOBLE 1 Step Cup™ test lid in sealed pouch
- One (1) cup for sample collection
- One (1) instruction booklet

## **Materials Needed But Not Provided**




- Stopwatch or clock

# Drug Test




## Urine Screening Test - Results in 5 minutes

The NOBLE 1 Step Cup™ tests for the possible use of marijuana (THC), cocaine (COC), opiates (OPI), methamphetamines (MET), amphetamines (AMP), phencyclidine (PCP), benzodiazepine (BZO), barbiturates (BAR), methadone (MTD), tri-cyclic antidepressants (TCA), ecstasy (MDMA) and/or oxycodone (OXY), depending on the test purchased. The test you purchased may test for fewer drugs.




The NOBLE 1 Step Cup™ is for healthcare professionals including professionals at point of care sites. For in vitro diagnostic use only.

**Control**   
**Drug 2**   
**Drug 1** 




**IF YOU GET A NEGATIVE RESULT**, this means the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even though the person took drugs. Some reasons why this might happen are:

**Control**   
**Drug 2**   
**Drug 1** 

- the urine sample was collected at the wrong time, it was collected before the drug got into the urine or after it was no longer in the urine
- the person took a drug other than the one tested for in this test. E.g. they might have taken LSD, when this test is for drugs other than LSD

**Control**   
**Drug 2**   
**Drug 1** 

**IF YOU GET A "PRELIMINARY POSITIVE"** result, this means the sample may contain one or more of the drugs being tested for, and you should take the second step in the process. Send the urine to our laboratory for additional testing. However, it is possible to get a "preliminary positive" when the person did not take the drugs.

**Control**   
**Drug 2**   
**Drug 1** 

- Things such as diet pills, inhalers and cough syrup can cause a preliminary positive result.

# Collecting the Urine Sample

Run the test as soon as possible after you collect the sample. The NOBLE 1 Step Cup™ testing can be performed on a “fresh” warm urine sample. Do not test chilled or refrigerated urine samples unless they have been brought to room temperature first.

**CAUTION!** Urine samples may be potentially infectious. Wash your hands with soap and warm water before and after collecting the urine sample and performing the NOBLE 1 Step Cup™.

## **NEVER REUSE THE SAME TEST CUP.**

Follow these steps to help reduce the possibility of the device altering his or her urine sample.

- Have the donor wash his or her hands with soap and warm water at a sink prior to collecting their urine sample. Make sure the soap has been rinsed off and both hands are dry.
- Where possible, turn off the water to the bathroom sinks, toilets, and tubs. Bathroom sinks usually have water shut off handles under the sink.
- Limit access to the bathroom and kitchen cabinets. Vinegar, bleach, and detergents may interfere with obtaining a “clean” urine sample.

## How much urine do I need?

The NOBLE 1 Step Cup™ requires just 30 ml of urine. Fill the collection cup to the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Minimum Fill Line:  
30ml of urine



### **DO NOT REUSE THE TEST KIT**

To test a new specimen, use a new Millennium Drug Screen Cup. The test kit **CANNOT** be used to retest the same specimen.

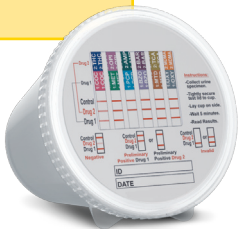
# Performing the NOBLE 1 Step Cup™

1. Fill specimen collection cup to at least the minimum fill level as indicated on collection cup.

**IMPORTANT:** If the urine or test cup are cold, bring them to room temperature before you begin.

2. Remove the lid from the sealed pouch.
3. Secure the lid to the cup containing the sample, and then place the cup on its side, as shown in the illustration below.
4. Wait at least five minutes to read the results.  
**DO NOT READ RESULTS AFTER 10 MINUTES.**

**CAUTION:** Be certain to place on a flat surface to ensure proper migration of the urine sample to the lid containing the test.



