

# Australia Breathalysers

## ToxTilt Urine Drug Test Cup Package Insert

English

*For Forensic and Workplace Use Only.*

### INTENDED USE

The ToxTilt 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         | Cocaine                        | 150             |
| MET          | Methamphetamine | d-Methamphetamine              | 300             |
| OPI          | Opiates         | Morphine                       | 300             |
| THC          | Marijuana       | 11-nor- $\Delta^9$ -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 ToxTilt 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 ToxTilt 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 ToxTilt 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 ToxTilt Cup Lid with the included printed Adulterant Colour Chart.

The following specimen validity / adulteration tests are included in the ToxTilt 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. |
| GLUT         | Glutaraldehyde        | Tests for the presence of an aldehyde, which should not be found in human urine.                                                               |
| CREA         | Creatinine            | Tests for specimen dilution (excessive hydration).                                                                                             |

### REAGENTS FOR DRUG TEST

The test contains membrane strips contain 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

- ToxTilt Urine Drug Test Cup
  - a) Clear Cup Base with Temperature Label
  - b) Cup Lid with Integrated Test and Adulteration Strips
- Package Insert
- 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.



- Collect a fresh urine sample in the Clear Cup Base with Temperature Label above minimum fill line.
- Remove the ToxTilt Cup Lid with Integrated Test and Adulteration Strips from the sealed pouch. Secure the Cup Lid tightly until snug. Ensure Cup Lid is secured properly before proceeding.
- 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.



- Tilt the cup on its side to activate the test. Leave the cup on a flat surface. Start the timer.
- 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 ToxTilt 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) |     |     |     |     |     |  |
|----------|-----|-----|-----|-----|-----|--|------------------------------------------|-----|-----|-----|-----|-----|--|
| OPI      | COC | MET | AMP | BZO | THC |  | OPI                                      | COC | MET | AMP | BZO | THC |  |
| C        |     |     |     |     |     |  | C                                        |     |     |     |     |     |  |
| T        |     |     |     |     |     |  | T                                        |     |     |     |     |     |  |

  

| NOT-NEGATIVE (TO OPI & THC) |     |     |     |     |     |  | NOT-NEGATIVE (TO COC, AMP & THC) |     |     |     |     |     |  |
|-----------------------------|-----|-----|-----|-----|-----|--|----------------------------------|-----|-----|-----|-----|-----|--|
| OPI                         | COC | MET | AMP | BZO | THC |  | OPI                              | COC | MET | AMP | BZO | THC |  |
| C                           |     |     |     |     |     |  | C                                |     |     |     |     |     |  |
| T                           |     |     |     |     |     |  | T                                |     |     |     |     |     |  |

  

| INVALID (NO "C" LINE/S - MET & BZO) |     |     |     |     |     |  | INVALID (NO "C" LINE/S - MET, BZO & THC) |     |     |     |     |     |  |
|-------------------------------------|-----|-----|-----|-----|-----|--|------------------------------------------|-----|-----|-----|-----|-----|--|
| OPI                                 | COC | MET | AMP | BZO | THC |  | OPI                                      | COC | MET | AMP | BZO | THC |  |
| C                                   |     |     |     |     |     |  | C                                        |     |     |     |     |     |  |
| T                                   |     |     |     |     |     |  | T                                        |     |     |     |     |     |  |

**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 ToxTilt 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 cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

**Accuracy**  
Using randomised specimens from the ToxTilt 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 ToxTilt 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 ToxTilt 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  | 150 |
| Methoxyphenamine      | 2,000  | amphetamine             |     |
| L-Amphetamine         | 10,000 | Maprotiline             |     |
| 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- | 3,750  |
| L-Methamphetamine        | 6,000 | methamphetamine         |        |
| 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 <sup>9</sup> -THC-9 COOH | 50     | 11-nor-Δ <sup>9</sup> -THC-9 COOH | 30     |
| Δ <sup>9</sup> -THC               | 17,000 | Δ <sup>8</sup> -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 ToxTilt 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           | Diffunisal             | 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             |
| Billirubin           | 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.     |
|  | Store between 2 - 30°C.           |
|  | Do not use if package is damaged. |
|  | Single use only. Do not reuse.    |

|  |                                    |
|--|------------------------------------|
|  | Contains sufficient for <n> tests. |
|  | Use by date.                       |
|  | Batch code.                        |
|  | Catalogue Number.                  |

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Version: 1.0  
Authorised for Release: 28 April 2025

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