PLEASE READ THE PACKAGE INSERT CAREFULLY BEFORE PERFORMING THE TEST

1 test

Multi Drug Urine Test

Disposable home immersion test for the simultaneous detection of amphetamine, cocaine, morphine, heroin, marijuana and hashish in urine.
Medical device for self-testing.

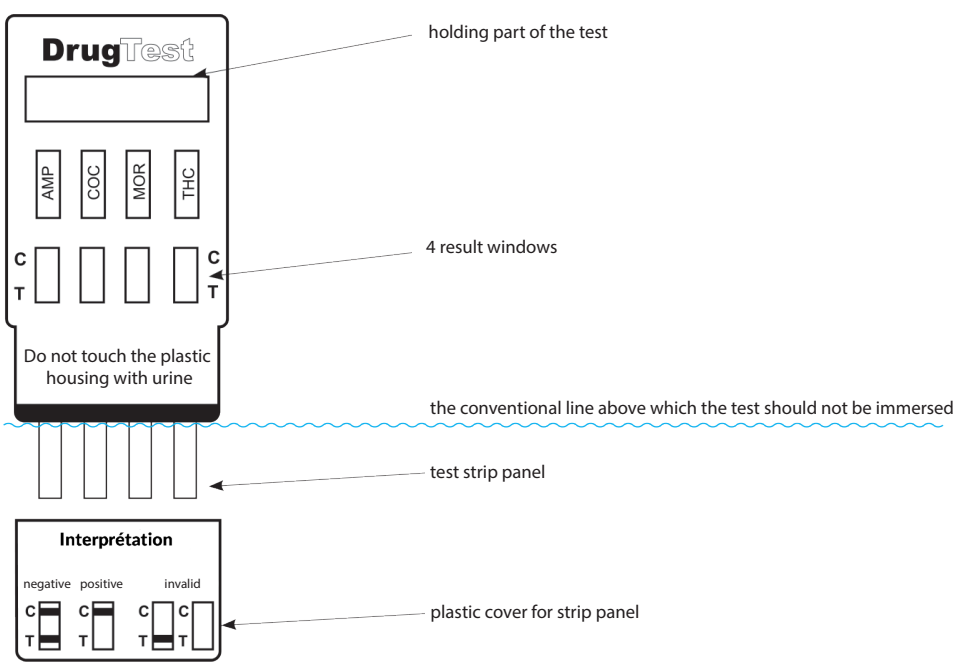
INTRODUCTION

The Urine Multi-Drug Test is a multi-parameter test and consists of 4 test strips placed in one plastic housing. Each strip is responsible for detecting a different drug in the urine: AMP - amphetamine, COC - cocaine, MOR - morphine and heroin, THC - marijuana and hashish. The Urine Multi-Drug Test should be used when it is not known exactly which drug was taken. Performing the test with the Urine Multi-Drug Test is very simple - just immerse the test strips panel into the urine sample, and the results in the form of colored bands can be read after just 5 minutes. The Urine Multi-Drug Test provides information about the pathological condition caused by drug use and is thus helpful in diagnosing drug addiction. The test is also helpful in monitoring therapeutic activities related to the treatment of these addictions.

KIT CONTENTS

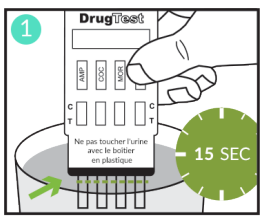
The kit of the Urine Multi-Drug Test contains the equipment necessary to perform one test:
» 1 sealed foil pouch containing: 1 test and 1 desiccant
» 1 package insert with instructions for using the product
Before performing the test, prepare a paper towel and a watch, which will be needed to measure the time of reading the test result.

TEST STRUCTURE



IMPORTANT NOTES BEFORE TESTING

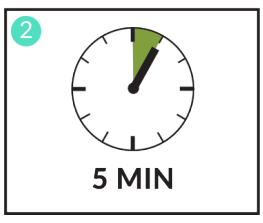
» The test should be performed on a fresh urine sample collected in a clean and dry container.
» Urine can be collected at any time of the day.
» However, if the test cannot be performed immediately after urine collection, the tested urine can be stored for up to 48 hours in a refrigerator (temperature 2 - 8°C). Before performing the test, remove the urine container from the refrigerator and leave it for half an hour at room temperature.
» If the test was stored at 2 - 8°C, take it out of the refrigerator half an hour before testing and bring it to room temperature.
» When immersing the test into the urine, make sure that:
the urine does not come into contact with the plastic housing - the test must not be immersed in the urine too deep, i.e. it must not be immersed above the lower edge of the plastic housing, the test was immersed in urine long enough (usually 15 seconds) for control bands to appear in the result windows, the tested urine did not enter the test result windows directly.