NOBLE 1 Step Cup™ 12 Drug Test  
Pictured

# Reading The Results

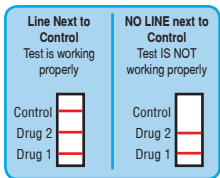
## NOBLE 1 Step Cup™

The NOBLE 1 Step Cup™ screens for marijuana (THC), cocaine (COC), methamphetamines (MET), opiates (OPI), amphetamines (AMP), ecstasy (MDMA), phencyclidine (PCP), benzodiazepine (BZO), barbiturates (BAR), methadone (MTD), tricyclic antidepressants (TCA) and oxycodone (OXY), depending on the test purchased.

### STEP 1:

Check that the test is working properly by looking for a red or pink line next to the word control. You should be able to see this line on all test strips. If you do not see a red or pink line next to the word Control on all test strips, your test is not working correctly. We recommend you send the sample for laboratory confirmation.

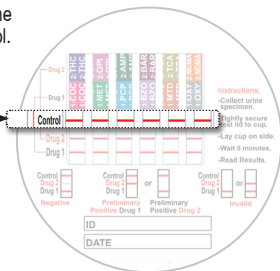
**Note:** There are multiple test strips; each strip has a Control region and two (2) drug regions.



### STEP 2:

Read test only if a red or pink line appears next to the word Control.

Read test only if a red or pink line appears next to the word Control on all test strips.

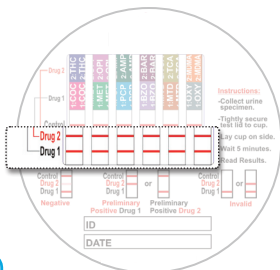


12 Drug Test Pictured

## NEGATIVE

If a red or pink line appears next to the word Drug, the sample is considered negative for that drug. If a red or pink line appears next to the word Drug for all drugs, the sample is considered negative and no further testing is required.

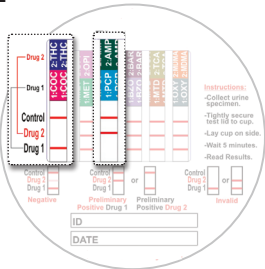
**IMPORTANT:** Certain lines may appear lighter or thinner than other lines. ANY RED OR PINK LINE NEXT TO THE WORD DRUG, NO MATTER HOW DARK OR FAINT, IS CONSIDERED A NEGATIVE RESULT.



## PRELIMINARY POSITIVE

If NO red or pink line appears next to the word Drug on any test strip, the urine sample may contain that drug. This test shows a preliminary positive for both Marijuana (THC) and Phencyclidine (PCP), and a negative for all other drugs.

**IMPORTANT:** No red or pink line next to the word Drug indicates a preliminary positive result for that drug. Clinical consideration and professional judgement should be applied to any drug of abuse result, particularly when preliminary positive results are indicated.

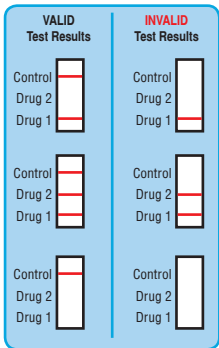
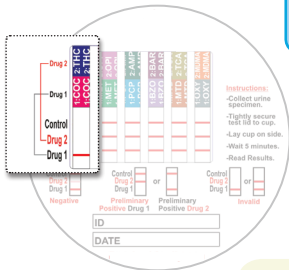
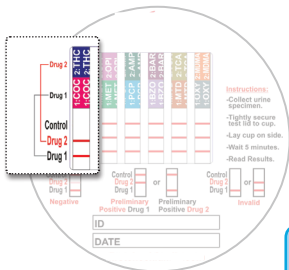


The above test result shows a preliminary positive for both Marijuana (THC) and Phencyclidine (PCP), and a negative for all other drugs.

## Invalid Test

A colored line should always appear next to the word Control. If no line appears next to the word Control, do not read the results for that drug.

Each test pictured below is an example of an "invalid test" for the first test strip - Cocaine and Marijuana (COC: THC). If you get an invalid test, we recommend that you contact us at 1-877-836-5713.



