Accurate

One Step Urine Cup From LaneWorkSafe

Package Insert

Instruction Sheet for testing of any combination of the following drugs:
AMP/BZO/COC/THC/MET/MOP/K2
Including Specimen Validity Tests (S.V.T.) for: Oxidants/PCC, pH, Creatinine

These devices are intended for Workplace Testing for substances of abuse.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Cups must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

INTENDED USE

The ***Accurate*** Test Cup is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 300)	D-Amphetamine	300
Benzodiazepines (BZO 200)	Oxazepam	200
Cocaine (COC 300)	Benzoylecgonine	300
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Methamphetamine (MET 300)	d-Methamphetamine	300
Morphine (MOP)	Morphine	300
Synthetic Marijuana (K2-30)	JWH-018, JWH-073	30

Configurations of the Accurate Cup come with any combination of the above listed drug analytes with or without S.V.T. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

WHAT IS ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.
One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, creatinine and to detect the presence of oxidants.

PRINCIPLE (FOR DOA TESTS)

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible coloured line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the coloured line will not form in the test region. A drug-positive urine specimen will not generate a coloured line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.
To serve as a procedural control, a coloured line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

• Test Cups • Package insert • Adulteration Colour Chart (when applicable)

Materials Required But Not Provided

• Timer

DIRECTIONS FOR USE

Allow the test to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it within one hour.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Technician dates and initials the security seal and attaches the security seal over the cup cap.
5. Technician peels off label to reveal adulteration strip(s), if applicable.
6. Technician peels off the label on the multi-drug test card to view results.
7. Read the adulteration strips between 3-5 minutes with the help of colour chart provided separately. Refer to your Drug Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
8. The drug strip result should be read at 5 minutes. Do not interpret the result after 10 minutes.

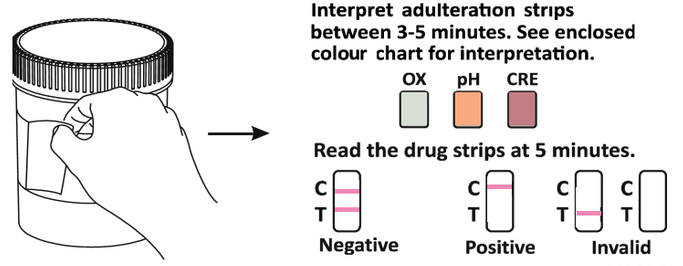

DIAGRAM 1

For non-negative (positive) sample requiring Confirmatory Testing by a NATA Accredited Laboratory

The Accurate One Step Urine Cup has a specially designed Evacuation Port built into the screw cap. This allows urine sample to be extracted by the tester without exposure, spillage or any messy handling.

1. Slide opening on cap to the side to expose extraction port.
DO NOT PUT FINGER INSIDE. The Port is very sharp!
2. Depress Vacuum Urine Tube/Vials into Cap. The Rubber on Vial will pierce and the urine sample will extract automatically into Vial.
3. Repeat process as required
4. Once complete Vials are ready for transportation and further testing.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)
NEGATIVE:* A coloured line appears in the Control region (C) and coloured lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested. (See DIAGRAM 1)

*NOTE: The shade of the coloured lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A coloured line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact LaneWorkSafe.

INTERPRETATION OF RESULTS (S.V.T/ ADULTERATION)

(Please refer to the colour chart)
Semi Quantitative results are obtained by visually comparing the reacted colour blocks on the strip to the printed colour blocks on the colour chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A 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.

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.

2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.

3. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

4. pH: Testing for the presence of acidic or alkaline adulteration. Based on well known double pH indicator method.

% AGREEMENT WITH COMMERCIAL KIT

	AMP 300	BZO 200	COC 300	THC 50	MET 300	MOP 300	K2 30
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*

* Note: Based on GC/MS data instead of Commercial Kit.

