Amazewell™

Multi-Drug Urine Test Cup

INSTRUCTIONS FOR USE

PLEASE READ ALL THE INFORMATION IN THIS INSERT BEFORE PERFORMING THE TEST



INTENDED USE

Multi-Drug Urine Test Cup is a rapid drug screening test for the qualitative detection of drugs and drug metabolites in human urine. Drug test cut-off concentrations are listed below. It is intended for home use.

Test	Calibrator	Cut-off level		
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL		
Barbiturates (BAR)	Secobarbital	300 ng/mL		
Buprenorphine (BUP)	Buprenorphine	10 ng/mL		
Benzodiazepines (BZO)	Oxazepam	300 ng/mL		
Cocaine (COC)	Benzoylecgonine	300 ng/mL		
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL		
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamp- hetamine	500 ng/mL		
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL		
Morphine300 (MOP300)	Morphine	300 ng/mL		
Morphine2000 (MOP2000)	Morphine	2000 ng/mL		
Methadone (MTD)	Methadone	300 ng/mL		
Oxycodone (OXY)	Oxycodone	100 ng/mL		
Phencyclidine (PCP)	Phencyclidine	25 ng/mL		
Propoxyphene (PPX)	Propoxyphene	300 ng/mL		
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL		
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL		

WHAT IS MULTI-DRUG URINE TEST CUP?

Multi-Drug Urine Test Cup is a qualitative test for the detection of the drugs listed in the table below. The tests may be configured as single drug tests or multiple drug tests in any combination up to a maximum of 15 drugs. Only one cutoff concentration will be included per drug per device.

included per drug per device.

The tests provide only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained. Please refer to the Mailing a Urine Sample for Confirmation Testing Section.

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

Drug (Identifier)	Cut-off level	Minimum detection time	Maximum detection time	
Amphetamine (AMP)	1000 ng/mL	2-7 hours	2-4 days	
Barbiturates (BAR)	300 ng/mL	2-4 hours	1-3 weeks	
Buprenorphine (BUP)	10 ng/mL	4 hours	1-3 days	
Benzodiazepines (BZO)	300 ng/mL	2-7 hours	1-4 days	
Cocaine (COC)	300 ng/mL	1-4 hours	2-4 days	
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	300 ng/mL	3-8 hours	1-3 days	
Methylenedioxymetham- phetamine (MDMA)	500 ng/mL	2-7 hours	2-4 days	
Methamphetamine (MET)	1000 ng/mL	2-7 hours	2-4 days	
Morphine300 (MOP300)	300 ng/mL	2 hours	2-3 days	
Morphine2000 (MOP2000)	2000 ng/mL	2 hours	2-3 days	
Methadone (MTD)	300 ng/mL	3-8 hours	1-3 days	
Oxycodone (OXY)	100 ng/mL	1-3 hours	1-2 days	
Phencyclidine (PCP)	25 ng/mL	4-6 hours	7-14 days	
Propoxyphene (PPX)	300 ng/mL	6-12 hours	1-3 days	
Tri-cyclic Antidepressants (TCA)	1000 ng/mL	8-12 hours	7-14 days	
Marijuana (THC)	50 ng/mL	2 hours	Up to 5+ days	

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

Urine collection time is very important in 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 TIMES?" Urine can be collected at any time of the day.

HOW TO COLLECT URINE?

Remove a test cup from the foil pouch by tearing at the notch. Use it as soon as possible. In order to achieve accurate results, the cup should be filled to at least the minimum urine level mark

Note: This test can be used on urine samples only. Do not use this device to test anything but urine.

HOW TO DO THE TEST?

Test must be performed at room temperature 59-86°F (15-30°C).

- 1. After the urine has been collected, tighten lid, and place the test cup on a flat surface.

 IMPORTANT: The cap should be tightened to the position indicated.
- 2. Peel off label and read the results. The drug test results should be read at 5 minutes.

 The drug test results remain stable for up to thirty minutes. See the illustration below.



READING THE RESULTS

Preliminary positive (+)

A rose-pink band is visible in the control region, but no color band appears in the test region. This indicates a preliminary positive result for this specific drug. Preliminary positive results must be sent to a lab for a more reliable test. Please refer to the section "Mailing a Urine Sample for Confirmation Testing Section".