**IMPORTANT:** In both examples, no line appears next to the word Control in the first test strip - Cocaine and Marijuana (COC: THC). The test results displayed for that test strip are "invalid".

# Understanding the Results

A preliminary 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 reliability of drug tests. Certain drug of abuse tests are more accurate than others.

## What Is Meant By A Preliminary Positive Test Result?

The NOBLE 1 Step Cup™ is considered a “screening test”. It is the first step in a two-step process. Screening tests are not as accurate as laboratory tests, and it is possible to get a preliminary positive result when the person did not take drugs. For example, some medicines and food may cause the screening tests to incorrectly read positive. Things such as diet pills, inhalers and cough syrup can cause a positive result.

### **SPECIAL NOTE REGARDING PRESCRIPTION DRUGS**

A positive test result for a prescription drug (BZO, BAR, MTD, TCA, OXY) does not mean that an individual is abusing that drug.

## What Does A Negative Screening Result Mean?

This means there is no drug present in the sample, or not enough drug to be considered a preliminary positive test result.

**Samples that are negative do not need further testing.**

It is possible to get a negative result even though the person took drugs. Some reasons this may happen include:

- The urine sample was collected at the wrong time relative to when the person took the drugs (sample was collected before the drug got in the urine or after the drug was no longer in the urine).
- The person took another drug other than the ones being tested for with the NOBLE 1 Step Cup™.
- The urine sample was adulterated. Bleach and other strong chemicals can degrade drugs in the urine. Also, if other liquids are added to the urine, the urine gets diluted and the concentration of the drug may drop below the level where it can be detected by the test.

Screening tests may not detect amounts of drugs in a urine sample that are below the cut-off level (see page 14). Even though some level of drug may be present in a urine sample, the sample would still be considered NEGATIVE if the drug level is below the cut-off level.

# Test Limitations

The NOBLE 1 Step Cup™ is not reusable. Follow the test instructions precisely. Use only human urine samples with this test.

There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant and oxycodone tests in urine. The Drug Test shows the drug was or was not present at the cutoff level. (See cut-off levels on page 14)

Certain over-the-counter or prescription drugs may cross-react with the NOBLE 1 Step Cup™ and cause a preliminary positive result for certain drugs. Listed in the chart on the next page are some common medications which may cause a preliminary positive result for the test.

For a complete list of drugs which may cross-react with this test, please log on to our website at [www.noblemedical.com](http://www.noblemedical.com). We recommend that you consult with your primary health care provider to better understand how your medications may interfere with this test.

The test will only give accurate results on urine samples. Bleach, cleaning supplies and other liquids may dilute the urine and the test may not be accurate.

Once the test starts, read the results after five minutes.

Drinking large amounts of liquids may dilute the urine so that the drug (if present) cannot be detected.

Failure to use the NOBLE 1 Step Cup™ as directed may result in an inaccurate screening result.

If the sample or test are cold, you must bring them to room temperature before you begin.

Our laboratory must receive the sample within seven days.

Liability is limited to the purchase price of this test kit.

**Examples of common medications that may cross-react with the NOBLE 1 Step Cup™**

<b>Drug or Medication</b>	<b>May Cause Positive For</b>
<b>Lortab</b>	Opiates (OPI)
<b>Lorcet</b>	Opiates (OPI)
<b>Tylenol 3</b>	Opiates (OPI)
<b>Vick's Inhaler</b>	Methamphetamines (METH)
<b>Xanax</b>	Benzodiazepines (BZO)

# The NOBLE 1 Step Cup™ Cut-off Levels

Samples at or near the cut-off level provide the greatest margin of error.

