J-Catch XR Multi-Drug Test Cup

nstruction of use for testing of any combination of the following drugs: \mP/BAR/BZO/BUP/COC/THC/MET/MTD/ MDMA/MOP/ OXY/PCP/PPX/TCA

Please read all instructions before use.

TENDED HEE

INTENDED USE

U-Catch XR Multi-Drug Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

	1000ng/mL	Tri-cyclic Antidepressants (TCA)
	300ng/mL	Propoxyphene(PPX)
	25ng/mL	Phencyclidine (PCP)
. (3	100ng/mL	Oxycodone (OXY)
100	300ng/mL	Morphine(MOP300)
*	500ng/mL	Methylenedioxymethamphetamine-ecstasy (MDMA)
	300ng/mL	Methadone (MTD)
1.	1000ng/mL	Methamphetamine (MET)
18	50ng/mL	marijuana (THC)
	300ng/mL	Cocaine (COC)
	10ng/mL	Buprenorphine(BUP)
127	300ng/mL	Benzodiazepines (BZO)
	300ng/mL	Barbiturates (BAR)
1	1000ng/mL	Amphetamine (AMP)
1804	Cut-off level	Drug(Identifier)

Configuration of the U-Catch XR Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

What are the U-Catch XR Multi-Drug Test Cup?

The U-Catch XR Multi-Drug Test Cup are drug-screening tests that will give you a result for the presence of abuse in human urine. During testing, a urine sample moves upward on the test strip. A drug-positive urine sample will not produce a colored line in the specified test line area of the strip. A drug-negative urine sample will produce a colored line in the test line area. A colored line will always show in the control line area.

WARNINGS AND PRECAUTIONS

- Immunoassay for in vitro diagnostic use only.
- Do not use after expiration date.
- The test Cup should remain in the sealed pouch until use.
- Do not re-use the test.
- The used test Cup should be discarded according to local regulations

CONTENTS OF THE KIT

- Drug Test Cup
- Desiccant
- Instruction for use
- Collection Cup
- Drug Screen Procedure

 Pre-addressed and pre-paid mailing box for shipping samples for confirmation testing

NOT INCLUDED IN PACKAGE

Watch, timer or clock

STORAGE

Store at 39 \sim 86 °F (4 \sim 30 °C) in the sealed pouch up to the expiration date.

· DO NOT FREEZE

Keep away from direct sunlight, moisture and heat.

URINE COLLECTION AND PREPARATION

 Collect urine sample in the provided cup. Urine collected at any time of the day may be used.

HOW TO PERFORM THE TEST?

- Remove the U-Catch XR Multi-Drug Test Cup from the sealed pouch and use within the first hour after opening.
- 2. Peel off label and collect urine specimen in the provided cup.
- Screw the cap onto the cup and immediately start the timer.
- Read the results. The drug test results should be read at 5 minutes. The drug test results remain stable for up to thirty minutes.









Note: If the urine cup contains adulterated strips, please refer to the accompanying adulterated strips standard colorimetric chart for result interpretation. If the color development of the adulterated strips meets the requirements of the color card, follow the operation steps to interpret the results of the test items. If the color of the adulterated bar does not meet the requirements of the color card, considering the possibility of adulteration of urine, whether it is necessary to re-sample and test again, it needs to be analyzed and judged according to the actual situation on the spot.

INTERPRETATION OF TEST RESULTS

Preliminary positive (+)

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T), a preliminary positive result is indicated for the corresponding drug of that specific test zone.

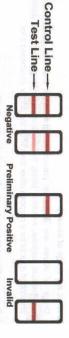
Negative (-)

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T), it indicates that the

concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

NO line appears in the "C" region, then the result is Invalid. Another test should opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling,



be sure to provide the lot number for the test.

Note: There is no meaning attributed to line.

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

UNDERSTANDING THE TEST RESULTS

A positive result does not mean a person took illegal drugs. A negative result does not mean a person did not take illegal drugs. There are many factors that affect the test. Certain drug tests are more accurate than others.

<u>IMPORTANI</u>: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS/MS is the preferred confirmatory method.

What Is A False Positive Test?

A false positive test result means the drug is not present but shows a positive result by the device. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

A false negative test means the drug is present but is not detected by the device Diluted or contaminated urine specimens may cause a false negative result.

TEST LIMITATIONS

- This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
- There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause incorrect results.
- Contaminated urine samples may produce incorrect results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of contamination, repeat the test with another urine sample.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 6. 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.

PERFORMANCE CHARACTERISTICS

A lay user study was performed at three intended user sites. There were 300 lay persons for the drug test. They had different educational and professional backgrounds. Their age range was from 18 to >50. Urine samples were prepared at the various concentrations. These concentrations were prepared by adding drug(s) into drug-free pooled urine samples. The concentrations of the samples were confirmed. Lay user results were compared to results obtained by LC/MS/MS. It demonstrated that lay users understood the device's instructions and could use the device accurately.

