GABA

One Step Gabapentin Test Dip Card (Urine)

Package Insert

This Instruction Sheet is for testing of Gabapentin.
A rapid, one step test for the qualitative detection of single drug and its metabolites in human urine.
For professional in vitro diagnostic use only.

INTENDED USE

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

Test	Calibrator	Cut-off
Gabapentin (GABA)	Gabapentin	1000 ng/mL

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) 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 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 behaviour, and drug reaction with eosinophilia and systemic symptoms.

The One Step Gabapentin Test Dip Card (Urine) yields a positive result when Gabapentin in urine exceed 1000 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 compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a 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 show up in the test line region of the specific drug strip. The presence of sTherefore, the colored line will not 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.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugate (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal Gabapentin antibody.

PRECAUTIONS

- For Forensic Use Only. Do not use after the expiration date.
- The test dip card 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 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). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card 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 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 clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

• Test dip card • Desiccant • Package insert

Materials Required But Not Provided

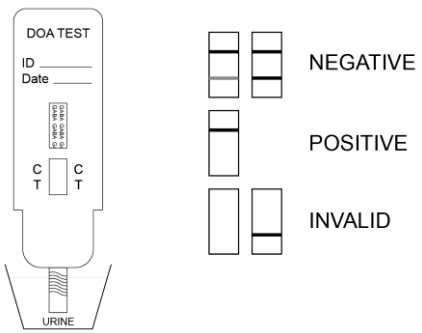
• Specimen collection container • Timer

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.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.



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 apparent color line adjacent should be in the test region (T).
This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable
color line.

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 One Step Gabapentin Test Dip Card (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.

PERFORMANCE CHARACTERISTICS

Accuracy

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

Method		Other Commercial Rapid Test		Total Results
Gabapentin Rapid Test Dip card	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
500	-50%	30	30	0
750	-25%	30	26	4
1000	Cutoff	30	15	15
1250	+25%	30	3	27
1500	+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 (Urine) at a read time of 5 minutes.

Compound	Concentration (ng/mL)
Gabapentin (GABA)	1000
Pregabalin	>100,000

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork 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 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>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 (Urine) 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.

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 One Step Gabapentin Test Dip Card (Urine) at a concentration of 100 μg/mL.

Non Cross Reacting 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-Propanolol	Zomepirac
Clonidine	Cortisone	d-Pseudoephedrine	

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