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IVD



See external label



15°C-30°C



$\Sigma=25$  or 50 tests

REF

Cat # 121025-1

# OneStep TCA RapiCard™ InstaTest

Cat # 121025-1

For Qualitative In Vitro Diagnostic Use

## INTENDED USE

Cortez Diagnostics Inc. TCA is a one-step immunoassay intended to provide qualitative rapid detection of tricyclic antidepressants (TCA) at a cutoff concentration of 1000 ng/ml in human urine. It is for health care professional use only.

*This assay provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) 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 obtained.*

## SUMMARY AND EXPLANATION OF THE TEST

Tricyclic Antidepressants (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure. TCA can be taken orally or intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from few hours to few days. The commonly used tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting TCA or metabolites of TCA in human urine has been used for screening the abuse of TCA. This test is able to detect amitriptyline, desipramine, imipramine and nortriptyline at a cut off level of 1,000 ng/ml.

## PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-TCA antibodies coupled to colloidal gold (the immunogen is a blend of amitriptyline, desipramine, imipramine and nortriptyline); and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with TCA-BSA, and the Control line is coated with goat anti-rabbit IgG antibody. Cortez TCA Test is a competitive binding immunoassay. The TCA and or TCA metabolites in the urine specimen compete with the TCA-BSA coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-TCA antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of TCA and/or TCA metabolites in the urine specimen is below the cutoff (1,000 ng/ml), the Test line appears as a visible burgundy line. If the level of TCA and/or TCA metabolites in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line, regardless of the presence of TCA metabolites.

## REAGENTS AND MATERIAL SUPPLIED

1. 25 test devices, each sealed in a pouch with a dropper pipette.
2. 1 package insert (Instructions for Use).

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Timer

## STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

**Do not freeze and/or expose the kit to temperatures over 30°C (86°F).**



## SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for at least 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

## PRECAUTION

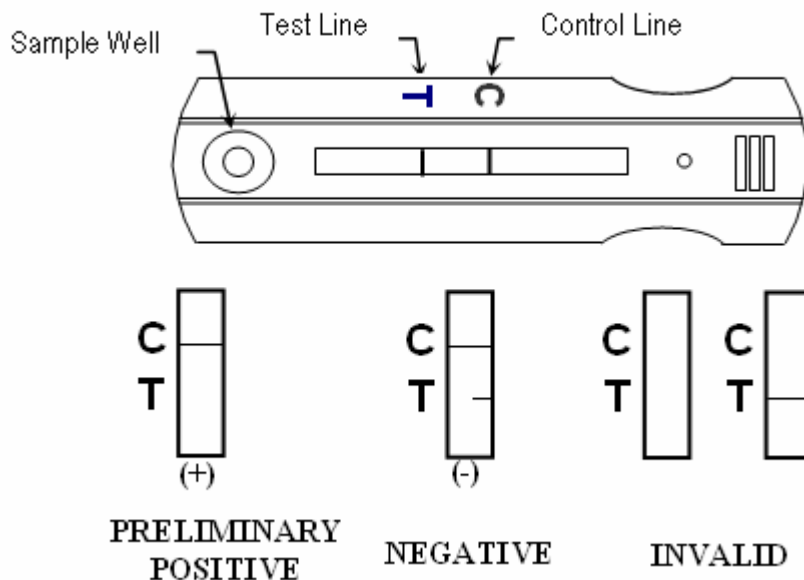
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

## ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, must be equilibrated to room temperature before testing.
2. Remove the test device from pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the urine specimen.

## INTERPRETATION OF RESULTS

**IMPORTANT:** Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.



### Positive:

If only the C line appears, the test indicates that the TCA level in the sample is at a cutoff of 1000 ng/ml or higher.

**Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.**

### Negative:

If both the C line and T line appear, the test indicates that the TCA level is below 1000 ng/ml.

Note: A very faint T line should be considered negative.

### Invalid:

If no Control (C) line develops within 5 minutes, repeat the assay with a new test device.

## QUALITY CONTROL

### 1. Built-in Control Features

This test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates an adequate volume of specimen has been absorbed and the capillary flow has occurred. The C line should always appear. If the Control line does not develop within 5 minutes, review the entire procedure and repeat test with a new device.

### 2. External Quality Control

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

## LIMITATIONS

1. This test is for professional in vitro diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These samples may interfere with the test and cause false results.

## EXPECTED VALUES

This test is capable of detecting TCA at a cutoff level of 1000 ng/ml or higher.

## PERFORMANCE CHARACTERISTICS

### 1. Accuracy

The accuracy was determined by comparing the results with the HPLC/MS data. This study was carried out in house, using eighty (80) blind labeled clinical urine specimens. The detailed data is shown in the table in this section.

The results agreed 100% with the TCA HPLC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Two (2) discrepancies were observed on the specimens with the HPLC/MS data between 75% of the cutoff and the cutoff.