FREQUENTLY ASKED QUESTIONS

1. What does the U-Catch XR Multi-Drug Test Cup do?

These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the

additional testing. test suggests that drugs may be present, you send the sample to a laboratory for

2. What is "cut-off level"?

called negative. that concentration the test is called positive, and below that concentration it is The cut-off level is the specified concentration of a drug in a urine sample. Above

3. What are drugs of abuse?

prescribed it for or for a purpose other than what the doctor prescribed it for. Drugs of abuse are illegal or prescription medicines that are taken non-medical purpose, including taking the medication for longer than your doctor for a

4. Common Street Names for the Drugs to be detected?

420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi. Oxycodone (OXY) OC, Ocycotton, OX, and Kicker			Notriptyline (TCA) Pamelor	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trank, white horizon and zoom.	Methadone (MTD) Amidone, Dolophine, Methadose	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.	Buprenorphine(BUP) Bupe, Subbies, Temmies	Methylenedioxymetham Ecstasy, E, X, XTC, Adam, Clarity, Lover's	Methamphetamine Speed, Ice, Chalk, Meth, Crystal, Crank, (MET) Glass	Blow, C, candy, coke, do a line, freeze, girl, happy dust, Mama coca, mojo, monster, nose, pimp, shot smoking gun, snow, sugar, sweet stuff, and white powder.	Oxazepam (BZO) Benzos, Downers, Nerve Pills, Tranks	Secobarbital(BAR) Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets	Speed, Jelly Beans or Super Jellies , Hearts, Uppers, Pick me ups or Wake me ups, Wake ups Get ups, Boot ups, Sparkles	Diag
gic, Peter Pan, sheets, som rizon and zoom. rizon and zoom. y, bobby, boom, chira, chror yreens, hash, herb, Mary Ja, root, skunk, stack, torch, and Kicker	glic, Peter Pan, sheets, som rizon and zoom. rizon and zoom. y, bobby, boom, chira, chror greens, hash, herb, Mary Ja , root, skunk, stack, torch,	gic, Peter Pan, sheets, som rizon and zoom.	gic, Peter Pan, sheets, som	ina, black whack, CJ,	, Methadose	lack pearl, brown sugar, capite, dope, good horse, H, halittle boy, mud, perfect high,	mies	Adam, Clarity, Lover's Speed	Meth, Crystal, Crank, Fire,	s, do a line, freeze, girl, hap ojo, monster, nose, pimp, sl sugar, sweet stuff, and whit	lerve Pills, Tranks	embutal, Phenobarbital, Revis, Seconal, Tuninal,	or Super Jellies , Hearts, s or Wake me ups, Wake up sparkles	Common Street Names

5. How accurate is the test?

positives as well as false negatives for those who use drug-testing kits. accurate as lab tests. In some cases, certain foods and drugs may cause false The tests are sensitive to drugs and accurate. These tests, however, are not as

6. If the test results are negative, can the conclusion be that the urine is free of

the drug levels were below the detection limit of this test. according to the directions, either the urine sample is free of the drugs tested for, or This means that if the sample was collected properly and the test was performed

7. Does a preliminary positive screen test mean that you have found of abuse? This means that the test has reacted with something in the sample and the sample

must be sent to the lab for a more accurate test.

8. What should I do, if the lab test confirms a positive result?

If you do not believe the test result, please consult with your physician. They will If you have received a confirmed positive result, please consult with our staff on a information on both the test and the meaning of the result. have your background medical history and be able to provide you with detailed important that you remain calm and do not react in a negative way to the situation. proper course of action. We will help you identify counselors who can help you. It is

