



iCUP™ URINE TEST DRUG SCREEN CUP

Instructions for Use For Forensic Use Only

English

INTENDED USE

The iCup™ Urine Test Drug Screen Cup (iCup™) is a rapid, one step lateral flow chromatographic immunoassay for the qualitative detection of the following drugs and metabolites in human urine.

Abbreviations	Test Name	Calibrator	Screening Cut-off (ng/mL)
AMP	Amphetamines	d-Amphetamine	500
AMP	Amphetamines	d-Amphetamine	1,000
BAR	Barbiturates	Secobarbital	300
BZO	Benzodiazepines	Oxazepam	300
BUP	Buprenorphine	Buprenorphine	10
COC	Cocaine	Benzoylcegonine	150
COC	Cocaine	Benzoylcegonine	300
ETG	Ethyl Glucuronide	Ethyl Glucuronide	500
FTY	Fentanyl	Norfentanyl	20
HRN	Heroin	6-Acetylmorphine	10
K2	K2	JWH-018 Pentanoic Acid	20
KET	Ketamine	Ketamine	1,000
THC	Marijuana	11-nor-Δ⁹-THC-9 COOH	50
MTD	Methadone	Methadone	300
mAMP	Methamphetamines	d-Methamphetamine	500
mAMP	Methamphetamines	d-Methamphetamine	1,000
MDMA	Methylenedioxymethamphetamine	d,l-Methylenedioxymethamphetamine	500
MOP	Morphine	Morphine	300
OPI	Opiates	Morphine	2,000
OXY	Oxycodone	Oxycodone	100
PCP	Phencyclidine	Phencyclidine	25
TRA	Tramadol	Tramadol	200

These screening assay tests provide preliminary results. A more specific alternative analytical method, such as Gas chromatography/mass spectrometry (GC-MS) or liquid chromatography tandem mass spectrometry (LC-MS/MS) must be used to obtain confirmed results. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Screening Tests

Modern screening methods are designed to rapidly identify a sample as either negative or presumptive positive if the substance is above a set cut-off concentration.

Confirmation Tests

A confirmation test is able to definitively detect individual compounds by matching them to a commercially prepared reference standard using one of the following:

- GC-MS (Gas Chromatography - Mass Spectrometry)
- GC-MS/MS (Gas Chromatography - Tandem Mass Spectrometry)
- LC-MS/MS (Liquid Chromatography - Tandem Mass Spectrometry)

Confirmation tests provide qualitative results of drugs and/or drug metabolites present in the sample. Only a confirmation test would allow the laboratory to make the distinction between illicit, prescription medicines or over the counter medication. Confirmation results are expressed as positive or negative and are legally defensible.

TEST PRINCIPLE

The iCup™ is a collection cup that incorporates drug immunoassays based on the principle of competitive binding. Free drug in the sample competes with drug-conjugate on the membrane at the test region for binding sites on the gold labeled anti-drug antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

Specimen Validity Tests (SVT)

Adulterated or diluted urine samples may cause erroneous results in drug tests. Specimen Validity Tests or adulteration tests help determine the integrity of the urine sample. Results are interpreted visually by comparing the color pads on the adulteration strips to the printed color blocks on the color chart.

- **OX/PCC (Oxidants/Pyridinium Chlorochromate):** tests for the presence of oxidants such as bleach. Normal: Negative.
- **pH:** tests for adulteration with acidic or alkaline adulterants. Normal 4-9.
- **CRE (Creatinine):** tests for specimen dilution. Normal: 20-100 mg/dL.
- **S.G. (Specific Gravity):** tests for specimen dilution. Normal: 1.003-1.025.

MATERIALS

Materials Provided

- 25 Multi-drug cups
- 25 Security seal labels
- 5 SVT color charts (if included)
- 1 Instructions for use
- 2 Procedure cards

Materials Required But Not Provided

- Timer

Test Reagents

- Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. Heroin (HRN) contains anti-drug recombinant Fab-fragment antibody and corresponding drug protein conjugates.
- The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

SVT Reagents

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
OX/PCC	0.36%	99.64%
pH	0.06%	99.94%
CRE	0.04%	99.96%
S.G.	0.25%	99.75%

CUP STORAGE AND STABILITY

Precautions

- DO NOT FREEZE.
- Do not use after the expiration date.

