# TCA

## One Step Tricyclic Antidepressants

## Test Device (Urine)

## Package Insert

**Cata:** TCA-102 **Format:** Device

**Version:** Z **Effective Date:** 2020-07

**For professional *in vitro* diagnostic use only.**

### INTENDED USE

The TCA One Step Tricyclic Antidepressants Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Tricyclic Antidepressants in urine at a cut-off concentration of 1000ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, 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 used.

### INTRODUCTION

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders,TCA Overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects, TCA overdoses the most common cause of death from prescription drugs. TCAs are taken orally or Sometimes by injection.TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The TCA One Step Tricyclic Antidepressants Test Device (Urine) yields a positive result when the concentration of Nortriptyline in urine exceeds 1.000ngmL.

### PRINCIPLE

The TCA One Step Tricyclic Antidepressants Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Tricyclic Antidepressants, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Tricyclic Antidepressants-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Tricyclic Antidepressants level exceeds the cut-off level, because it will saturate all the binding sites of anti-Tricyclic Antidepressants antibodies.

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

### REAGENTS

The test contains drug-bovine protein antigen conjugate on the membrane and the conjugate pad of each test contains monoclonal anti-drug antibody.

### KIT COMPONENTS

| | |
|---|---|
| **Individually packed Test Devices** | Each Device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions. |
| **Package insert** | For operation instruction. |

### MATERIALS REQUIRED BUT NOT PROVIDED

| | |
|---|---|
| **Specimen collection container** | For specimens collection use. |
| **Timer** | For timing use. |

### PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

### STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

### SPECIMEN COLLECTION AND STORAGE

- The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

### PROCEDURE

**Bring tests, specimens and/or controls to room temperature (15-30°C) before use.**

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

### INTERPRETATION OF RESULTS

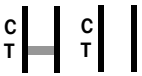
**POSITIVE RESULT:**


Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

**NEGATIVE RESULT:**


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

**INVALID RESULT:**




Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

### QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS OF THE TEST

1. The TCA One Step Tricyclic Antidepressants Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.1,2
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.

6. Test does not distinguish between drugs of abuse and certain medications.

## PERFORMANCE CHARACTERISTICS

**A. Accuracy**

198 clinical urine specimens were analyzed by GC-MS and by the TCA One Step Tricyclic Antidepressants Test Device (Urine).Each test was performed by three operators. Samples were divided by concentration into five categories: negative, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

| Method | | GC/MS | | | | | |
|---|---|---|---|---|---|---|---|
| The TCA One Step Tricyclic Antidepressants Test Device | | Neg. | Neg. (< –50% cutoff) | Near cutoff neg. (-50% cutoff to cutoff) | Near cutoff pos. (cutoff to +50% cutoff) | Pos. (> +50% cutoff) | % agreement with GC/MS |
| TCA 1000 | Positive | 0 | 0 | 3 | 25 | 56 | 97.6% |
| | Negative | 82 | 17 | 13 | 2 | 0 | 97.4% |

**B. Precision**

A study was conducted at three physician offices for Tricyclic Antidepressants (1000ng/mL)by professional operators using three different lots of product to demonstrate the within run, between run and between operator precision.An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

| Drug Conc. | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| Negative | 10 | 10 | 0 | 10 | 0 | 10 | 0 |
| -50% Cut-off | 10 | 10 | 0 | 10 | 0 | 10 | 0 |
| -25% Cut-off | 10 | 9 | 1 | 10 | 0 | 9 | 1 |
| +25% Cut-off | 10 | 1 | 9 | 1 | 9 | 1 | 9 |
| +50% Cut-off | 10 | 0 | 10 | 0 | 10 | 0 | 10 |

**C. Effect of Urinary Specific Gravity**

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively.The TCA One Step Tricyclic Antidepressants Test Device (Urine) was tested in duplicate using fifteen drug free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**D. Effect of Urinary pH**

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH adjusted urine was tested with the TCA One Step Tricyclic Antidepressants Test Device (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

**E. Cross-Reactivit**

The following tables list the concentrations of compounds (ng/mL) above which the TCA One Step Tricyclic Antidepressants Test Device (Urine) identified positive results at 5 minutes.