PERFORMING THE TEST

Just before testing, open the foil pouch by tearing it open. Remove the test by grabbing its upper part (holder). Be careful not to touch the test result windows with your fingers. The pouch also contains a desiccant, which should be disposed of in the household waste.

» Remove the plastic cover from the test strips panel. Immerse the test strips protruding from the housing into the tested urine so as not to touch the surface of the urine with the lower edge of the plastic housing.[1]



» The test strips panel should be immersed in urine and held in it for about 15 seconds, until control bands C appear in the result windows for individual test strips.

» When control bands appear, remove the test panel from the urine and place the test on a level surface

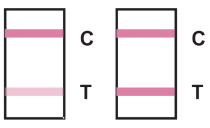
» Read the result independently for each drug after 5 minutes after immersion of the test strips panel in the urine.[2]

» NOTE: **Results read after more than 8 minutes should be ignored.** After 8 minutes, the color intensity of the bands may change or a new band may appear.

INTERPRETATION OF TEST RESULTS

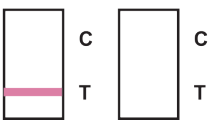
POSITIVE RESULT:

Only one colored band appears: in the control zone C. No colored band in the test zone T. The presence of a drug or its metabolite is found in the urine.



NEGATIVE RESULT:

Two colored bands appear in test zone T and control zone C. The color intensity of the test band may be weaker or stronger than that of the control band. However, if any trace of a test band appears, the test result should be interpreted as negative.
No drug or its metabolite is found in the urine tested.



INVALID RESULT:

Only the test band T appears or no band appears. The test should be repeated using a new test kit.

PRECAUTIONS

» The test is for external use only.
» Store the test kit at 2 - 30°C. Do not freeze.
» Do not use the test after the expiration date stated on the package.
» Do not use the test if the foil pouch is damaged, as moisture in the air may have damaged the test.
» The test is for single use only.
» Dispose of used test as normal household waste.
» Keep the test out of the reach of children.
» **Do not make any medical decisions without first consulting your doctor.**

TEST PRINCIPLE

The Urine Multi-Drug Test consists of 4 test strips housed in one plastic case. Each of these strips is an independently operating test in which the drug or its metabolite contained in the tested urine enters into appropriate immunological reactions with the active substances (colored drug or metabolite conjugate and anti-drug or metabolite antibody conjugate with colloidal gold) that have been applied to the membrane in the production process of the test.

When a drug or its metabolite is present in the urine tested, only one colored band appears on the test strip. If the drug or its metabolite is not present in the urine tested, two colored bands appear on the test strip.
The Urine Multi-Drug Test is an immunochromatographic test for the qualitative detection of the following drugs in urine:

Abbrv	Drug	Detected substance	Cut-off	Approximate detection time after use	Elimination rate after use (indicative)
AMP	amphetamine	d-amphetamine	1000 ng/mL	4 – 6 hours	2 - 3 days
COC	cocaine	benzoylecgonine	300 ng/mL	2 - 6 hours	2 - 3 days
MOR	morphine and heroin	morphine	300 ng/mL	2 - 6 hours	1 - 3 days
THC	marijuana and hashish	11-nor-Δ9-THC-9-COOH	50 ng/mL	1 - 3 hours	2 - 10 days, 10 - 20 days with prolonged use

Drug derivatives and their concentrations [ng/mL] above which the Urine Multi-Drug Test shows a positive result:

