One Step Drug of Abuse Test

(Dip Card)

Package Insert for Gabapentin Screen Test

This instruction sheet is for the testing of Gabapentin (GAB) drug.
A rapid, one step screening for the qualitative detection of Gabapention and its metabolites in human urine.

For Forensic Use Only

INTENDED USE

The ***One Step Drug of Abuse Test*** is a lateral flow chromatographic immunoassay for the qualitative detection of Gabapentin and its metabolite in urine at the following cutoff concentration:

Test	Calibrator	Cut-off
Gabapentin (GAB)	Gabapentin	2,000ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The ***One Step Drug of Abuse Test*** is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine with the use of an instrument.

GABAPENTIN(GAB)
Gabapentin, developed under the brand name Neurontin, is used to treat epilepsy, neuralgia, hot flashes, and sleep pediculitis. This drug is generally used for the treatment of local epilepsy. Gabapentin is also the first choice for the treatment of neuropathic pain in diseases such as diabetic neuritis, severe pain after herpes, and central neuropathic pain. About 14% of patients with neuropathic pain can be improved. Side effects include drowsiness and dizziness. Serious side effects may include increased risk of suicide, agitation, eosinophilia, and systemic symptoms. Whether it is harmful to pregnancy or breastfeeding is unclear. Patients with renal failure should use a lower dose.

The GAB assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Gabapentin in urine exceeds 2,000 ng/ml.

PRINCIPLE

The ***One Step Drug of Abuse Test*** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against its 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 dip card. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, 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 dip card 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 dip card coated with drug-protein conjugates (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 antibody specific to Gabapentin drug.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- The test is for single use only.
- While urine is not classified by OSHA or the CDC as biological hazard unless visibly contaminated with blood, the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test dip card and urine specimen should be discarded according to federal, state, and local regulations.

STORAGE AND STABILITY

Store as packaged in sealed pouch at 4-30°C (39-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device 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 precipitates should be allowed to settle to obtain a clear specimen for testing.

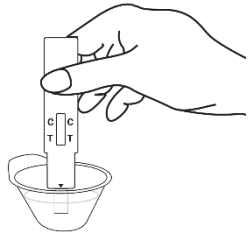
MATERIALS

Materials Provided
• Test dip card • Desiccants • Package insert
Materials Required But Not Provided
• Specimen collection container • Disposable gloves • 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 dip card from the foil pouch. Remove the cap from the test dip card. Label the dip card with patient or control identifications.
2) Immerse the absorbent tip into the urine sample for 1 minute. Urine sample should not touch the plastic device.
3) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
4) Read result at 5 minutes. **DO NOT READ RESULT AFTER 5 MINUTES.** (Fig. 1)



(Fig. 1)

INTERPRETATION OF RESULTS

(Please refer to the illustration below)

NEGATIVE: Two lines appears.* 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 failures. 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 color 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.

LIMITATIONS

1. The ***One Step Drug of Abuse Test*** 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.[4,5,6]
2. There is a possibility 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 and a new test dip card.
4. A positive result does not indicate intoxication of the donor, the concentration of the drug in the urine, or the route of drug administration.
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.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy
In the comparison study, the ***One Step Drug of Abuse Test*** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for Gabapentin listed on the follow table. Clinical specimens were quantified by GC/MS analysis before testing.

Test	Compound Contributed to the Total of GC/MS
GAB	Gabapentin

The following results are tabulated from these clinical studies:

	GAB
Positive Agreement	100%
Negative Agreement	100%
Overall Agreement	100%

Analyte	GAB	
	Pos	Neg
Negative Samples	0	5
Near Cut-off Negative Sample (Between 50% of cut-off and cut-off)	0	18
Near Cut-off Positive Samples (Between cut-off and 150% of cut-off)	19	0
Positive Samples (>150% of cut-off)	18	0
Agreement with GC/MS	100%	100%

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

GABAPENTIN (GAB)

Gabapentin) Conc. (ng/mL)	Total Number of Determinations	Results	Precision
No drug present	60	60 Negative	>99%
1000	60	60 Negative	>99%
3000	60	60 Positive	>99%

Analytical Sensitivity
A drug-free urine pool was spiked with Gabapentin at concentration listed. The results are summarized below.

Drug Concentration Cut-off Range	N	GAB	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	30	0
Cut-off	30	0	30
+25% Cut-off	30	0	30
+50% Cut-off	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 Drug of Abuse Test*** at a read time of 5 minutes.

GABAPENTIN (GAB)	**Result**
(Gabapentin, Cut-off = 2,000ng/mL	Positive at 2,000ng/mL
Diflunisal	Positive at 100,000ng/mL

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 Gabapentin drug at 50% below and 50% above cut-off levels respectively. The ***One Step Drug of Abuse Test*** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrated that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF THE 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 Drug of Abuse Test***. The results demonstrated that varying ranges of pH do no interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug-positive urine containing Gabapentin. The following compounds show no cross-reactivity when tested with the One Step Drug of Abuse Test at concentrations at 100µg/mL.