Identifier	Drug Name	Cut-off Level
<b>THC</b>	† Tetrahydrocannabinol	50 ng/ml
<b>COC</b>	† Cocaine	300 ng/ml
<b>MET</b>	† Methamphetamine	1000 ng/ml
<b>AMP</b>	† Amphetamine	1000 ng/ml
<b>MDMA</b>	† Ecstasy	500 ng/ml
<b>OPI</b>	† Morphine,heroin,codeine	2000 ng/ml
<b>PCP</b>	† Phencyclidine	25 ng/ml
<b>BZO</b>	Benzodiazepines	300 ng/ml
<b>BAR</b>	Barbiturates	300 ng/ml
<b>MTD</b>	Methadone	300 ng/ml
<b>TCA</b>	Tri-cyclic Antidepressants	1000 ng/ml
<b>OXY</b>	Oxycodone	100 ng/ml

† The Substance Abuse and Mental Health Services Agency (SAMHSA), has set “cut-off” levels when testing for Marijuana, Cocaine, Amphetamine, Opiates, PCP, Ecstasy and Methamphetamine. The NOBLE 1 Step Cup™ is manufactured to conform to those standards. Screening tests may not detect amounts of drugs in a urine sample that are below the cut-off level. Even though some level of drug may be present in a urine sample, the sample would still be considered NEGATIVE if the drug level is below the cut-off level.

# How Long Can Drugs Be Detected In Urine?

Each drug is cleared by the body at different rates. When you can find drugs in the urine depends on the drug taken, how often the person takes the drug, and how the drug was taken. The table below, shows minimum and maximum times you can detect drugs in urine.

Drug	Drug Street Name(s)	Approximate Detection Time	
		Min	Max
Marijuana (THC)	pot, grass, weed, doobie, joint, roach	2 hours	up to 40 days**
Cocaine (COC)	coke, snow, blow, candy, crack	1 – 4 hours	2 - 4 days
Methamphetamines (MET)	crystal meth, speed, glass	2 – 7 hours	2 - 4 days
Amphetamine (AMP)	speed, amp, black beauties	2 – 7 hours	2 - 4 days
Ecstasy (MDMA)	E, XTC, X	2 – 7 hours	2 - 4 days
Opiates (OPI)	heroin, morphine	2 hours	2 - 3 days
Phencyclidine (PCP)	angel dust, rocket fuel	4 – 6 hours	7 - 14 days
Benzodiazepines (BZO)	Downers	2 – 7 hours	1 - 4 days
Barbiturates (BAR)	Downers, barbs, red devils	2 – 4 hours	1 – 3 weeks
Methadone (MTD)	Done	3 – 8 hours	1 – 3 days
Tri-cyclic Antidepressants (TCA)	--	8 – 12 hours	2 – 7 days
Oxycodone (OXY)	--	1 – 3 hours	1 – 2 days

\*\* sometimes longer depending on smoking patterns

# About Confirmation Testing

Negative samples do not need further testing. You should send preliminary positive samples to our laboratory for confirmation. Confirmation testing should be performed on all positive test results.

**If you need assistance call:**

NOBLE MEDICAL

1-877-836-5713

## Commonly Asked Questions

**Q. The test line is lighter than the line for Control. Does this mean some drug is present?**

A. No. The lines need not be the same shade or intensity. The control line may look darker than a test line, or vice versa.

**Q. What if I forget to read the result after five minutes?**

A. The test must be read after five minutes. If you read the result too early, or after 10 minutes, the test results may be wrong.

**Q. I am not sure of my test result. What should I do?**

A. The test is working properly as long as the colored line is visible in the Control Window. The result is negative when there is a line next to the word Drug. The result is a preliminary positive when there is no line next to the word Drug.

**Q. Do I have to wait the full 5 minutes before reading the test?**

A. Yes. We recommend that you wait the full 5 minutes before reading the result.

# Quality Control

A procedural control is included in the test. A colored line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

It is recommended that external positive and negative controls be tested with each new lot or shipment of product, with each new operator (i.e. one who has not performed the test recently), when problems (storage, operator, instrument, or other) are suspected or identified, and as otherwise required by your laboratory's internal quality system procedures. Depending on storage conditions, operators may also test controls monthly as a check on continued storage conditions. Control specimens should be performed the same as patient specimens (refer to Directions for Use and Interpretation of Results). If unexpected results are seen when running the external positive or negative controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another cup. If the problem persists, discontinue use of the test kit immediately and call (1-877-836-5713).