Cup Storage

- Store in sealed pouch either at room temperature or refrigerated 36-86°F (2-30°C).
- The test cup is stable through the expiration date printed on the sealed pouch.
- The used test cup should be discarded according to federal, state and local regulations.
- The performance of this product has not been established when stored outside the recommended conditions.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection

- Collect a fresh urine specimen in the provided test cup.
- Alternatively, collect urine in a clean and dry container and store per the below recommended storage conditions prior to testing.
- Urine collected at any time of the day may be used.

Specimen Storage

iCup™ Screening Test

- For best results specimens should be tested immediately in the iCup™ following collection. If a separate urine collection cup container with lid (other than the iCup™) is used, urine specimen may be stored as follows:
 - a. Stored at room temperature for up to 2 hours prior to testing in iCup™.
 - b. Refrigerated at 36-46°F (2-8°C) for up to 48 hours prior to testing in iCup™ unless an SVT is included, in which case storage of urine specimens should not exceed 4 hours.
 - c. Frozen and stored below -4°F (-20°C) for up to 3 months prior to testing in iCup™.
- Refrigerated specimens must be brought to room temperature and frozen specimens should be thawed, brought to room temperature and mixed well before testing.

Confirmation Testing

Urine specimens to be sent for confirmation testing must be either refrigerated or frozen depending on the timeframe the lab uses to perform confirmation testing with the same guidelines above.

Precautions

- This method has been tested using urine in the iCup™ only. Other fluids and other urine containers have not been evaluated. For best results specimens should be tested in the iCup™ immediately.
- Urine specimens may be potentially infectious; proper handling and disposal methods should be established.
- Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.
- Do not use urine preservatives.

QUALITY CONTROL

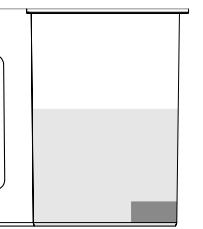
A Procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control samples are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

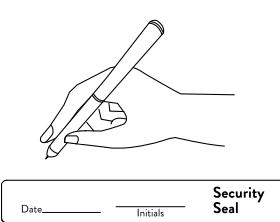
DIRECTIONS FOR USE

- Read the full instructions before using the test. The instructions and procedures described in this package insert must be followed carefully.
- Test cups are single use only. Do not re-use.
- If either the iCup™ or the specimen, or the controls are not at room temperature, they must equilibrate to room temperature 59-86°F (15-30°C) before testing.
- When the donor is ready to provide a sample, remove cup from sealed pouch and use immediately.

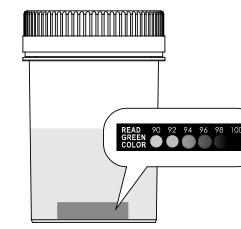
1. Collect donor's specimen in cup. A minimum of 30 mL (Minimum Fill Line on the Cup) is required to run the test. Place cup on flat surface. Ensure a tight seal by twisting the cap until an audible click is heard. Do not lift or tilt cup throughout testing procedure.



3. Initial and date the security seal label.



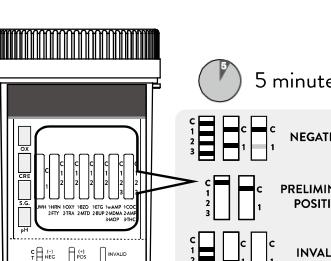
2. If sample is tested immediately after collection, read temperature strip within 2-4 minutes. If temperature is outside of the normal range of 90-100°F (33-38°C) it may indicate tampering of the specimen. Another specimen should be collected and tested.



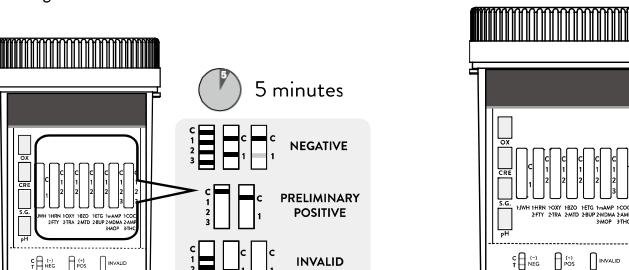
4. Place security seal label over lid.
5. Peel off label to view results. See enclosed color chart for interpretation.



