Tianeptine (TIA) Rapid Test (Urine) Package Insert

A rapid test for the qualitative detection of Tianeptine in human urine.
For professional in vitro diagnostic use only.

【INTENDED USE AND SUMMARY】

The Tianeptine (TIA) Rapid Test (Urine) is a lateral flow chromatographic immunoassay for the detection of Tianeptine in urine at a cut-off concentration of 1,000 ng/mL.

This assay provides only a qualitative, preliminary 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】

Tianeptine is an antidepressant drug with structural similarities to the tricyclic antidepressant agents and a selective promoter of 5-HT uptake in the body and in vivo. It is often used to treat depression and various anxiety and depression-based neuroses, can also be used for menopausal psychosis, and is also effective for depressive neurosis, chronic alcoholism and depression after alcohol withdrawal. However, excessive use of Tianeptine can cause side effects. The most common adverse effects are nausea, constipation, abdominal pain, headache, dizziness and changes in dreaming, long-term use can cause dependence and withdrawal.[1]

The elimination half-life of Tianaeptine is about 2.5 h, only a very small amount of Tianaeptine is excreted through the kidneys (8%), and its metabolites are excreted mainly through the kidneys. The main metabolite (MC5;pentanoic acid) has some minor antidepressant activity.[2]

The Tianeptine (TIA) Rapid Test (Urine) is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Tianeptine in urine. The Tianeptine (TIA) Rapid Test (Urine) yields a positive result when the Tianeptine in urine exceeds the cut-off level.

【PRINCIPLE】

The Tianeptine (TIA) Rapid Test (Urine) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Tianeptine, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Tianeptine-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Tianeptine level exceeds the cut-off level because it will saturate all the binding sites of anti-Tianeptine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred..

【REAGENTS】

The test contains mouse monoclonal anti-Tianeptine antibody coupled particles and Tianeptine-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

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

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

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 well before testing.

【MATERIALS】

Materials Provided

- Test Panels
- Package Insert

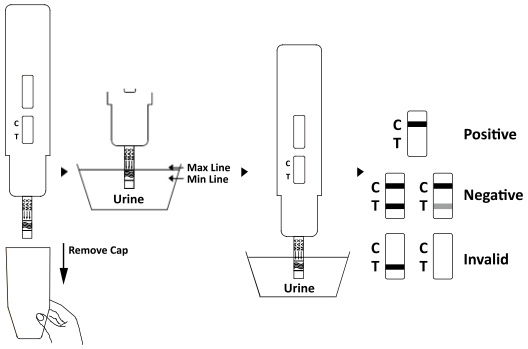
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test Panel from the sealed pouch.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the strip to at least the level of the Min line, but not above the Max line on the test.**
4. Place the test Panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. **Read the drug test result at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Tianeptine concentration is below the detectable cut-off level.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Tianeptine concentration exceeds the detectable cut-off level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control 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 good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Tianeptine (TIA) Rapid Test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. GC/MS or LC/MS is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.
6. This test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERSTICS】

Accuracy

A side-by-side comparison was conducted using the Tianeptine (TIA) Rapid Test (Urine) and GC/MS at the cut-off of 1,000ng/mL. Testing was performed on specimens previously collected. The following results were tabulated:

Method		GC/MS		Total Results
Tianeptine (TIA) Rapid Test	Results	Positive	Negative	
	Positive	48	3	51
	Negative	2	67	69
Total Results		50	70	120
% Agreement		96.0%	95.7%	95.8%

Analytical Sensitivity

A drug-free urine pool was spiked with Tianeptine at the following concentrations: 0ng/mL, 500ng/mL, 750ng/mL, 1,000ng/mL, 1,250ng/mL, 1,500ng/mL and 3,000ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Tianeptine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	27	3
1,000	Cut-off	30	15	15
1,250	+25%	30	4	26
1,500	+50%	30	0	30
3,000	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by Tianeptine (TIA) Rapid Test at 5 minutes.

Drug	Conc.(ng/mL)
Tianeptine	1,000
Tianeptine Metabolite MC5 Sodium Salt	3,000

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high and low specific gravity ranges were spiked with drugs at 500ng/mL and 1,500ng/mL of Tianeptine. The Tianeptine (TIA) Rapid Test was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Tianeptine (TIA) Rapid Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the interference-reactivity of the test with compounds either drug-free urine or drug positive urine. The following compounds show no interference-reactivity when tested with the Tianeptine (TIA) Rapid Test at a concentration of 100 µg/mL.