# Specificity

The specificity for the NOBLE 1 Step Cup™ was determined by testing various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine. The following compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
<b>Amphetamines</b>			
d-Amphetamine	1,000	d-Methamphetamine	50,000
dl-Amphetamine	2,500	(+/-)3,4-MDMA	50,000
(+/-)3,4-MDA	1,250		
<b>Barbiturates</b>			
Secobarbital	300	Butabarbital	400
Allobarbital	600	Butalbital	300
Alphenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Phenobarbital	450
Barbital	1500		
<b>Benzodiazepines</b>			
Oxazepam	300	Flunitrazepam	300
Alprazolam	400	Flurazepam	300
Bromazepam	250	Lorazepam	500
Chlordiazepoxide	300	Medazepam	300
Clobazam	1000	Nitrazepam	250
Clonazepam	500	Nordiazepam	150
Clorazepate	150	Prazepam	500
Desalkylflurazepam	200	Temazepam	200
Diazepam	450	Triazolam	450
Estazolam	300		
<b>Cocaine</b>			
Benzoyllecgonine	300	Cocaine	300
<b>Methamphetamine</b>			
d-Methamphetamine	1000	(+/-)3,4-MDMA	3,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4-MDEA	50,000	Mephentermine	75,000
(+/-)3,4-MDA	100,000		
<b>MDMA</b>			
(+/-)3,4-MDMA	500	(+/-)3,4-MDA	4,000
(+/-)3,4-MDEA	450		
<b>Methodone</b>			
(+/-) Methodone	300	Methodol	1,500

**Opiates**

Morphine	2,000	Hydrocodone Hydromorphone	4,000
Codeine	2,000	Morphine-3-glucuronide	5,000
Ethylmorphine	1,000	Nalorphine	2,500
Heroin	5,000		5,000

**Oxycodone**

Oxycodone	100	Morphine	>100,000
Hydrocodone	5000	Codeine	50,000
Hydromorphone	50,000	Heroin	>100,000

**PCP**

Phencyclidine	25	Tenocyclidine	2,000
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**THC**

11-nor-9-THC-9-COOH	50	9-tetrahydrocannabinol	5,000
11-hydroxy-9-THC	1,000	Cannabinol	10,000
8-tetrahydrocannabinol	5,000	Cannabidiol	>100,000

**Tricyclic Antidepressant**

Nortriptyline	1,000	Promazine	1,500
Nordoxepin	2,000	Desipramine	400
Trimipramine	2,000	Doxepin	3,000
Amitriptyline	1,500	Maprotiline	2,000

# Interference

Two pools of drug-free urine were spiked with drug standards to 50% below and 50% above cutoff concentrations. The drug concentrations were confirmed by GC/MS. The following compounds were evaluated for potential positive and/or negative interference with the NOBLE 1 Step Cup™. All compounds were dissolved in the spiked sample solutions and tested with the NOBLE 1 Step Cup™. An unaltered sample was used as a control. No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 ng/ml.

Acetaminophen	Ibuprofen
Acetone	(+/-)-Isoproterenol
Albumin	Ketamine
Ampicillin	Levorphanol
Ascorbic Acid	Lidocaine
Aspartame	(+)-Naproxen
Aspirin	Niacinamide
Atropine	Nicotine
Benzocaine	(+/-)-Norephedrine
Bilirubin	Oxalic Acid
Caffeine	Penicillin-G
Chloroquine	Pheniramine
(+)-Chlorpheniramine	Phenothiazine
(+/-)-Chlorpheniramine	l-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline
Furosemide	Tyramine
Glucose	4-Dimethylaminoantipyrine
Guaiaacol Glyceryl Ether	(1R,2S)-(-)-N-Methyl-Ephedrine
Hemoglobin	

NOBLE MEDICAL  
NOBLE 1 Step Cup™

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Web site: [www.noblemedical.com](http://www.noblemedical.com)