ALP Rapid Test Dipstick (Urine)
Package Insert

REF DALP-101/111 | **English**

A rapid test for the qualitative detection of Alprazolam in human urine.
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The ALP Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of alprazolam in urine at a cut-off concentration of 100ng/ml. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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】

Alprazolam, available under the trade name Xanax among others, is a short-acting anxiolytic of the benzodiazepine class. It is commonly used for the treatment of panic disorder, and anxiety disorders, such as generalized anxiety disorder (GAD) or social anxiety disorder (SAD). [1] [2] Alprazolam, like other benzodiazepines, binds to specific sites on the GABAA receptor. It possesses anxiolytic, sedative, hypnotic, skeletal muscle relaxant, anticonvulsant, and amnestic properties.

A mean half-life of alprazolam of 16.3 hours has been observed in healthy elderly subjects (range: 9.0-26.9 hours, n=16) compared to 11.0 hours (range: 6.3-15.8 hours, n=16) in healthy adult subjects.

Alprazolam and its metabolites are excreted primarily in the urine. The pharmacokinetics of alprazolam and two of its major active metabolites (4-hydroxyalprazolam and α-hydroxyalprazolam) are linear, and concentrations are proportional up to the recommended maximum daily dose of 10 mg given once daily. [3] Peak concentrations in the plasma occur in one to two hours following administration. Plasma levels are proportionate to the dose given; over the dose range of 0.5 to 3.0 mg, peak levels of 8.0 to 37ng/ml were observed. [3]

【PRINCIPLE】

The ALP Rapid Test Dipstick (Urine) is an immunoassay based on the principle of competitive binding. Drugs which 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. Alprazolam, 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 Alprazolam-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 Alprazolam level exceeds the cut-off level, because it will saturate all the binding sites of anti-Alprazolam antibody.

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 in 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- Alprazolam antibody coupled particles and alprazolam -protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For medical and other 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 or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

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.

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 before testing.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Timer

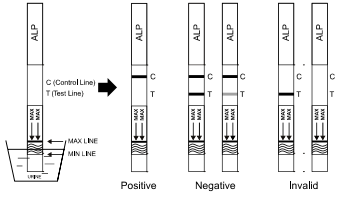
【DIRECTIONS FOR USE】

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

1.Bring the pouch or canister to room temperature before opening it. Remove the Test Dipstick from the sealed pouch or canister and use it within one hour.

2.With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.

3.Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the alprazolam 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 alprazolam 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 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 good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The ALP Rapid Test Dipstick (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other 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 indicates presence of the drug or its metabolites but does not indicate level of 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. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the Alprazolam concentration is below the detectable level of 100ng/ml. Positive result means the concentration of Alprazolam is above the level of 100ng/ml. The ALP Rapid Test Dipstick has a sensitivity of 100ng/ml.

【PERFORMANCE CHARACTERISTICS】

A side-by-side comparison was conducted using the ALP Rapid Test Dipstick and GC/MS at the cut-off of 100ng/ml. Testing was performed on 98 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
ALP Rapid Test Dipstick	Results	Positive	Negative	
	Positive	20	2	22
	Negative	2	74	76
Total Results		22	76	98
% Agreement		90.9%	97.4%	95.9%

Analytical Sensitivity

A drug-free urine pool was spiked with Alprazolam at the following concentrations: 0ng/ml, 50ng/ml, 75ng/ml, 100ng/ml, 125ng/ml, 150ng/ml and 300ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Alprazolam Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
75	-25%	30	28	2
100	Cut-off	30	17	13
125	+25%	30	3	27
150	+50%	30	0	30
300	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the ALP Rapid Test Dipstick (Urine) at 5 minutes.

Compound	Concentration (ng/ml)	Compound	Concentration (ng/ml)
Benzodiazepines	300	Alprazolam	100
a-hydroxyalprazolam	1,500	Flunitrazepam	200
Bromazepam	900	(±) Lorazepam	3,000
Chlordiazepoxide	900	RS-Lorazepamglucuronide	200
Clobazam	200	Midazolam	6,000
Clonazepam	500	Nitrazepam	200
Clorazepatedipotassium	500	Norchlordiazepoxide	100
Delorazepam	900	Nordiazepam	900
Desalkylflurazepam	200	Oxazepam	300
Diazepam	300	Temazepam	100
Estazolam	6000	Triazolam	3,000

