Atlas Medical CE

Tramadol TML
Rapid Test Device
(Urine)

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

Store at 2-30°C

INTENDED USE

The TML Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Tramadol in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
TML (Tramadol)	Cis-Tramadol	100

INTRODUCTION

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

The TML Rapid Test Device (Urine) detects Tramadol through visual interpretation of color development on the device. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test consists of a reagent strip mounted in a plastic housing. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.

The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

MATERIALS

Materials Provided

- Individually packed test devices.
- Package insert.
- Disposable dropper.

Materials Required but Not provided

- Centrifuge.
- Timer.
- Positive and negative controls.

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.
- Care should be taken to protect the components of the 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 TML Rapid Test Device (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. 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.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable dropper, transfer 3 drops of specimen (approximately 120 µL) to the specimen well (S) of the device and start the timer.

Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

As the test begins to work, color will migrate across the membrane.

3. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

INTERPRETATION OF RESULTS

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

NEGATIVE: 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: Control band fails to appear. Results from any test which has not produced a control band at the specified read 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 color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or 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, confirming 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 TML Rapid Test Device (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Tramadol.
2. This assay provides a preliminary analytical test result only. 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 National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Tramadol only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Tramadol in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Tramadol and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the TML Rapid Test Device (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

B. Reproducibility

The reproducibility of the TML Rapid Test Device (Urine) was verified by blind tests performed at four different locations. Samples with Tramadol concentrations at 50% of the cut-off were all determined to be negative, while samples with Tramadol concentrations at 200% of the cut-off were all determined to be positive.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with Tramadol concentrations at 50% of the cut-off yielded negative results, and controls with Tramadol concentrations at 150% of the cut-off yielded positive results.

D. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the TML Rapid Test Device (Urine) identified positive results at 5 minutes.

Tramadol related compounds	**Concentration (ng/ml)**
Tramadol	100
(+/-)Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000
(+)-Chlorpheniramine	100,000

The following compounds were found not to cross-react when tested at concentrations at 100 µg/ml.

Acetaminophen	Dihydrocodeine	(+)-Naproxen
Acetophenetidine	(+)-cis-Diltiazem	Nifedipine
Acetylcodeine	Dimenhydrinate	Nimesulide
Acetylsalicylic acid	4-Dimethylaminoanti pyrine	Nitrazepam
Alprazolam	Diphenhydramine	Olanzapine
Amikacin	DL-Tryptophan	Opipramol
Aminopyrine	DL-Tyrosine	Oxalic acid
Amitriptyline	Dopamine	Oxazepam
Amoxicilline	Doxepin	Oxycodone
Amphetamine	Doxylamine	Oxymetazoline
Ampicilline	d-Propoxyphene	Pennicilline G
Apomorphine	Ecgonine HCl	Perphenazine
Ascorbic acid	Ecgonine methylester	Pheniramine
Aspartame	Ephedrine	Phenothiazine
Atropine	(+/-)Epinephrine	Phentermine
Baclofen	Erythromycine	(+/-) Phenylpropanolam ine
Benzocaine	Estron 3 sulfate	beta-phenylethyla mine
Bilirubin	Ethylmorphine	Prednisolone
Bromazepam	Etodolac	Prednisone
Buprenorphine	Fenfluramine	Procaine
Caffeine	Fentanyl	Promazine
Cannabidiol	Flupentixol	Promethazine
Cannabinol	Fluoxetine	Prothipendyl
Carbamazepine	Furosemide	Protriptyline
Chloramphenicol	Gastrozepin	Quetiapine
Chlordiazepoxide	Gentamicin	Quinidine
Chloroquine	Gentisic acid	Ranitidine
Chlorpheniramine	Guaiacol Glyceryl Ether	Rifampicine
Chlorprothixene	Hemoglobin	Risperidone
Cholesterol	Hydralazine	Salbutamol
Chorptothixene	Hydrochlorothiazide	Salicylic acid
Cimetidine	Hydrocodone	Secobarbital
Ciprofloxacin	Hydrocortisone	Sertraline
Citalopram	Ibuprofen	Spironolactone
Clindamycin	Imipramine	Sulfamethoxazole
Clobazam	(-)Isoproterenol	Sulindac
Clomipramine	Ketamine	Temazepam
Clonazepam	Ketoprofen	Thebaine
Clonidine	L - Thyroxine	Theophylline
Clorazepate	Lincomycin	Thiamine
Clozapine	Lidocaine	Thioridazine
Cocain	Loperamide	Tobramycin
Codein	L-Phenylephrine	Triamterene
(-)Cotinine	Maprotiline	Trimethoprim
Creatinine	Meperidine	Trimipramine
Cyclobenzaprine	Mephentermine hemisulfate salt	Tyramine
Delorazepam	Methadone	Vancomycin
Desipramine HCl	Methamphetamine	Venlafaxine
Dexamethasone	3,4-Methylenedioxya mphetamine	Verapamil
Dextromethorphan	3,4-Methylenedioxy-methamphetamine	Zolpidem
Diacetylmorphine	N-Methylephedrine	
Diazepam	Metoclopramide	
Diclofenac	Metoprolol	
Dicumarol	Metronidazole	
Diflunisal	MOR-3-Beta-D Glucuronide	
DL-Propanolol	Nalorphine	
Digoxin	Naloxone	

REFERENCES

Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.

Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.

Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.

McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.

Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

Atlas Medical
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

PPI1703A01
Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry