One Step Tramadol Urine Test

Catalog No. See Pouch Label

One Step Tramadol Urine Test is a rapid one step test for the qualitative detection of tramadol and its principal metabolites in human urine at specified cut-off level.
For in vitro diagnostic use only. For professional use only.

INTENDED USE

One Step Tramadol Urine Test is a lateral flow chromatographic immunoassay for the detection of Tramadol in human urine at the cut-off concentration of 1000 ng/ml. This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) 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 used.

SUMMARY

Tramadol [2-(dimethylaminomethyl)-1-(3-methoxyphenyl)cyclohexanol] is used similarly to codeine, to treat moderate to moderately severe pain. It is a synthetic analog of the phenanthrene alkaloid codeine and, as such, is an opioid and also a prodrug (codeine is metabolized to morphine, tramadol is converted to O-desmethyltramadol). Tramadol and its metabolites are excreted primarily in the urine with observed plasma half-lives of 6.3 and 7.4 hours for tramadol and O-desmethyltramadol(denoted M1), respectively. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

PRINCIPLE

One Step Tramadol Urine Test is a competitive immunoassay that is used to screen for the presence of tramadol in urine. It is chromatographic absorbent device in which tramadol and its metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.
When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.
When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes

CONTENT OF THE KIT

1. 25 tests per kit, one test in one pouch.
2. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use.

STORAGE AND STABILITY

Store at 4 ºC ~30 ºC in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

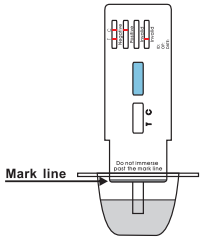
Collect a urine sample in the urine cup. Urine specimens may be refrigerated (2ºC~8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (10ºC to 30ºC)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the mark line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface
5. Read the result at 5 minutes. Do not read after 5 minutes.

IMPORTANT： Do not allow the urine level to exceed the mark line, otherwise the test will not perform correctly.



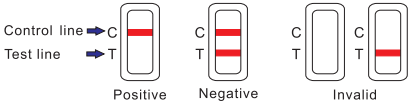
INTERPRETATION OF RESULTS

Positive (+)
A rose-pink band is visible in the control region. No color band appears in the test region. This positive result indicates that the tramadol concentration is equal to or higher than the detection limit(1000 ng/ml).

Negative (-)
A rose-pink band is visible in the control region and the test region. This negative result indicates that the tramadol concentration is zero or below the detection limit(1000 ng/ml).

Invalid
If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine

the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

A. Sensitivity

One Step Tramadol Urine Test has set the screen cut-off for positive specimens at 1000 ng/mL for tramadol as a calibrator. The test device has been proved to detect above 1000 ng/mL of tramadol in urine at 5 minutes.

B. Specificity and cross reactivity

To test the specificity of the test, the test device was used to test tramadol, its metabolites and other components of the same class that are likely to be present in urine, All the components were added to drug-free normal human urine. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
Tramadol	1000

C. Interfering substances

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, for example Acetoacetic Aci, Acetone, Albumin etc., we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with One Step Tramadol Urine Test at a concentration of 100 μg/ml.

(1R,2S)-(-)- Ephedrine
Fentanyl citrate
Alprazolam
Dextropropoxyphene napsylate
Phenobarbital
Pseudoephedrine
Methamphetamine
Esomeprazole magnesium
Mifepristone
Ketoconazole
Glibenclamide
Montelukast
Fenofibrate
Mosapride citrate
Dirithromycin
Cefradine
Rifampicin
Clopidogrel sulfate
Oxycodone acetaminophen
Pantoprazole
Aripiprazole
Propranolol
Diclofenac sodium
Dopamine
Clarithromycin
Nifedipine(1231)
Amlodipine mesylate
Loratadine
Atropine
Doxylamine
Gabapentin
Dextromethorphan hydrobromide
Cortisone
Trazodone
Diazepam
Lofexidine
Sodium Valproate
Amitriptyline
Risperidone
O3-Monoacetylmorphine
2-phthalimidoethyl acetate
Procaine
Exazepam
Diphenoxylate
Barbital
Glucose
Scyclovir
Aminophylline
Venlafaxine
Loperamide
Glipizide
Mirtazapine
Doxepin
Meperidine
Methadone
Naltrexone
Secobarbital
Fluoxetine
Ranitidine
Benzoylecgonine
Caffeine
Tetracycline
Ampicillin
Isosorbide dinitrate
Hydrochlorothiazide
Carbamazepine
Amiodarone
Nifedipine
Phenoxymethylpenicillin
Potassium
Pioglitazone
Nitroglycerin
Lamotrigine
Levothyroxine Na
Vitamin B2
Triamterene
Prednisone
Estrogen
Cephalexin
Perphenazine
Clomipramine
Penfluridol
Pholcodine
Thebaine
Naloxone
Nitrazepam
Cocaine
Ecstasy
Aspirin
Gliclazide
Simvastatin
Lidocaine
Topiramate
Spironolactone
Nimodipine
Viprofloxacin
Clozapine
Enalapril maleate
Nikethamide
Levonorgestrel
Atomoxetine
Pravastatin sodium
Olanzapine
Prednisone Acetate
Phenytoin sodium
Ampicillin
Fluvoxamine
Piracetam
Citalopram
Chlorpromazine
Codeine phosphate
Papaverine
Omeprazole
Amphetamine
Flunitrazepam
Morphine
Methamphetamine
Propylthiouracil;
Lansoprazole
Lisinopril
Atorvastatin
Domperidone
Acetaminophen
Captopril
Metoprolol Tartaric Acid
Furosemide
Sertraline
Quetiapine
Vitamin B1
Sildenafil citrate
lithium carbonate
Isoprenaline
Chlorpromazine
Haloperidol
Paroxetine
Dutoxetine

BIBLIOGRAPHY OF SUGGESTED READING

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MEANING OF SYMBOLS ON PACKAGE


Keep away from sunlight

Store between 4°C and 30°C


Keep dry


Do not re-use

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Distributed by:
American Drug Test
3482 Keith Bridge Rd
Cumming, GA 30041
Phone: 770-252-9900