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical Dipstick of coded specimens containing, according to GC/MS, no alprazolam, 25% above and below the cut-off and 50% above and below the cut-off of alprazolam was provided to each site. The following results were tabulated:

Alprazolam Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 50ng/ml and 150ng/ml of Alprazolam.The ALP Rapid Test Dipstick (Urine) 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 alprazolam to 50ng/ml and 150ng/ml. The spiked, pH-adjusted urine was tested with The ALP Rapid Test Dipstick (Urine) in duplicate. 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 cross-reactivity of the test with compounds in either drug-free urine or alprazolam positive urine. The following compounds show no cross-reactivity when tested with The ALP Rapid Test Dipstick (Urine) at a concentration of 100ug/ml.

Non Cross-Reacting Compounds

Acetaminophen	Deoxycorticosterone	MDE	β-Phenylethylamine
Acetophenetidin	Dextromethorphan	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diclofenac	Meprobamate	Prednisolone
Acetylsalicylic acid	Diflunisal	Methadone	Prednisone
Aminopyrine	Digoxin	L-Methamphetamine	Procaine
Amitryptyline	Diphenhydramine	Methoxyphenamine	Promazine
Amobarbital	Doxylamine	(±)3,4-Methylenedioxy-amphetamine	Promethazine
Amoxicillin	Ecgonine	(±)-3,4-Methylenedioxy-methamphetamine	D,L-Propranolol
Ampicillin	Ecgonine methylester	Morphine-3-β-D glucuronide	D-Propoxyphene
L-Ascorbic acid	(-)-ψ-Ephedrine	Morphine Sulfate	D-Pseudoephedrine
D,L-Amphetamine sulfate	[1R,2S](-) Ephedrine	Nalidixic acid	Quinacrine
Apomorphine	(L) - Epinephrine	Ranitidine	Quinidine
Aspartame	Erythromycin		Quinine
Atropine	β-Estradiol	Naltrexone	
Benzilic acid	Naloxone	Naproxen	Salicylic acid
Benzoic acid	Estrone-3-sulfate	Niacinamide	Secobarbital
Benzoylecgonine	Ethyl-p-aminobenzoate	Nifedipine	Serotonin
Benzphetamine	Fenoprofen	Norcodein	Sulfamethazine
Bilirubin	Furosemide	Norethindrone	Sulindac
(±)–Brompheniramine	Gentisic acid	D-Norpropoxyphene	Tetracycline
Caffeine	Hemoglobin	Noscapine	Tetrahydrocortisone, 3-Acetate
Cannabidiol	Hydralazine	D,L-Octopamine	Tetrahydrocortisone 3-(β-D-glucuronide)
Cannabinol	Hydrochlorothiazide	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrocodone	Oxolinic acid	Thiamine
Chloramphenicol	Hydrocortisone	Oxycodone	Thioridazine
Chlorothiazide	O-Hydroxyhippuric acid	Oxymetazoline	D,L-Tyrosine
(±)–Chlorpheniramine	p-Hydroxyamphetamine	Papaverine	Tolbutamide
Chlorpromazine	p-Hydroxy-methamphetamine	Penicillin-G	Triamterene
Chlorquine	3-Hydroxytyramine	Pentazocine	Trifluoperazine
Cholesterol	Ibuprofen	Pentobarbital	Trimethoprim
Clomipramine	Imipramine	Perphenazine	Trimipramine
Clonidine	Iproniazid	Phencyclidine	Tryptamine
Cocaethylene	(±) - Isoproterenol	Phenelzine	D,L-Tryptophan
Cocaine	Isoxsuprine	Phenobarbital	Tyramine
Codeine	Ketamine	Phentermine	Uric acid
Cortisone	Ketoprofen	Trans-2-phenylcyclo-propylamine hydrochloride	Verapamil
(-) Cotinine	Labetalol	Zomepirac	
Creatinine	Loperamide		
Maprotiline	L-Phenylephrine		

【BIBLIOGRAPHY】

1. Work Group on Panic Disorder (January 2009). APA Practice Guideline for the Treatment of Patients With Panic Disorder (2nd ed.).
2. "FDA approved labeling for Xanax revision 08/23/2011" (PDF).Federal Drug Administration. 2011-08-23. p. 4. Retrieved 2011-09-14.
3. "Xanax XR (Alprazolam) Clinical Pharmacology – Prescription Drugs and Medications". RxList. First DataBank. July 2008.

Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C – 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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