» Amphetamine derivatives: d-Amphetamine (1000), l-Amphetamine (100000), 3,4- Methylenedioxyamphetamine (MDA) (1 250), Phentermine (1 250), Paramethoxyamphetamine (PMA) (625), Tyramine (100 000)
» Cocaine derivatives: Benzoylecgonine (300), Cocaine (1 000), Ecgonine (100 000)
» THC derivatives:11-nor-Δ9-THC-9-COOH(50),11-nor-Δ8-THC-9-COOH(50),Δ9-tetrahydrocannabinol (15 000), Δ8-tetrahydrocannabinol (15 000), Cannabinol (>20 000)
» Morphine derivatives: Morphine (300), Acetylcodeine (150), Buprenorphine (3 125), Codeine (250), Diacetyl morphine (Heroine) (250), Dihydrocodeine (586), Ethylmorphine (200), Hydrocodone (12 500), Hydromorphone (12 500), 6-Monoacetylmorphine (250), Morphine-3-glucuronid (2 500), Nalorphine (25 000), Thebaine (25 000)

Cross-reaction testing of the Urine Multi-Drug Test has shown that the following compounds do not give false-positive results below 100 µg/mL:

(-)-Ephedrine	b-Phenylethyl-amine	Guaiacol Glyceryl Ether	Protonix
(+)-Naproxen	Caffeine	Hemoglobin	Pseudoephedrine
4-Dimethylaminoantipyrine	Chloroquine	Ibuprofen	Quinidine
Acetaminophen	Chlorpheniramine	Imipramine	Ranitidine
Acetone	Creatine	Isoproterenol	Sertraline
Albumin	Dextromethorphan	Lidocaine	Trimeprazine
Amitriptyline	Dextrorphan tartrate	Methadone	Tyramine
Ampicillin	Dopamine	Oxalic Acid	Venlafaxine
Aspartame	Erythromycin	Penicillin-G	Vitamin C (Ascorbic Acid)
Aspirin	Ethanol	Pheniramine	
Benzocaine	Furosemide	Phenothiazine	
Bilirubin	Glucose	Procaine	

LIMITATIONS OF THE METHOD

» The Urine Multi-Drug Test is an in vitro diagnostic test designed to detect the presence of drugs and/or their metabolites in human urine.
» The Urine Multi-Drug Test provides preliminary analytical results only. Additional laboratory tests should be performed to confirm the results; gas chromatography and/or mass spectrometry (GC/MS) is recommended.
» All results, especially positive ones, require confirmation with additional laboratory tests.
» Failure to follow the test instructions as well as some substances and agents may interfere with the test, resulting in false results.
» Positive results only indicate the presence of the drug/metabolite in the urine sample tested and do not indicate the level of intoxication.
» Negative results do not preclude the presence of the drug/metabolite in the urine as the concentration of the drug/metabolite may be lower than the minimum detection level (cut-off) for the test parameter.
» The Urine Multi-Drug Test does not differentiate between drugs and medications.

ANSWERS TO THE MOST COMMON QUESTIONS

What should you do if you test positive for any drug?

If a positive result is obtained for any drug, the person whose urine was tested should be monitored. If the positive result persists, you should contact the appropriate unit for professional help.

Does a negative result mean that the person whose urine was tested was not taking drugs?

A negative result generally means that no drugs or their metabolites were detected in the urine tested. However, getting a negative result does not always mean that the person whose urine was tested was not taking drugs because:
» there are easily available masking substances that, when added to urine with a drug or its metabolite, give a false-negative result,
» if too much time has passed since the drug was used, the level of the drug or its metabolite in the tested urine is so low that the test may not detect it.

What does an invalid test result mean?

In very rare cases, only the test band T or no band may appear in the result windows. This most often happens when:
» the test was immersed in the urine too deep - above the lower edge of the plastic housing,
» the test was immersed in the urine for a short time - no control bands appeared in the result windows,
» the tested urine got directly into the result windows of the test.
In such cases, the result is invalid and the test should be repeated using a new test, strictly following the test instructions.

What to do to be sure of getting the correct result?

If you want to be sure that you are getting correct results, follow the instructions for performing and reading the test result carefully.

Date of last revision of the package insert: 20.06.2022
Version 10 AT/EN

SYMBOLS

CE 1434

	Read the package insert carefully before performing the test	IVD	For in vitro diagnostic use only
	For single use	2°C 30°C	Store at 2-30°C
LOT	Lot number		Expiration date

Manufacturer:
Hydrex Diagnostics Sp. z o.o.
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controly medical devices