The overall agreement was 97.5%.

|                    |                            | TCA Test |          | Total | Agreement |
|--------------------|----------------------------|----------|----------|-------|-----------|
|                    |                            | Positive | Negative |       |           |
| HPLC/MS<br>(ng/ml) | Drug-free                  | 0        | 40       | 40    | 100%      |
|                    | <75%<br>(0-750)            | 0        | 10       | 10    | 100%      |
|                    | 75%-Cutoff<br>(750-1000)   | 2        | 8        | 10    | 80%       |
|                    | Cutoff-125%<br>(1000-1250) | 8        | 0        | 8     | 100%      |
|                    | Positive<br>(>1250)        | 12       | 0        | 12    | 100%      |
| Total              |                            | 22       | 58       | 80    | 97.5%     |

## 2. Reproducibility

### Off- site evaluation

This study was done off-site at three (3) Physician's Office Laboratories (POL) and a clinical reference laboratory by personnel with diverse educational backgrounds and work experience. One hundred (100) urine samples were divided into six groups, and spiked with nortriptyline at 0 ng/ml (40 members), 764 ng/ml (10 members), 1024 ng/ml (10 members), 1224 ng/ml (10 members), 1425 ng/ml (18 members), and 1825 ng/ml (12 members). All samples were blind labeled and tested. Same results were obtained for all samples except one with ID =12 at the four evaluation sites. A total of four hundred (400) devices were evaluated, and they all yielded the expected results except nine (9) tested with samples at the concentration of 764 ng/ml. The discrepancies are shown in the following table.

| ID | Expected Result | Conc. (ng/ml) | POL #1 | POL #2 | POL # 3 | Ref. Lab |
|----|-----------------|---------------|--------|--------|---------|----------|
| 12 | -               | 764           | +      | -      | -       | -        |
| 41 | -               | 764           | +      | +      | +       | +        |
| 94 | -               | 764           | +      | +      | +       | +        |

The results from the four evaluation sites agreed 97.8% ((400-9)/400) with the concentration of nortriptyline and 99% with each other, indicating a high reproducibility.

### In-house evaluation

This study was conducted with three different lots. Specimens used in this study were the same used for the outside evaluation. The devices were tested for five consecutive days five times each, for a total of 25 assays for each standard.

The results were in 100% agreement among the replicates within each lot. No significant inter-lot or inter-day variation occurred across the three different lots of devices.

## 3. Cross-Reactivity

A study was conducted to evaluate the cross-reactivity of compounds structurally related to TCA. The following compounds, when spiked into known drug-free urine pools and then tested, showed a positive response at the concentration listed.

| Description     | Conc.(ng/ml) | Description   | Conc.(ng/ml) |
|-----------------|--------------|---------------|--------------|
| Amitriptyline   | 1,000        | Nordoxepine   | 1,000        |
| Clomipramine    | 5,000        | Nortriptyline | 1,000        |
| Cyclobenzaprine | 1,500        | Perphenazine  | 75,000       |
| Desipramine     | 1,000        | Promazine     | 15,000       |
| Doxepine        | 3,000        | Protriptyline | 2,000        |
| Imipramine      | 1,000        | Trimipramine  | 2,000        |

## 4. Interference

To evaluate the possible interference of structurally unrelated compounds, the following analytes, usually found in urine and commonly prescribed therapeutic drugs, were spiked in drug-free urine pools, as well as TCA positive (spiked with TCA to the level of 1000 ng/ml) urine pools, and then tested. No significant interference with either negative or positive results was observed at the concentrations listed in the following table:

Compounds tested and found not to interfere with the test at 1.0 mg/ml concentration in urine

|                          |                                    |
|--------------------------|------------------------------------|
| Acetylsalicylic Acid     | Cortisone                          |
| Amikacin                 | Dextromethorphan                   |
| Ampicillin               | Methadone                          |
| Arterenal                | Methanol                           |
| Aspirin                  | Oxalic Acid                        |
| Atropine                 | Penicillin-G<br>(Benzylpenicillin) |
| Benzoic Acid             | Pheniramine                        |
| Benzoylcegonine          | Phenylpropanalamine                |
| Caffeine                 | Ranitidine                         |
| (+)-<br>Chlorpheniramine | Salicylic Acid                     |
| Cocaine                  | Thioridazine                       |
| Codeine                  | Trifluoperazine                    |

Biological analytes tested and found no interference with the test at the concentrations listed

| Biological Analytes         | Concentration |
|-----------------------------|---------------|
| Albumin                     | 2 mg/ml       |
| Bilirubin                   | 1 mg/ml       |
| Creatine                    | 1 mg/ml       |
| Glucose                     | 2 mg/ml       |
| Hemoglobin                  | 1 mg/ml       |
| PH                          | 4.5 – 8.5     |
| Uric Acid                   | 1 mg/ml       |
| Vitamin C (L-Ascorbic Acid) | 1 mg/ml       |

*There is a possibility that other substances and/or factors not listed, may interfere with the test and cause false results.*

Effect of Specific Gravity: Eight (8) human urine specimens with the specific gravity ranging from 1.002 to 1.035 g/ml were collected in house. Each was spiked with nortriptyline to three levels, 750, 1,500, and 2,000 ng/ml. All those specimens were tested, separately. The results indicated that the specific gravity of urine, ranging from 1.002 to 1.035, did not affect the performance.

## REFERENCES

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4. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th Edition. Biomedical Publ., Davis, CA; pp 35-39, 215-218, 392-395, 562-564, 1995.

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| <b>Date Adopted</b> | <b>Reference No.</b>                           |
|---------------------|------------------------------------------------|
| <b>2005-09-27</b>   | <b>DA-Tricyclic Antidepressants (TCA)-2008</b> |



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