Tramadol Urine Rapid Test (Cassette)

Cat. No.:DTS248
Pkg.Size:

Intended use

The Tramadol Rapid Test are immunochromatography based one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. The tests are intended for use by Healthcare Professionals only. Below is a list of cut-off concentrations for each drug using our tests.
Tramadol 200ng/ml of Tramadol
This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.
cut-off concentration of 2000 ng/ml for Opiates Test

General Description

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucoronidation or sulfation in the liver.

Principle Of The Test

The Tramadol Rapid Test device is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody -dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.
A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Reagents And Materials Provided

1. The Tramadol Rapid Test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
• Test zone: contains drug bovine protein antigen conjugates
• Control zone: contains Goat anti-mouse IgG antibody
• Conjugate pad: contains mice monoclonal anti-drug antibody.
2. Instruction for use.

Materials Required But Not Supplied

1. Urine collection container.

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2. Timer or clock.

Storage

The test device should be stored at 2 to 30 °C and will be effective until the expiration date stated on the package. The product is humidity- sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

Specimen Collection And Preparation

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8 °C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

Assay Procedure

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 µl) of sample in to the sample well.
5. Read the results at 5 minutes after adding the sample.

Quality Control

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentrtion, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which is not provided with this test kit are commercially available.
The Tramadol Rapid Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Interpretation of Results

Positive:
One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut-off level.
Negative:
Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen. It only indicates the level of tested drug in the specimen is less than cut-off level.
Invalid:
If there are no colored bands, the test result is invalid. Retest the sample with a new device.
Note: A borderline(+/-) in test line zone should be considered negative result.

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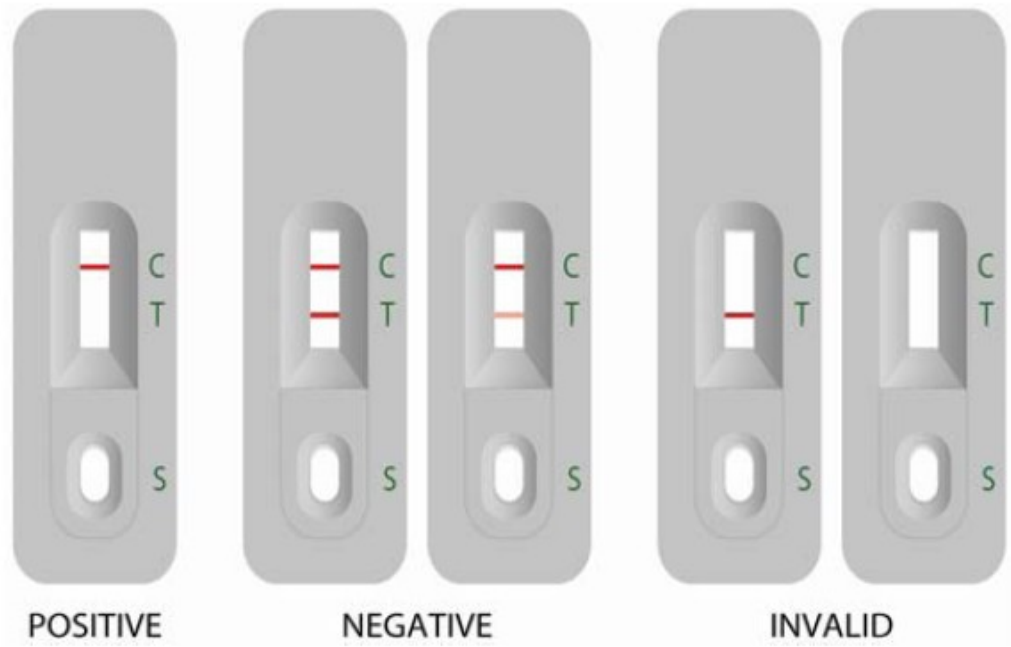

Expected Values

The Tramadol Rapid Test is a qualitative assay. It identifies the drug(s) in human urine at its cut-off concentration or higher. The concentration of the drug(s) can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

Sensitivity

The cut-off concentrations (sensitivity level) of The Tramadol Rapid Test are determined to be: TRA 200 ng/ml.

Specificity

The following table lists compounds that are detected by Tramadol Rapid Test which produced positive results when tested at levels equal or greater than the concentrations listed below:
The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified.
Acetaminophen, Arterenol, Caffeine, Cortisone, Digoxin, Ephedrine, Histamine, Isoproterenol, Methylphenidate, Penicillin G, Pseudoephedrine, Tetrahydrozoline, Tryptophan, 4-Acetamidophenol, Aspartame, Camphor, Deoxyephedrine, Diphenhydramine, Epinephrine, Hydrochlorothiazide, Lidocaine, Neomycin, Quinine antidine, Theophyline, Tyramine, Acetylsalicylic acid, Ascorbic acid, Chloroquine, Dextromethorphan, Ecgonine, Gentisic acid, Homatrophine, Meperidine, Niacinamide, Phenylpropanolamine Promethazine, Salicyclic acid, Thioridazine, Amikacin, Atrophine, Chlopheniramine, Digitoxin, Ecgonine methyl ester, Guaiacol glycer ester, Ibuprofen, Methaqualon, Perphenazine, Tetracycline, Trifluoperazine

Tests	Compounds	Cut-off (ng/ml)
Tramadol	Tramadol N-desmethyl-tramadol O-desmethyl-tramadol	200 500 20,000

Accuracy

The accuracy of the Tramadol test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of tramadol Eighty one urine

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specimens with GC/MS confirmed tramadol concentration were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 95, Negative % agreement: 98

Precision

The precision of The Tramadol Rapid Test were determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 40 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

Interferences

The Tramadol Rapid Test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.
The following substances were tested and confirmed did not interfere with The Tramadol Rapid Test at the listed concentrations.
Glucose 2000 mg/dl
Human albumin 2000 mg/dl
Human hemoglobin 10 mg/dl
Urea 4000 mg/dl
Uric acid 10 mg/dl

Precautions

1. Do not use the product beyond the expiration date.
2. Handle all specimens as potentially infectious.
3. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
4. Use a new urine specimen cup for each sample to avoid cross contamination.

Limitations

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer “SPECIFICITY” section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

REFERENCES

1. Urine testing for drugs of abuse, NIDA Research Monograph 73 (1986)
2. Steven B. Karch, Drugs of abuse hand book, CRC Press, 1st. Ed. (1998)
3. Ray H. Liu and Bruce A. Goldberger, Handbook of workplace drug testing, AACC Press, Washington DC (1995)

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