

Australia Breathalyzers

ToxTest KC 600 Urine Drug Test Cup Package Insert

English

For Forensic and Workplace Use Only.

INTENDED USE

The ToxTest KC 600 Urine Drug Test Cup is a rapid, lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Abbreviation	Test	Calibrator	Cut-off (ng/mL)
AMP	Amphetamine	d-Amphetamine	300
BZO	Benzodiazepines	Oxazepam	200
COC	Cocaine	Benzoyllecgonine	150
MET	Methamphetamine	d-Methamphetamine	300
OPI	Opiates	Morphine	300
THC	Marijuana	11-nor- Δ^9 -THC-9 COOH	50

This assay provides only a preliminary 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. Professional judgment should be applied to any drug of abuse test result, particularly when not-negative results are indicated.

TEST SUMMARY

The ToxTest KC 600 Urine Drug Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human urine.

TEST PRINCIPLE

The ToxTest KC 600 Urine Drug Test Cup is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the 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 line region of the specific drug strip. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, the coloured line will not form in the test line region.

A drug-positive urine specimen will not generate a coloured line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and correct membrane wicking has occurred.

SPECIMEN VALIDITY / ADULTERATION TESTS

The ToxTest KC 600 Urine Drug Test Cup features six (6) specimen validity / adulteration tests. Adulterated or diluted urine specimens may cause incorrect drug test results.

Specimen validity / adulteration tests help determine the integrity of a urine sample. Results are interpreted by visually comparing the colour pads of the specimen validity / adulteration strips on the ToxTest KC 600 Cup Lid with the included printed Adulterant Colour Chart.

The following specimen validity / adulteration tests are included in the ToxTest KC 600 Urine Drug Test Cup

Abbreviation	Test	Description
OXI	Oxidants	Tests for the presence of oxidizing agents such as bleach. Human urine should not contain oxidants.
SG	Specific Gravity	Tests for specimen dilution (excessive hydration).
pH / PH	Potential of Hydrogen	Tests for the presence of acidic or alkaline adulterants in urine. Normal range 4-9.
NIT	Nitrite	Tests for commonly used commercial adulterants that work by oxidizing cannabinoid metabolite THC-COOH. Human urine should not contain nitrite.
GLU	Glutaraldehyde	Tests for the presence of an aldehyde, which should not be found in human urine.
CRE	Creatinine	Tests for specimen dilution (excessive hydration).

REAGENTS FOR DRUG TEST

The test contains membrane strips with anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates on the test line. A goat anti-rabbit IgG polyclonal antibodies and rabbit IgG are used on the control line.

STORAGE AND STABILITY

- The test should remain in the sealed pouch until immediately before use.
- Store in sealed pouch at 2-30°C. Do not freeze.
- The test is stable until the expiration date printed on the sealed pouch.
- Do not use if the expiry date has passed.
- Used test kits should be discarded in accordance with local regulations.

SPECIMEN COLLECTION

The urine specimen should be collected using the Clear Cup Base with Temperature Label. Follow the detailed Directions for Use below.

MATERIALS



Materials Provided

- ToxTest KC 600 Urine Drug Test Cup
 - a) Cup with Integrated Test / Adulteration Strips and Temperature Label
 - b) Key (stored in the lid of cup)
- Package Insert (this document)
- Adulterant Colour Chart

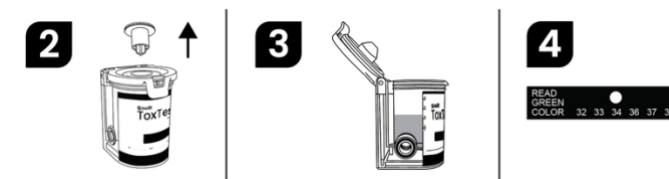
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test kit to reach room temperature (15-30°C) prior to testing.

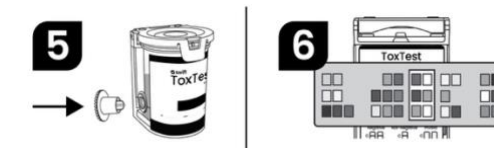
- Remove the ToxTest KC 600 Urine Drug Test Cup from the sealed pouch.



- Remove the key from the lid of the cup.

- Open the lid and collect a fresh urine sample above minimum fill line. Close the lid by pressing down until an audible click is heard.

- Check the Temperature Label within 4 minutes of specimen collection. Read the green colour dot on the Temperature Label. The proper range for an unadulterated specimen is 32°C - 38°C.



- Place the cup on a flat surface and push the key into the inlet on the left hand side of the cup. Start a timer.

- Remove the peel off label covering the test panel on the cup. Read the adulteration test results between 3 and 5 minutes. Compare the colours of the adulteration tests with the included printed Adulteration Colour Chart.

If the result/s indicate specimen adulteration, do not proceed to interpret the drug test results. Instead, either re-test the specimen using a new ToxTest KC 600 Urine Drug Test Cup or collect a new urine specimen from the donor.

- Read the drug test results as soon as all Control (C) and Test (T) lines appear. Wait 5 minutes before declaring test not-negative. Do not interpret the drug test results after 10 minutes.

