GAB Rapid Test Dipstick (Urine)
Package Insert

REF DGAB-101/111 | English

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

【INTENDED USE】

The GAB Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of Gabapentin in urine at a cut-off concentration of 2000ng/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】

Gabapentin, sold under the brand name Neurontin among others, is a medication which is used to treat epilepsy (specifically partial seizures), neuropathic pain, hot flashes, and restless legs syndrome. [1, 2]

Common side effects of gabapentin include sleepiness and dizziness. Serious side effects include an increased risk of suicide, aggressive behavior, and drug reaction with eosinophilia and systemic symptoms.[1] In 2009 the U.S. Food and Drug Administration issued a warning of an increased risk of suicidal thoughts and behaviors in patients taking some anticonvulsant drugs, including gabapentin,[3] modifying the packaging inserts to reflect this.[4]

The oral bioavailability of gabapentin enacarbil (as gabapentin) is greater than or equal to 68%, across all doses assessed (up to 2,800 mg), with a mean of approximately 75%.[5,6] Gabapentin undergoes little or no metabolism.[7,8]The T-max of the instant-release (IR) formulation of gabapentin enacarbil (as active gabapentin) is about 2.1 to 2.6 hours across all doses (350 – 2,800 mg) with single administration and 1.6 to 1.9 hours across all doses (350 – 2,100 mg) with repeated administration.[9]

The GAB Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes an antibody to selectively detect elevated levels of gabapentin in urine. The GAB Rapid Test Dipstick (Urine) yields a positive result when gabapentin in urine exceeds 2000ng/ml.

【PRINCIPLE】

The GAB 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. Gabapentin, 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 Gabapentin-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 Gabapentin level exceeds the cut-off level, because it will saturate all the binding sites of anti- Gabapentin 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 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-Gabapentin antibody coupled particles and Gabapentin-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 or closed canister 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: For canister packaging, immediately close the canister tightly after removing the required number of the test dipstick(s). Record the initial opening date on the canister. 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

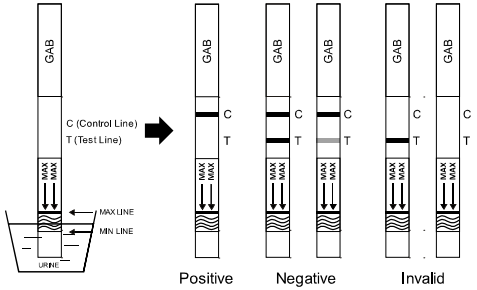
Materials Required But Not Provided

- 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 closed canister to room temperature before opening it. Remove the Rapid Test Dipstick from the sealed pouch or closed canister and use it within one hour.
2. With arrows pointing toward the urine specimen**, immerse the rapid test dipstick vertically in the urine specimen for at least 10-15 seconds**. Do not pass the maximum line (MAX) on the Rapid Test Dipstick when immersing the strip. See the illustration below.
3. Place the rapid 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 Gabapentin 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 Gabapentin 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 GAB 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 Gabapentin concentration is below the detectable level of 2000ng/ml. Positive result means the concentration of Gabapentin is above the level of 2000ng/ml. The GAB Rapid Test Dipstick has a sensitivity of 2000ng/ml.

【PERFORMANCE CHARACTERISTICS】

A side-by-side comparison was conducted using The GAB Rapid Test Dipstick and GC/MS at the cut-off of 2000ng/ml. Testing was performed on 92 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
GAB Rapid Test Dipstick	Results	Positive	Negative	
	Positive	24	1	25
	Negative	2	65	67
Total Results		26	66	92
% Agreement		92.3%	98.5%	96.7%

Analytical Sensitivity

A drug-free urine pool was spiked with Gabapentin at the following concentrations: 0ng/ml, 1000ng/ml, 1500ng/ml, 2000ng/ml, 2500ng/ml, 3000ng/ml and 6000ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Gabapentin Concentration (ng/ml)	Percent of Cut-off	n	Visual Results	
			Negative	Positive
0	0	30	30	0
1000	-50%	30	30	0
1500	-25%	30	28	2
2000	Cut-off	30	16	14
2500	+25%	30	3	27
3000	+50%	30	0	30
6000	3X	30	0	30

Analytical Specificity

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

Compound	Concentration (ng/mL)
Gabapentin	2000

Precision

A study was conducted by three laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Gabapentin, 25% Gabapentin above and below the cut-off and 50% Gabapentin above and below the 2000ng/ml cut-off were provided to each site. The following results were tabulated:

Gabapentin Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1000	10	10	0	10	0	10	0
1500	10	9	1	9	1	8	2
2500	10	2	8	2	8	2	8
3000	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 1000ng/ml and 3000ng/ml of Gabapentin. The GAB 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 Gabapentin to 1000ng/ml and 3000ng/ml. The spiked, pH-adjusted urine was tested with The GAB 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 Gabapentin positive urine. The following compounds show no cross-reactivity when tested with The GAB Rapid Test Dipstick (Urine) at a concentration of 100μg/ml.

