

# ALL TEST™ PGB Rapid Test Dipstick (Urine) Package Insert

REF DPG-101 English

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

**INTENDED USE**  
The PGB Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of pregabalin in urine at a cut-off concentration of 50 µg/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.

**SUMMARY**  
Pregabalin, also known as β-isobutyl-γ-amino butyric acid (beta-isobutyl-GABA), is a medication used to treat epilepsy, neuropathic pain, fibromyalgia, and generalized anxiety disorder.<sup>[1]</sup> Common side effects include: sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, and weight gain. Potentially serious side effects include angioedema, drug misuse, and an increased suicide risk.<sup>[2]</sup>

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. The Pregabalin is predominantly excreted unchanged in urine (≥ 98%)<sup>[3]</sup>. Pregabalin mean elimination half-life is 6.3 hours.<sup>[4]</sup> 50% would be expected to have negative urine specimens within 3 days and a total of 5 days would be needed to achieve negative urine specimens in the subject with the maximum urinary concentration measured.<sup>[5]</sup>

The PGB Rapid Test Dipstick (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 Pregabalin in urine. The PGB Rapid Test Dipstick (Urine) yields a positive result when Pregabalin in urine exceed 50µg/mL.

**PRINCIPLE**  
The PGB 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 drugconjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Pregabalin, 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 pregabalin-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 Pregabalin level exceeds the cut-off level, because it will saturate all the binding sites of anti-pregabalin 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-pregabalin antibody coupled particles and pregabalin-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 90 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

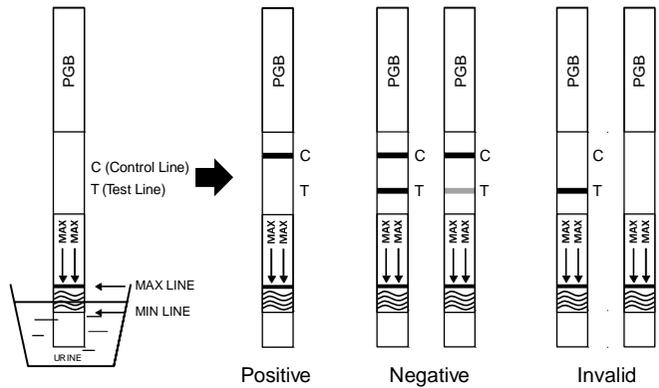
### Materials Provided

- Test Dipsticks
  - Package insert
- Materials Required But Not Provided
  - Timer

## DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.
- 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 above.
- 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 pregabalin concentration is below the detectable cut-off level.

**NOTE:** The shade of color in the test line region (T) may vary, but this 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 pregabalin 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

- The PGB 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- The PGB Rapid Test Dipstick can only be used with urine specimen.

## EXPECTED VALUES

This negative result indicates that the pregabalin concentration is below the detectable level of 50 µg/ml. Positive result means the concentration of Pregabalin is above the level of 50 µg/ml. The PGB Rapid Test Dipstick has a sensitivity of 50 µg/ml.

## PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using The PGB Rapid Test Dipstick and GC/MS at the cut-off of 50 µg/ml. Testing was performed on 97 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
PGB Rapid Test Dipstick	Positive	20	22
	Negative	2	75
	<b>Total Results</b>	22	97
<b>% Agreement</b>	90.9%	97.3%	95.9%

## Analytical Sensitivity

A drug-free urine pool was spiked with pregabalin at the following concentrations: 0 µg/ml, 25 µg/ml, 37.5 µg/ml, 50 µg/ml, 62.5 µg/ml, 75 µg/ml and 150 µg/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Pregabalin Concentration (µg/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	25	5
50	Cut-off	30	15	15
62.5	+25%	30	5	25
75	+50%	30	0	30
150	3X	30	0	30

## Analytical Specificity

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

Compound	Concentration (µg/ml)
Pregabalin	50

## 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 pregabalin, 25% pregabalin above and below the cut-off and 50% pregabalin above and below the 50 µg/ml cut-off was provided to each site. The following results were tabulated:

Pregabalin Concentration (µg/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	8	2
62.5	10	2	8	2	8	2	8
75	10	0	10	0	10	0	10
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 25 µg/ml and 75 µg/ml of pregabalin. The PGB 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 pregabalin to 25 µg/ml and 75 µg/ml. The spiked, pH-adjusted urine was tested with The PGB 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 pregabalin positive urine. The following compounds show no cross-reactivity when tested with The PGB Rapid Test Dipstick (Urine) at a concentration of 100 µg/ml.

## Non Cross-Reacting Compounds

Acetaminophen	d/Chlorpheniramine	Sulfamethazine
N-Acetylprocainamide	Chloroquine	Tetracycline
Aminopyrine	Clonidine	Tetrahydrocortisone 3 (β-D-glucuronide)
Ampicillin	l-Cotinine	Thioridazine
Apomorphine	Deoxycorticosterone	Tolbutamide
Atropine	Diclofenac	Trifluoperazine
Benzoc acid	Digoxin	d/l-Tryptophan
d/l-Brompheniramine	l-Ψ-Ephedrine	Uric acid
Chloral-hydrate	Estrone-3-sulfate	Ketoprofen
Chlorothiazide	(-)-Epinephrine	Loperamide
Chlorpromazine	Fenoprofen	Meprobamate
Cholesterol	Genitistic acid	Nalidixic acid
Cortisone	Hydralazine	Niacinamide
Creatinine	Hydrocortisone	Norethindrone
Dextromethorphan	p-Hydroxytyramine	Noscapine
Diffunisal	Iproniazid	Oxalic acid
Diphenhydramine	Isosuxprine	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
lbutrofen	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	Quinine	Verapamil
Chloramphenicol	Salicylic acid	Zomepirac

## BIBLIOGRAPHY

- Frampton, JE (September 2014). "Pregabalin: a review of its use in adults with generalized anxiety disorder." *CNS Drugs* 28 (9): 835-54.
- "Pregabalin". The American Society of Health-System Pharmacists. Retrieved Oct 23, 2015.
- D.R. Guay. Pregabalin in neuropathic pain: a more "pharmaceutically elegant" gabapentin? *Am. J. Geriatr. Pharmacother.* 3: 274-287 (2005).
- "Summary of product characteristics" (PDF). European Medicines Agency. 6 March 2013. Retrieved 6 May 2013.
- "Detection times of Pregabalin in urine after illicit use: when should a positive specimen be considered a new intake?" *Ther Drug Monit.* 2013 Feb;35(1):137-40.

## Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number	REF	Catalog #
	Do not use if package is damaged				

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Number: 145261702  
Effective date: 2016-12-16