FOR FORENSIC AND PROFESSIONAL USE ONLY

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

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

INTRODUCTION
Tramadol is a quai-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 receptor. Large doses of tramadol can develop tolerance and pharmacological dependency and lead to abuse. Tramadol, as well as its metabolites, are handled. Handle all specimens as if they contain infectious agents.

Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable plastic gloves and eye protection when specimens are assayed.

Humidity and temperature can adversely affect results.

Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY
• The kit should be stored at 2-30°C until the expiry date printed on the sealed pack.

• The test must remain in the sealed pouch or closed container until use.

• Do not freeze.

• Kits should be kept out of direct sunlight.

• 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 Strip (Tramadol) 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.

• Embalmed should be stored in refrigerator, frozen or allowed to settle and only the clear supernatant should be used for testing.

• Perform testing immediately after specimen collection. Do not leave specimen extensively metabolised after metabolic half-life, i.e., approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is metabolised in the liver. Care must be taken to get an appropriate cut-off concentration.

• Bring specimens to room temperature prior to testing. Frozen specimens should 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 biological agents.

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

1. Remove the test from the sealed pouch, or remove one strip from the rack, allowing a small gap between strips. For test results, the assay should be performed within one hour. Controls should be closed tightly after use.

2. Hold the strip at the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.

3. Hold the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.

4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and 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: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). NEGATIVE: Only one colored band appears in the control region (C). No apparent colored 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 expected time may be disregarded. 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 Tramadol present in the specimen. Therefore, and due to color of in the test region should be considered positive. 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 control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST
• The TML Rapid Test Strip is for forensic and professional 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 confirm definitive results. Results obtained by this method (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. Adults, such as breath and/or urine, 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; they may be taken prior to 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 Strip (Tramadol) was compared and showed excellent agreement with available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be negative were examined under both tests. The results were >99% in agreement.

B. Reproducibility
The reproducibility of the TML Rapid Test Strip (Tramadol) was verified by the test performance at four different locations. Samples with Tramadol concentrations at 50% of the cut-off were all determined as being positive and testing with Tramadol concentrations at 200% of the cut-off were all determined as being positive.

C. Precision
Test precision was determined by blind tests with control solutions.

D. Specificity
This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely eliminate the risk of cross-reaction. Therefore, please preclude the possibility of urine adulteration prior to testing.

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