| Tricyclic Antidepressants **related Compound** | **Concentration (ng/mL)** |
|---|---|
| Tricyclic Antidepressants | 1000 |
| Amitriptyline | 2000 |
| Clomipramine | 12500 |
| Desipramine | 200 |
| Doxepine | 2000 |
| Imipramine | 400 |
| Maprotiline | 2000 |
| Promazine | 1500 |
| Promethazine | 25000 |
| Trimipramine | 3000 |

**F. Non Cross-Reacting Compounds**

The following compounds yielded negative results up to a concentration of 100 µg/mL:

| | | |
|---|---|---|
| 4-Acetamidophenol | Gatifloxacin | Penfluridol |
| Acetaminophen | Gemfibrozil | Penicillin G potassium salt |
| Acetylsalicylic Acid | Gentisic Acid | Penicillin G sodium salt |
| Albumin | Gliclazide | Perphenazine |
| Amoxicillin | Glipizide | Phenacetin |
| Ampicillin | Glyburide | Phenelzine Sulfate |
| Ampicillin trihydrate | Guaiacol | Phenothiazine |
| Aspartame | Guaifenesin | 2-Phenylethylamine |
| Atropine | Hemoglobin | Pioglitazone |
| Baclofen | Hydralazine HCl | Piracetam |
| Benzoic Acid | Hydrochlorothiazide | Pravastatin sodium |
| Berberine Chloride Hydrate | Hydrocortisone | Prednisone |
| Bilirubin | Ibuprofen | Procaine |
| Caffeine | Isoprenaline | Zomepirac |
| Cephalexin | Ketoconazole | 6-Propyl-2-thiouracil |
| Cephradine | Ketoprofen | Pyridoxine |
| Chloral hydrate | Lamotrigine | Pyrilamine Maleate |
| Chloramphenicol | L-Ascorbic acid | Pyrogallic |
| Chlorpheniramine Maleate | Levofloxacin | Quetiapine Fumarate |
| Chlorpromazine | Lidocaine | Quinine |
| Cholesterol | Lidocaine Monohydrate | Quinolinic acid |
| Ciprofloxacin hydrate | Lisinopril Dihydrate | R,R(-)-Pseudoephedrine |
| Clarithromycin | Lithium carbonate | Ranitidine base |
| Clonidine solution | Loperamide | Ranitidine |
| Creatinine | Loratadine | Riboflavin |
| D(-)-Norgestrel | L-Thyroxine sodium | Rifampicin |
| d,l-Propranolol | Meprobamate | Risperidone |
| Deoxycorticosterone | Minocycline | Salicylic acid |
| Dextromethorphan solution | Mosapride Citrate | Sertraline HCl |
| Diciofenac | Nalidixic acid | Simvastatin |
| Diflunisal | Naloxone HCl | Sodium 2-Propylvalerate |
| Digoxin | Naltrexone HCl | Sulfamethazine |
| 4-Dimethyl-aminoantipyrine | Naproxen | Sulindac |
| Diphenhydramine | Nicotinamide | Tetracycline |
| 5,5-Diphenylhydantoin | Nicotinic acid | Tetrahydrozoline |
| D-Lactose monohydrate | Nifedipine | Theophylline |
| D-Leucyl-L-tyrosine Hydrate | Nimodipine | Thiamine |
| Dopamine | Norethisterone Acetate | Thioridazine solution |
| Droperidol | Norfloxacin Nicotinic | Tolbutamide |
| Enalapril Maleate | Noscapine | Topiramate |
| Erythromycin | (±)-Octopamine | 2,4,7-Triamino-6-Phenylpteridine |
| Estradiol | Ofloxacin | Trimethoprim |
| Estrone | Olanzapine | Tryptamine |
| Ethyl 4-aminobenzoate | Oxalic acid, anhydrous | Tyramine |
| Fluoxetine | Oxolinic acid | Uric acid |
| Fotemustine | Paliperidone | (±)-Verapamil |
| Furosemide | Vitamin B1 | Gabapentin |
| Pantoprazole sodium | | |

## LITERATURE REFERENCES


1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
2. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse.* National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986


**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
| | Consult Instruction for use | | Tests per kit | | Do not use if package is damaged |
| IVD | For in vitro diagnostic use only | | Use by date | | Do not reuse |
| 2℃ 30℃ | Store between 2-30°C | LOT | Lot Number | REF | Catalogue number |
| | Keep away from sunlight | | Keep dry | | Manufacturer |
| | Caution | | Date of manufacture | EC REP | Authorized Representative |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