6. If SVT strip is included, read the results between 3 and 5 minutes after urine collection.
7. Read drug test results at 5 minutes. Do not read past 10 minutes. If control line is not present, the test is invalid. Negative can be interpreted as soon as a clear, defined line has formed at both the control and test line region.



8. Test results may be photographed / photocopied if required.



INTERPRETATION OF SVT (IF INCLUDED)

To determine if SVT results are Normal or Abnormal, compare the color of each SVT pad to the corresponding color block on the color chart within 3-5 minutes of urine collection. An abnormal SVT result may indicate tampering of the specimen. Another specimen should be collected and tested.

INTERPRETATION OF DRUG TEST RESULTS

CONTROL LINE: Ensure that a control line is present on each test strip.

NEGATIVE: A colored line in the control line region (C) and the test line region (T), even if faint, for a specific drug indicates a negative result. This indicates either the drug is not present or the drug is below the cut-off.

NOTE: The intensity of the test and control lines may vary.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line fails to appear. Alternative factors may result in control line failure. If no control line appears in any of the test strips, review the procedure. Another specimen should be collected and tested.

DRUG ASSAY TEST LIMITATIONS

1. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
2. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
3. A negative result may not necessarily indicate drug-free urine. Negative results can still be obtained when drug is present but below the cut-off level of the test.
4. The test does not distinguish between illicit and prescription drugs.

SPECIMEN VALIDITY TEST LIMITATIONS

1. The SVT are not quantitative and are not intended for clinical diagnosis.
2. Color blindness may affect interpretation of results.

EXPECTED VALUES

Window of Detection

Substances	Up to 1-3 days
Amphetamines	Shorter acting up to 1-2 days
Barbiturates	Long-acting up to 7 days
Benzodiazepines	Ultra short acting up to 12 hours
Buprenorphine	Short acting up to 1 day
Cocaine (metabolite/benzoylcegonine)	Intermediate acting up to 2-4 days
Ethyl Glucuronide	Long-acting up to 7 days
Fentanyl (norfentanyl)	Maintenance dose up to 10-12 days
*Heroin	Therapeutic dose up to 1-3 days
K2 (JWH-018 5-pentoxy acid)	Maintenance dose up to 10-12 days
Ketamine	Up to 2-3 days
Marijuana	Up to 1-4 days
Methadone	Up to 1-2 days
Methamphetamines	Up to 1-3 days
Methylenedioxymethamphetamine	Up to 2-4 days
Morphine	Up to 2-3 days
Opiates	Up to 2-3 days
Oxycodone	Up to 1-3 days
Phencyclidine	14 days (longer in chronic users)
Tramadol	Up to 2 days

Detection Times of Drugs of Abuse in Blood, Urine, and Oral Fluid. Verstraete, Alain G. April 2004, Therapeutic Drug Monitoring, Vol. 26, pp. 200-205.

* Cone EJ, Welch P et al. 'Forensic Drug Testing for Opiates detection of 6-acetylmorphine in urine as an indicator of recent heroin exposure; drug and assay considerations and detection times' Journal of Analytical Toxicology, Vol. 15, 1991.

PERFORMANCE CHARACTERISTICS

Accuracy - % Overall Agreement with LC-MS/MS

The qualitative screening results on the iCup™ were compared to the qualitative confirmation results on LC-MS/MS. A minimum of 40 positives and 40 negatives for each drug assay were tested internally by a trained professional. The results are shown in the table below.