Negative (-)

A rose-pink band is visible in the control region and the test region. This indicates that the drug is not present in the sample or is at a level that cannot be detected by this test.

Invalid

If a color band is not visible in the control region, or a color band is only visible in the test region, the test is invalid. You should repeat the test with a new test cup. If the test still shows an invalid result, please contact us at (888) 695-5248. When calling, be sure to provide the lot number for the test.

Note: There is no meaning to the colored line intensity or width. Any visible line is considered to be a line



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Certain lines may appear lighter or thinner than other lines.

ANY COLORED LINE VISIBLE IN THE "T" REGION. NO MATTER HOW DARK OR FAINT. SHOULD BE INTERPRETED AS A NEGATIVE RESULT AS LONG AS THE CONTROL LINE

The test cup provides a preliminary test result. All "preliminary positive" samples must be sent to a laboratory for a more reliable test.

Please refer to the section 'Mailing a Urine Sample for Confirmation Testing'.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIDENTIAL CONFIRMATION TESTIN

Only urine that gave preliminary positive result(s) should be sent to a lab for confirmation testing

- 1. Ensure that the cap is tightly closed.
- 2. Check the label identifying the drug that gave a preliminary positive result.
- 3. Place the Cup in the plastic bag and seal the plastic bag.
- 4. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. Please note that the mailing box is not pre-paid. You must attach the proper postage to have a carrier service deliver it
- 5. Place the mailing box in any US Postal Service Office.
- Note: The label contains the Personal Identification Number.

IMPORTANT: You may call or send an e-mail for the confirmed test results along with the Personal Identification Number. The phone number and email address are already printed on the mailing box. Please remember to mark down the phone number and email

CONTENTS OF THE KIT

- One pouch contains: a test cup and desiccant. The desiccant is used for storage only.
- · Leaflet with instruction for use

WHAT ELSE DO YOU NEED?

- · Plastic bag Mailing box

WARNINGS AND PRECAUTIONS

- · Do not use after expiration date.
- . The test cup should remain in the sealed pouch until use.

STORAGE AND STABILITY

- Store at 39 \sim 86 °F (4 \sim 30 °C) in the sealed pouch till the expiration date.
- Keep away from direct sunlight, moisture and heat.
 DO NOT FREEZE.

TEST LIMITATIONS

1. Contaminated urine samples may produce incorrect results. Bleach and other liquids can contaminate a sample and produce incorrect results. If a sample is suspected of being contaminated, obtain a new sample in a different unused cup.

2. A positive result does not indicate the level of intoxication, how the drug was taken, or how much drug is in the urine.

3. A negative result does not necessarily mean that there are no drugs in the urine. Negative results can be obtained when drug is present but at a low level not detected by

OUESTION AND ANSWERS

What Is A False Positive Test?

A false positive test result is an instance where the drug is not present, but the Multi-Drug Urine Test Cup produces a preliminary positive result. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this

What Is A False Negative Test?

A false negative test result is when drug is present but isn't detected by Multi-Drug Urine Test Cup. If bleach or other liquids are added to the sample, this may cause a false negative result.

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 1-800729-6686

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

BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications

Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988

Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring - Verlag, 1977.

Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992. Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986 Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New

York, Oxford University Press, 1983. McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

INDEX OF SYMBOL

1-86°F

39%-1

IVD







Catalogue number

Keep away from



Use-by date Batch code

Do not reuse

sunlight



In vitro diagnostic medical device



Do not use if package is damaged

Manufactured for:

Dochek USA INC

1111 W 35th St Unit 502, Chicago, IL, 60609 Tel: (888) 695-5248 (Monday - Friday 9:00 am - 5:00 pm, CST)

Email: sales@dochekusa.com

Made in China

Doc No.: Ver1.0 GB Rel.: 2023/05/31

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物料编码	13000510				
物料名称	使用说明书_毒品多联尿杯(0TC)_Amazewell版				
规格型号	320x120mm	颜色	C:82 M:88 Y:0 K:0		
版本	Ver1.0	材质	双铜纸105g		
语言	英语	申请人			
申请日期	2023. 07. 10	设计师	张玉菊		
变更内容					

审核	营销中心	研发部	国际注册部/体系部	#\ <i>\</i>	总经理	
	日期	日期	日期	111/注	日期	