Secobarbital(BAR) 2-4 hours 1-4 d Oxazepam (BZO) 2-7 hours 1-2 d Cocaine (COC) 14 hours 2-4 d Methamphetamine (MET) 2-7 hours 2-4 d Methylenedioxymethamphetamine (MDMA) 2-7 hours 2-4 d Buprenorphine(BUP) 4 hours 1-3 d Morphine (MOP) 2 hours 2-3 d Methadone (MTD) 3-8 hours 1-3 d Phencyclidine (PCP) 4-6 hours 7-14c Notriptyline (TCA) 8-12hours 2-7 d Marijuana (THC) 2 hours Up to 5-	Drug Minimum detection detection time Amphetamine (AMP) 2-7 hours 1-2 ds	2-4 hours 2-7 hours	1-4 hours	2-7 hours	2-7 hours	4 hours	2 hours	3-8 hours	4-6 hours	8-12hours	2 hours	Oxycodone(OXY) 4 hours 1-3 da	2-4 60150	Drug Amphetamine (AMP) Secobarbital(BAR) Oxazepam (BZO) Cocaine (COC) Methamphetamine (MET) Methylenedioxymethamphetamine (MDMA) Buprenorphine (BUP) Morphine (MOP) Methadone (MTD) Phencyclidine (PCP) Notriptyline (TCA) Marijuana (THC) Oxycodone(OXY)	Minimum detection time 2-7 hours 2-4 hours 2-7 hours 2-1 hours 3-8 hours 4-6 hours 3-8 hours 4-6 hours 4-6 hours 5-4 hours 6-4	Maximum detection time 1-2 days 1-4 days 2-4 days 2-4 days 2-4 days 2-3 days 1-3 days
4 hours 4) 2~4 hours	2-4 hours 2-7 hours 1-4 hours 2-7 hours 2-7 hours 2-7 hours 4 hours 2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 2 hours 2 hours 2-4 hours	1-4 hours 2-7 hours 2-7 hours 4 hours 2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 4 hours 2 hours 2 hours	2-7 hours 2-7 hours 4 hours 2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 4 hours 2 hours	2-7 hours 4 hours 2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 4 hours	4 hours 2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 4 hours 2 hours	2 hours 3-8 hours 4-6 hours 8-12hours 2 hours 4 hours 2-4 hours	3-8 hours 4-6 hours 8-12hours 2 hours 4 hours 2-4 hours	4-6 hours 8-12hours 2 hours 4 hours 2-4 hours	8-12hours 2 hours 4 hours 2-4 hours	2 hours 4 hours 2~4 hours	4 hours 2~4 hours	2~4 hours		Methadone metabolite (EDDP)	2 hours	2 to 6 days

CONFIRMATION TESTING

- . Write Identification Number on the label.
- 2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the
- 3. Please fill out name, return address, and cell phone number on Mailing Box.
- Place labeled vial in shipping bag and seal the bag.
- Place the sealed Shipping bag in the Mailing Box.
- Mail the box using any US Postal Service
- Contact the lab if you do not get the result in 5 days.

MORE INFORMATION AND RESOURCES

below for additional information and/or counseling regarding substance abuse prevention and treatment: You can contact your health care provider, or any of the following organizations listed

- 1-800-DRUGHELP / www.ade.org
- 1-877-SAMHSA-7 / www.samhsa.gov

- 1-800-NCA-CALL / www.ncadd.org
- 1-800-668-9277 / www.prideyouthprogram.org

1-877-409-9043 / www.thetreatmentcenter.org

BIBLIOGRAPHY OF SUGGESTED READING

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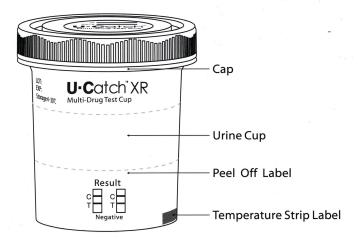
jud o COMPONENT Lot Number **Expiration Date** Store at 4°C~30°C Keep Dry Manufacturer Materials Included For Use Consult Instructions REF ND 3 \otimes IFU Sunlight Do Not Reuse Keep away from Catalogue Number Date of Manufacture Medical Device In Vitro Diagnostic Instruction for Use

IFU VER: TS-IU-C136-A0

RELEASE DATE: 2021/12/17

Drug Screen Procedure for

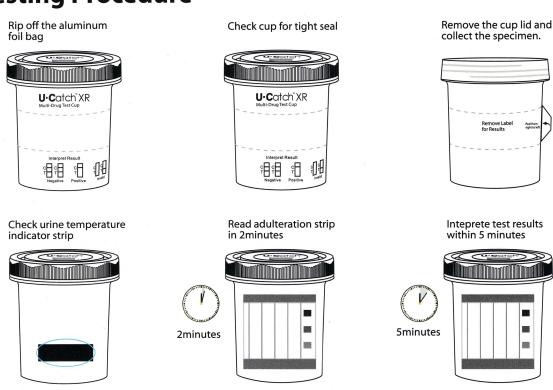
U-Catch XR Multi Drug Test Cup



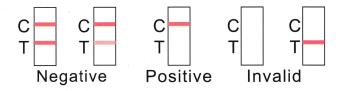
Before Testing

Bring the pouch to room temperature before opening it, remove the cup from the sealed pouch.

Testing Procedure



Interpret the results



All positive results are presumptive and should be confirmed by an alternative method.

Doc. No./Ver: TS-SI-C003 A0

Release Date: 30/12/2021

Shenzhen Bioeasy Biotechnology Co.,Ltd.

ADULTERATION COLOR CHART

TEST AND READING TIME	ABNORMAL (LOW)	NORMAL	ABNORMAL (HIGH)
Oxidant/Bleach 30s		Negative -	Positive
Specific Gravity 45s	1000	1.005 1.015 1.025	≥1.030
PH Immediate	2 3	4 5 7 9	≥10
Creatinine 45s	Negative 10	20 50 100 200mg/dl	
Nitrite 45s		0 0.1-0.2 0.5-5.0	>15mg/dl