HRN 10	HRN 10		95.7	89.5-98.8
	+	53	4	
	-	0	37	
K2 20	K21		>99.9	98.6-100.0
	+	44	0	
	-	0	168	
KET 1,000	KET 25		98.8	93.2-100.0
	+	43	0	
	-	1	36	
THC 50	THC 15		99.3	96.0-100.0
	+	101	0	
	-	1	36	
MTD 300	MTD 300		97.6	94.6-99.2
	+	40	5	
	-	0	167	
mAMP 500	mAMP 250		94.8	90.9-97.4
	+	76	3	
	-	8	125	
mAMP 1,000	mAMP 500		96.5	92.5 - 98.7
	+	105	0	
	-	6	59	
MDMA 500	MDMA 250		99.5	97.4-100.0
	+	43	0	
	-	1	168	
MOP 300	MOP 300		99.1	96.6 - 99.9
	+	38	0	
	-	2	172	
OPI 2,000	OPI 2,000		89.1	84.5-92.7
	+	144	7	
	-	20	76	
OXY 100	OXY 100		>99.9	98.2-99.2
	+	44	0	
	-	0	124	
PCP 25	PCP 25		97.2	93.9-99.0
	+	40	8	
	-	0	166	
TRA 200	TRA 200		97.6	94.0-99.4
	+	51	1	
	-	3	113	

These test assays provide preliminary results and may cross react to similar chemical compounds. In addition to the target analyte, the combination of cross reactants, may result in a positive result even if the target analyte is present below specified cut-offs.

Precision

A study was conducted by trained operators over 20 days using 3 different lots of product to demonstrate the within run, between run and between operator precision. A panel of coded specimens containing drug free urine, -50% cut-off, cut-off, +50% cut-off, 2x cut-off and 3x cut-off was tested for each drug assay. The results are summarized below.

Drug concentration	AMP 500 (n=180)		AMP 1,000 (n=240)		BAR 300 (n=180)		BZO 300 (n=180)	
	#neg	#pos	#neg	#pos	#neg	#pos	#neg	#pos
0% Cut-off	180	0	240	0	180	0	180	0
-50% Cut-off	180	0	240	0	180	0	178	2
Cut-off	18	162	32	208	49	131	24	156
+50% Cut-off	0	180	0	240	0	180	0	180
2X Cut-off	0	180	0	240	0	180	0	180
3X Cut-off	0	180	0	240	0	180	0	180

Drug concentration	BUP 10 (n=240)		COC 150 (n=180)		COC 300 (n=240)		ETG 500 (n=240)	
	#neg	#pos	#neg	#pos	#neg	#pos	#neg	#pos
0% Cut-off	240	0	180	0	240	0	240	0
-50% Cut-off	240	0	178	2	240	0	240	0
Cut-off	22	218	65	115	46	205	52	188
+50% Cut-off	0	240	0	180	0	240	240	0
2X Cut-off	0	240	0	180	0	240	240	0
3X Cut-off	0	240	0	180	0	240	240	0

Drug concentration	FTY 20 (n=180)		HRN 10 (n=180)		K2 20 (n=180)		KET 1,000 (n=180)	
	#neg	#pos	#neg	#pos	#neg	#pos	#neg	#pos
0% Cut-off	180	0	180	0	240	0	180	0
-50% Cut-off	180	0	180	0	237	3	180	0
Cut-off	68	112	135	45	47	193	96	84
+50% Cut-off	0	180	0	180	0	240	239	2
2X Cut-off	0	180	0	180	0	240	0	180
3X Cut-off	0	180	0	180	0	240	0	180

Drug concentration	THC 50 (n=180)		MTD 300 (n=180)		mAMP 500 (n=240)		mAMP 1,000 (n=240)		MDMA 500 (n=240)	
	#neg	#pos	#neg	#pos	#neg	#pos	#neg	#pos	#neg	#pos
0% Cut-off	180	0	180	0	240	0	240	0	240	0
-50% Cut-off	180	0	178	2	240	0	240	0	239	1
Cut-off	16	164	64	116	16	224	66	174	15	225
+50% Cut-off	0	180	0	180	0	240	0	240	0	240
2X Cut-off	0	180	0	180	0	240	0	240	0	240
3X Cut-off	0	180	0	180	0	240	0	240	0	240

Drug concentration	MOP 300 (n=240)	OPI 2,000 (n=180)	OXY 100 (n=180)	PCP 25 (n=240)	TRA 200 (n=240)	
Cut-off Range	#neg	#pos	#neg	#pos	#neg	#pos
0% Cut-off	240	0	180	0	240	0
-50% Cut-off	240	0	180	0	240	