Tramadol Rapid Test Strip Urine (TML)

IVD ***For In-Vitro diagnostic and professional use only***

2 30°C **Store at 2-30 °C**

INTENDED USE

The TML Rapid Test Strip (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 narcotic-like pain reliever and is used to treat moderate to severe pain. It is a Class C drug that is only available legally via prescription. Tramadol is a synthetic opiate and whilst it is not as potent as the strongest opiates like heroin, it still acts as an opiate, and prolonged use carries a number of risks especially among pregnant women and those with medical conditions such as epilepsy and asthma. In addition, mixing tramadol with alcohol can have serious consequences – an overdose is more likely and this can lead to a coma or respiratory failure and death.

PRINCIPLE

The TML Rapid Test Strip (Urine) detects Tramadol through visual interpretation of color development on the strip. 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.

MATERIALS

MATERIALS PROVIDED

- Test Strips (individually pouched or in canisters)
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

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

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).
- The test strip is stable through the expiration date printed on the sealed pouch.
- The test strip must remain in the sealed pouch until use.
- Do not freeze.
- 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.

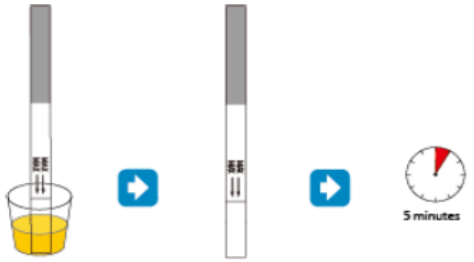
SPECIMEN COLLECTION AND PREPARATION

1. 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 a clear specimen for testing.
2. Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Allow test Strip, Urine specimens, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it.
2. Remove the test strip from the sealed pouch and use it as soon as possible.
3. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane
4. With arrows pointing toward the specimen, dip the strip into the specimen for at least 10-15 seconds.
5. Don't allow the specimen to reach above the level indicated by the arrows on the strip.
6. Remove the strip from the specimen, and place it on a flat, dry surface. start the timer and wait for the red line(s) to appear.
7. Read the test result at 5 minutes. **Do not interpret the result after 10 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration)

POSITIVE:

Only one colored lines appear. One colored line should be in the control line region (C); NO apparent colored line appears in the test line region (T).

NEGATIVE:

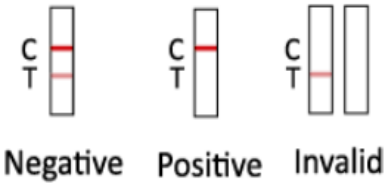
TWO colored line appears on the membrane. One colored line should be in the control line region (C), and another apparent colored line appears in the test line region (T).

INVALID:

Control line 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

- A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
- Control standards are not supplied with this kit; however, 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

- Atlas TML Test Strip (Urine) provides only a qualitative detection of Tramadol.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.

PERFORMANCE CHARACTERISTICS

Accuracy

The results were >99.9%

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.

Reproducibility

The reproducibility of the TML Rapid Test Strip (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.

Specificity

The following tables list the concentrations of compounds (ng/mL) above which the TML Rapid Test Strip (Urine) identifie 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 yielded negative results up to a concentration of 100 µg/mL:

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine tartrate	Dextrorphan	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	VitaminC(Ascorbic Acid)
Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Catfeine	Lidocaine	Ibuproten
Chloroquine	Methadone	

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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