INTERPRETATION OF DRUG TEST RESULTS

NEGATIVE					NEGATIVE (Do Not Compare Line Intensity)				
T1	AMP	MET	BZO	THC	T1	AMP	MET	BZO	THC
T2	COC	OPI			T2	COC	OPI		
C					C				
T1					T1				
T2					T2				

NOT-NEGATIVE (TO OPI & BZO)					NOT-NEGATIVE (TO AMP, MET & OPI)				
T1	AMP	MET	BZO	THC	T1	AMP	MET	BZO	THC
T2	COC	OPI			T2	COC	OPI		
C					C				
T1					T1				
T2					T2				

INVALID (NO "C" LINE - THC)					INVALID (NO "C" LINE - AMP/COC & THC)				
T1	AMP	MET	BZO	THC	T1	AMP	MET	BZO	THC
T2	COC	OPI			T2	COC	OPI		
C					C				
T1					T1				
T2					T2				

NEGATIVE: Lines present in both Control (C) and Test (T) regions.
NOTE: The shade of the lines will vary, but it should be considered negative whenever there is even a faint line.

NOT-NEGATIVE: Line present in the Control (C) region but no line present in the applicable Test (T) region/s.

INVALID: Control line not present.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test kit. If the problem persists, discontinue using the lot immediately and contact your distributor or Swift Toxicology.

QUALITY CONTROL

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

LIMITATIONS

- 1. The ToxTest KC 600 Urine Drug Test Cup provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.
- 2. A not-negative test result does not indicate the concentration of drug in the specimen or the route of administration.
- 3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the assay.

PERFORMANCE CHARACTERISTICS

Accuracy
Using randomised specimens from the ToxTest KC 600 Urine Drug Test Cup Kit, specimens were determined as either positive or negative at 5 minutes. These results were then confirmed by GC/MS.

	Agreement with GC/MS			
	Positive		Negative	TOTAL
AMP 300	>99%		99%	99%
BZO 200	>99%		98%	99%
COC 150	98%		97%	98%
MET 300	98%		98%	98%
OPI 300	95%		95%	95%
THC 50	98%		98%	98%

Analytical Sensitivity

Urine was spiked with drugs to target concentrations of ± 50% cut-off and at cut-off and tested with the ToxTest KC 600 Urine Drug Test Cup Kit. The results are summarized below.

Drug concentration	n	AMP 300		BZO 200		COC 150		MET 300	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
Cut-off	30	15	15	16	14	16	14	16	14
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug concentration	n	OPI 300		THC 50	
		-	+	-	+
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
Cut-off	30	15	15	14	16
+50% Cut-off	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the ToxTest KC 600 Urine Drug Test Cup identified not-negative results when read at 5 minutes.

AMPHETAMINE (AMP)			
d-Amphetamine	300	D,L-Amphetamine sulfate	75
Phentermine	300	(±) 3,4-Methylenedioxy amphetamine	150
Methoxyphenamine	2,000		
L-Amphetamine	10,000	Maprotiline	15,000
BENZODIAZEPINES (BZO)			
Oxazepam	200	Alprazolam	70
Norchlordiazepoxide	70	Temazepam	70
Clobazam	120	Nitrazepam	120
Desalkylflurazepam	120	Flunitrazepam	120
RS-Lorazepamglucuronide	120	Diazepam	200
Clonazepam	300	Clorazepatedipotassium	300
Bromazepam	600	Chlordiazepoxide	600
Delorazepam	600	Nordiazepam	600
α-hydroxyalprazolam	1,000	Triazolam	2,000
(±) Lorazepam	2,000	Estazolam	4,000
Midazolam	4,000		
COCAINE (COC)			
Benzoylcegonine	150	Cocaine HCl	120
Cocaethylene	10,000	Ecgonine	15,000
METHAMPHETAMINE (MET)			
d-Methamphetamine	300	(±)-3,4-Methylenedioxy-methamphetamine	3,750
L-Methamphetamine	6,000		
p-Hydroxymethamphetamine	7,500	Mephentermine	15,000
OPIATES (OPI)			
Morphine	300	Codeine	200
6-Monoacetylmorphine	300	Morphine-3-β-D-Glucuronide	800
Levorphanol	1,500	Hydromorphone	3,000
Ethylmorphine	6,000	Norcodeine	6,000
Thebaine	6,000	Procaine	15,000
Oxycodone	30,000	Hydrocodone	50,000
Normorphone	50,000	Oxymorphone	50,000
MARIJUANA (THC)			
11-nor-Δ ⁹ -THC-9 COOH	50	11-nor-Δ ⁸ -THC-9 COOH	30
Δ ⁹ -THC	17,000	Δ ⁸ -THC	17,000
Cannabinol	35,000		

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing above related calibrator substances. The following compounds demonstrated no false not-negative results on the ToxTest KC 600 Urine Drug Test Cup when tested with at concentrations of 100,000 ng/mL.

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

	Consult Instructions for Use.		Contains sufficient for <n> tests.
	Store between 2 - 30°C.		Use by date.
	Do not use if package is damaged.		Batch code.
	Single use only. Do not reuse.		Catalogue Number.

Swift Toxicology Australia

4/1 Corvalis Ln, Cambridge, TAS 7170, Australia

Phone: 1300 131 161 Email: support@swifttox.au

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