Non Cross-Reactivity Compounds

Acetophenetidin	Fenoprofen	Oxymetazoline
Acetylsalicylic acid	Furosemide	Promethazine Hydrochioride
Aminopyrine Aminophenazone	Gentisic acid	Penicillin
Amobarbital	Hydralazine	Perphenazine
Ascorbic acid L-Ascorbic acid	Hydrochlorothiazide	Phencyclidine
Amoxcillin	Hydrocodone	Phenobarbital
(±)-Amphetamine	Hydrocortisone	Prednisolone
protopine	a-Hydroxyhippuric acid	Procaine
Aspartame Asp-Phemethylester	Ibuprofen	Quinine

Atropine	(±) Isoproterenol hydrochloride [(-)isoprenaline]	Salicylic acid
Benzilic acid	Isoxsuprine	Serotonin creatinine
Benzoic acid	Ketamine	Sulfamethazine
Benzoylecgonine	Labetalol	Sulindac
Benzphetamine	Loperamide	Tetrahydrozoline
Chloral hydrate	Hemoglobin	Thebaine
Chloramphenicol	Meprobamate	Thiamine (vitamine B1)
Chlordiazepoxide	Methadone	Thioridazine
Chlorpromazine	Meperidine (Pethidine)	Triamterene
Cholesterol	Methoxyphenamine	Trifluoperazine
Clomipramine	(±)3,4-Methylendioxyamphetamine [(±)MDA]	d,l-Tryptophan
Clonidine	Methylphenidate HCl	Uric acid
Cocaine	Morphine-3-β-D-Glucuronide	Verapamil
Codeine	Naloxone	Zomepirac
Cortisone acetate	Naltrexone	Ampicillin
Creatinine	Norethindrone Norethisterone	Caffeine
Deoxycorticosterone	Noscapine	Ranitidine
Diazepam	Sodium oxalate	Trazodone
Diclofenac sodium salt	Oxolinic acid	Efavirenz
Propranolol HCl	Oxycodone	Oxymorphone
Diflunisal	Phenothiazine	Lithium acetoacetate
Digoxin	Albumin	Lidocaine
Diphenhydramine Hydrochloride	Kanamycin	Amoxapine
Doxylamine	Fluoxetine	Orphenadrine
Erythromycin	Metoprolol	Riboflavin (vitamine B2)
Benzocaine	Buprenorphine	Hydromorphone
Zopiclone	Clozapine	Alprazolam
Dexamethasone	Insulin	Clobazam
Carisoprodol	Salbutamol	Lorazepam
Metoclopramide	Nefopam	Nitrazepam
(+)-cis-Diltiazem	D-Glucose	Bromazepam
Haloperidol	Disulfiram	6-Acetylcodeine
Metronidazole	Clonazepam	Doxepin
Paroxetine	Terbutaline hemisulfate salt	Desipramine
Sertraline	Lorazepam	α-Hydroxyalprazolam
Heroin	7-Aminoflunitrazepam	D-Methamphetamine
Carbamazepine	Flunitrazepam	11-nor-Δ^9-THC-9COOH
Lansoprazole	Triazolam	Ciprofloxacin Hydrochloride
Tropicamide	Tinidazole	4-Amino-3-phenylbutric acid hydrochloricle
Atorvastatin	Doxycycline hydrochloride	prazosin hydrochlorlde
Candesartan	Lactulose	Xylazine
Pramipexol	Sodium 2-Propylvalerate	Vitamin B12
Rivaroxaban	Tenofovlr alafenamide fumarate	Pimecillin hydrochloride
Pipamperone	Emtricitabine	Alimemazine Tartrate
Pantoprazole	Fenofibrate	R(+)-Cathinone HCl
Isoniazid	Melatonine	3-Fluoromethcathinone HCl
Quetiapine Fumarate	Morphine Hydrochloride	N-Desmethylolanzapine dihydrochloride
Dihydrocodeine	Bisoprolol Fumarate	(-)-Isoproterenol hydrochloride
Gabapentin	Sulfasalazine	Phenytoin
omeprazole	Gatifloxacin	Demoxepam
levetiracetam	Carbamide	Hexobarbital
Ibuprofen	Oxalic acid	Etizolam
Olanzapine	Valproate	Cetirizine
Mirtazapine	Loratadine	Citalopram Hydrobromide
Bisulepini hydrochloridum	Bupropione	Lamivudine
Venlafaxine Hydrochloride	Lamotrigine	Escitalopram
Hydrocodone	Duloxetine Hydrochloride	Bromhexine HCL
Fexofenadine	Norbuprenorphine	Moxifloxacin
R-(-)-Apomorphine	Glutamine	Isotretinoin
Beclometasone dipropionate	Zaleplon	N-Vanillylnonanamide
Acamprosate Calcium	S(-)-Cathinone HCl	D-Glucuronic acid
Topiramate		

【BIBLIOGRAPHY】

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