Gabapentin Dip Test

One Step Gabapentin Test Dip Card (Urine)

Package Insert

For Forensic Use Only

A rapid, one step test for the qualitative detection of Gabapentin (GABA) and its metabolites in human urine.

INTENDED USE

The One Step Gabapentin Test Dip Card (Urine) is a lateral flow chromatographic immunoassay for the detection of *Gabapentin and its metabolites* in human urine.

Test	Calibrator	Cut-off (ng/mL)
Gabapentin (GABA)	Gabapentin	2000

This assay provides only a 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) and Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC-MS/MS)) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. This test does not distinguish between drugs of abuse and certain medications.

SUMMARY

Gabapentin is an anti-epileptic drug, also called an anticonvulsant. It affects chemicals and nerves in the body that are involved in the cause of seizures and some types of pain. Gabapentin is used in adults to treat neuropathic pain (nerve pain) caused by herpes virus or shingles (herpes zoster). In epilepsy, it may be used for those with partial seizures. It is recommended as one of a number of first line medications for the treatment of neuropathic pain in diabetic neuropathy, postherpetic neuralgia, and central neuropathic pain. Common side effects include sleepiness and dizziness. Serious side effects may include an increased risk of suicide, aggressive behavior, and drug reaction with eosinophilia and systemic symptoms.

The One Step Gabapentin Test Dip Card (Urine) yields a positive result when Gabapentin in urine exceeds 2000 ng/mL.

PRINCIPLE

The One Step Gabapentin Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drug which may be present in the urine specimen competes against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the specific drug strip. The presence of drug above the cutoff concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. 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.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged, Do not reuse the test.
- The test dip card should remain in the sealed pouch until use.
- Avoid cross-contamination of specimen by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Humidity and temperature can adversely affect results.
- The used test dip card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C until the expiry date printed on the pouch.
- The test dip card must remain in the sealed pouch until use.
- The kit should be kept out of direct sunlight.
- **DO NOT FREEZE.**
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

MATERIALS

Materials Provided

- Individually packaged single dip card
- Package insert

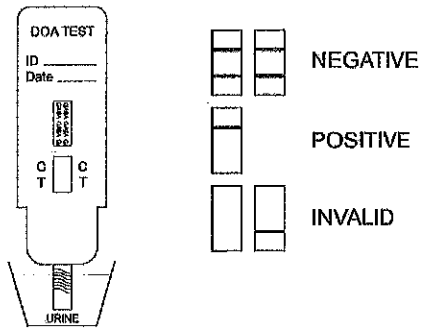
Materials Required But Not Provided

- Collection container/cup
- Timer

DIRECTIONS FOR USE

Allow the test dip card and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the test dip card from the foil pouch and use as soon as possible.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) With the arrows pointing toward the urine specimen immerse the sample tip vertically in the urine specimen for at least 10 - 15 seconds. Replace the cap back onto the device and place the device on a flat surface.
4) Read results at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES
5) Presumptive positive results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another color line in the test region (T).

This negative result indicates that the drug concentration is below the detectable level.

The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable 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 using a new test dip card. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A red 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 GABA Test should only be used for the qualitative detection of drugs of abuse in urine.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC-MS/MS) have been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted by laboratory personnel using the One Step Gabapentin Test Dip card) and a commercially available rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. The following results were obtained :

Method		Another Commercial Rapid Test		Total Results
Gabapentin Dip Test	Results	Positive	Negative	
	Positive	110	0	110
	Negative	0	150	150
Total Results		110	150	260
% Agreement		>99%	>99%	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with Gabapentin at the following concentrations: 0 ng/mL, -50% cutoff, -25% cutoff, cutoff, +25% cutoff and +50% cutoff. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Gabapentin (GABA) Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
1000	-50%	30	30	0
1500	-25%	30	26	4
2000	Cutoff	30	15	15
2500	+25%	30	3	27
3000	+50%	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step Gabapentin Test Dip Card at a read time of 5 minutes.

Compound	Concentration (ng/mL)
Gabapentin (GABA)	2,000
Pregabalin	40,000
Ibuprofen	10 ,000
Triazolam	90,000
Bilirubin	90,000
Diflunisal	15,000

Reproducibility

Reproducibility studies were carried out using commercially available stock solutions of the drug analytes listed. Dilutions were made from the stock solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Gabapentin (GABA) conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negatives	>99%
1000	40	40 negatives	>99%
3000	40	40 positives	>99%
4000	40	40 positives	>99%

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Gabapentin Test Dip Card was tested in duplicate using ten drug-free urine and spiked urine samples. 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 pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Gabapentin Test Dip Card (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference

The following compounds were evaluated for potential positive or negative interference with the GABA dip card. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the GABA Dip Card. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL

Interference Compounds

Acetophenetidin	l-Cotinine	Ketoprofen	Quinidine
N-Acetylprocainamide	Creatinine	Labetalol	Quinine
Acetylsalicylic acid	Deoxycorticosterone	Loperamide	Salicylic acid
Aminopyrine	Diclofenac	Meprobamate	Serotonin
Amoxicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
Ampicillin	Digoxin	Methylphenidate	Sulindac
l-Ascorbic acid	Diphenhydramine	Nalidixic acid	Tetracycline
Apomorphine	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Aspartame	β-Estradiol	Niacinamide	3-Acetate
Atropine	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzilic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Benzoic acid	Fenoprofen	Noscapine	Thiamine
Bilirubin	Furosemide	d,l-Octopamine	Thioridazine
d,l-Brompheniramine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Caffeine	Hemoglobin	Oxolinic acid	Tolbutamide
Cannabidiol	Hydralazine	Oxymetazoline	Triamterene
Chloralhydrate	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chloramphenicol	Hydrocortisone	Penicillin-G	Trimethoprim
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
d,l-Chlorpheniramine	3-Hydroxytyramine	Phenelzine	Uric acid
Chlorpromazine	d,l-Isoproterenol	Prednisone	Verapamil
Cholesterol	Isoxsuprine	d,l-Propranolol	Zomepirac
Clonidine	Cortisone	d-Pseudoephedrine	

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

Manufactured For: Healgen Scientific, LLC
3816 Fuqua St.
Houston, Texas 77047

Revised February 2020