Non Cross-Reacting Compounds

Acetaminophen	d/l-Chloropheniramine	Sulfamethazine
N-Acetylprocainamide	Chloroquine	Tetracycline
Aminopyrine	Clonidine	Tetrahydrocortisone (β-D-glucuronide)
Ampicillin	l-Cotinine	Thioridazine
Apomorphine	Deoxycorticosterone	Tolbutamide
Atropine	Diclofenac	Trifluoperazine
Benzoic acid	Digoxin	d/l-Tryptophan
d/l-Brompheniramine	l -Ψ-Ephedrine	Uric acid
Chloral-hydrate	Estrone-3-sulfate	Ketoprofen
Chlorothiazide	l(–)-Epinephrine	Loperamide
Chlorpromazine	Fenoprofen	Meprobamate
Cholesterol	Gentisic acid	Nalidixic acid
Cortisone	Hydralazine	Niacinamide
Creatinine	Hydrocortisone	Norethindrone
Dextromethorphan	p-Hydroxytyramine	Noscapine
Diflunisal	Iproniazid	Oxalic acid
Diphenhydramine	Isoxsuprine	Oxymetazoline
β-Estradiol	Ketamine	Penicillin-G
Ethyl-p-aminobenzoate	Labetalol	Perphenazine
Erythromycin	Meperidine	Trans-2-phenylcyclopropylamine hydrochloride
Furosemide	Methylphenidate	Prednisolone
Hemoglobin	Naproxen	d/l-Propranolol
Hydrochlorothiazide	Nifedipine	d-Pseudoephedrine
o-Hydroxyhippuric acid	d-Norpropoxyphene	Quinine
Ibuprofen	d/l-Octopamine	Ranitidine
d/l-Isoproterenol	Oxolinic acid	Serotonin
Acetophenetidin	Papaverine	Sulindac
Acetylsalicylic acid	Pentazocine hydrochloride	Tetrahydrocortisone 3-acetate
Amoxicillin	Phenelzine	Thiamine
l-Ascorbic acid	Phenylpropanolamine	d/l-Tyrosine
Aspartame	Prednisone	Triamterene
Benzilic acid	d-Propoxyphene	Trimethoprim
Benzphetamine	Quinacrine	Tyramine
Caffeine	Quindine	Verapamil
Chloramphenicol	Salicylic acid	Zomepirac

【BIBLIOGRAPHY】

1. "Gabapentin". The American Society of Health-System Pharmacists. Archived from the original on 8 September 2017. Retrieved 23 Oct 2015.
2. Wijemanne, S; Jankovic, J (June 2015). "Restless legs syndrome: clinical presentation diagnosis and treatment". Sleep medicine. 16 (6): 678 – 90.
3. "Suicidal Behavior and Ideation and Antiepileptic Drugs". U.S. Food and Drug Administration (FDA). Archived from the original on 1 August 2009.
4. "Neurontin packaging insert" U.S. Food and Drug Administration (FDA). 1 May 2009. Archived from the original on 14 December 2010. Retrieved 16 July 2010.
5. Agarwal P, Griffith A, Costantino HR, Vaish N (2010). "Gabapentin enacarbil - clinical efficacy in restless legs syndrome". Neuropsychiatr Dis Treat. 6: 151 – 8.
6. Calandre EP, Rico-Villademoros F, Slim M (2016). "Alpha2delta ligands, gabapentin, pregabalin and mirogabalin: a review of their clinical pharmacology and therapeutic use". Expert Rev Neurother. 16 (11): 1263 – 1277.
7. Calandre EP, Rico-Villademoros F, Slim M (2016). "Alpha2delta ligands, gabapentin, pregabalin and mirogabalin: a review of their clinical pharmacology and therapeutic use". Expert Rev Neurother. 16 (11): 1263 – 1277.
8. Bockbrader HN, Wesche D, Miller R, Chapel S, Janiczek N, Burger P (2010)."A comparison of the pharmacokinetics and pharmacodynamics of pregabalin and gabapentin". Clin Pharmacokinet. 49(10): 661 – 9.
9. Cundy KC, Sastry S, Luo W, Zou J, Moors TL, Canafax DM (2008). "Clinical pharmacokinetics of XP13512, a novel transported prodrug of gabapentin". J Clin Pharmacol. 48 (12): 1378 – 88.

Index of Symbols

	Attention, see instructions for use	Σ	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

Hangzhou AllTest Biotech Co., Ltd.
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www.alltests.com.cn

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