PRECISION

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical cup of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labelled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	8	2	8	2
375	10	2	8	2	8	2	8
450	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 200)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MARIJUANA (THC50)

11-nor-Δ9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

METHAMPHETAMINE (MET300)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE (MOP 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

K2 30

K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22.5	10	8	2	9	1	9	1
37.5	10	1	9	1	9	1	9
45	10	0	10	0	10	0	10

ANALYTICAL SENSITIVITY

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarised below.

Drug concentration Cut-off Range	AMP300		BZO200		COC300		THC50		MET300		MOP 300		K2 30	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	26	4	26	4	27	3	27	3	27	3
Cut-off	15	15	16	14	13	17	14	16	14	16	15	15	16	14
+25% Cut-off	4	26	3	27	3	27	3	27	1	29	5	25	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

ANALYTICAL SPECIFICITY

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Cup at 5 minutes.

AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	2,000

BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1,000	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2,000	Estazolam	4,000
RS-Lorazepamglucuronide	120	Triazolam	2,000
Midazolam	4,000		

COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000

MARIJUANA (THC50)			
Cannabinol	35,000	Δ8-THC	17,000
11-nor-Δ8-THC-9 COOH	30	Δ9-THC	17,000
11-nor-Δ9-THC-9 COOH	50		

METHAMPHETAMINE (MET300)			
ρ-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Methamphetamine	15,000

MORPHINE (MOP 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300

SYNTHETIC MARIJUANA (K2-30)			
JWH-018 5-Pentanoic acid	30	JWH-073 4-butanoic acid	30
JWH-018 4-Hydroxypentyl	250	JWH-018 5-Hydroxypentyl	300
JWH-073 4-Hydroxybuty	300		

NON CROSS-REACTING COMPOUNDS

Acetophenetidin	l-Ascorbic acid	Norethindrone	Chloramphenicol
Cortisone	Digoxin	Tetrahydrozoline	Hydrochlorothiazide
Zomepirac	Methylphenidate	Bilirubin	Papaverine
d-Pseudoephedrine	Sulindac	Fenoprofen	Trifluoperazine
N-Acetylprocainamide	Apomorphine	Noscapine	Chlorothiazide
Creatinine	Diphenhydramine	Thiamine	Hydrocortisone
Ketoprofen Quinidine	Nalidixic acid	d,l-Brompheniramine	Penicillin-G
Acetylsalicylic acid	Tetracycline	Furosemide	Trimethoprim
Deoxycorticosterone	Aspartame	d,l-Octopamine	d,l-Chlorpheniramine
Labetalol	Ethyl-p-aminobenzoate	Thioridazine	o-Hydroxyhippuric acid
Quinine	Naproxen	Caffeine	Perphenazine
Aminopyrine	Tetrahydrocortisone,	Gentisic acid	d,l-Tryptophan
Dextromethorphan	Atropine	Oxalic acid	Chlorpromazine
Loperamide	β-Estradiol	d,l-Tyrosine	3-Hydroxytyramine
Salicylic acid	Niacinamide	Cannabidiol	Phenelzine Uric acid
Amoxicillin Diclofenac	3-acetate	Hemoglobin	Cholesterol
Meprobamate	Benzilic acid	Oxolinic acid	d,l-Isoproterenol
Serotonin	Estrone-3-sulfate	Tolbutamide	Prednisone
Ampicillin	Nifedipine	Chloral hydrate	Verapamil
Diflunisal	Tetrahydrocortisone	Hydralazine	Clonidine
Methoxyphenamine	Benzoic acid	Oxymetazoline	Isoxsuprine
Sulfamethazine	Erythromycin	Triamterene	d,l-Propanolol

PRECAUTIONS

The test Cup should remain in the sealed pouch until use.

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Cup should be discarded according to local regulations.

BIBLIOGRAPHY

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Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	LWS	Authorised Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufactured for:
LaneWorkSafe Pty Ltd
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