Gabapentin Non-Cross-Reacting Compounds:

Acebutolol HCl
Acepromazine-D6 HCl
Acetaminophen
N-Acetylprocainamide
Acetophenetidin
Alprazolam
Alphenal
Amoxicillin
Ampicillin
Amitriptyline HCl
S(+)-Amphetamine
R(-)-Amphetamine
Amobarbital
(±)-Amphetamine
R(-)-Apomorphine HCl
Aprobarbital
Aspirin
Aspartame
L-Ascorbic Acid
Atropine
6-Acetylmorphine
Acetylsalicylic Acid
Benzphetamine
Benzilic Acid
Benzoylecgonine
SS Benzoic Acid
Bilirubin
Brompheniramine Maleate
Buprenorphine
Buspirone HCl
Butalbital
Butabarbital
Cannabidiol
Cannabinol
Caffeine
Cetirizine HCl
Chlordiazepoxide HCl
Chlorothiazide
Chloroquine
Chlorpheniramine Maleate
Chlorpromazine HCl
Chloramphenicol
Chloralhydrate
Cholesterol
Chlorothiazide
Clomipramine
Clonazepam
Clonidine HCl
Clozapine
(-)-Cotinine
Cocaethylene
Cocaine HCl
Codeine
Cortisone
Creatinine
Cyclopentobarbital
Citalopram Hydrobromide
Dextromethorphan
Desipramine
Diazepam
Diclofenac Sodium Salt
Dicyclomine
Digoxin
4-Dimethylaminoantipyrine
Dihydrocodeine HCl
5,5-Diphenylhydantoin
Diphenhydramine
Dopamine
Doxylamine
Ecgonine Methyl Ester
Ecgonine HCl
Efavirenz
Ethylone
Ethylmorphine
Fenoprofen
Fentanyl
Furosemide
Gentisic Acid
D-Glucuronic Acid
Glutethimide
Guaifenesin
Hemoglobin Porcine
Heroin HCl
Hippuric Acid
Hydralazine HCl
Hydromorphone
Hydrocodone
α-Hydroxyhippuric Acid
21-Hydrooxyprogesterone
p-Hydroxymethamphetamine
Hydrocortisone
Hydrochlorothiazide
4-Hydroamphetamine HCl
Ibuprofen
Imipramine
Iprazid
Isoxsuprine HCl
Isoproterenol HCl
Ketamine HCl
Ketoprofen
Emetine Dihydrochloride Hydrate
(±)-Ephedrine HCl
[1R,2S]-(-)-Ephedrine
Erythromycin
Eserine
Estazolam
β-Estradiol
(±)-EDDP
Ethyl-p-aminobenzoate
JWH-018 Pentanoic Acid
JWH-073 Butanoic Acid
Labetalol HCl
Levorphanol
Loperamide HCl
Lorazepam
Maprotiline HCl
(±)-MDEA
(±)-MDA
Meperidine
Meprobamate
Methamphetamine HCl
(±)-Methadone
S(+)D-Methamphetamine
L-Methamphetamine
Methylphenidate
(±)-MDMA
(±)-MDPV
Methyprylon
Morphine
Morphine-3-β-D-Glucuronide
Morphine Sulfate Salt
Nalidixic Acid
Nalorphine HCl
Nicotinamide
Nimesulide
Nifedipine
Norcodeine
Nordoxepin HCl
Norfloxacin
Norethisterone
D-Norpropoxyphene Maleate Salt
Noroxymorphone HCl
Norfentanyl
Noscapine
Nylidrin HCl
(±)-Octopamine HCl
Oxalic Acid
Oxolinic Acid
Oxycodone
Oxymetazoline
Papaverine
PCP
Pentobarbital
Pentazocine
Perphenazine
Penicillin G Sodium
Phenelzine Sulfate Salt
Phenobarbital
Phentermine HCl
Phenethylamine
L-Phenylephrine
Phenylpropanolamine HCl
Prednisolone
Prednisone Acetate
Procaine HCl
Promazine HCl
Promethazine
D-Propoxyphene
Propranolol HCl
Pseudoephedrine
Phenytoin
Quinine
Quinidine
Quinacrine
Ranitidine HCl
Sertraline HCl
Sulfamethazine
Sulindac
Temazepam
Terfenadine
Terbutaline
Tetraethylthiuram Disulfide
Δ-8-THC
Tetracycline
Tetrahydrocortisone 3-(β-D-Glucuronide-(-)-Δ9-THC)
(±)-11-Hydroxy-Δ-9-THC
(-)-11-Nor-9-Carboxy-Δ^9-THC
Thebaine
Theophylline
Thioridazine
Thiamine HCl
DL-Thyroxine
Tolbutamide
Tramadol
Triamterene
Tryptamine
Trifluoperazine HCl
DL-Tryptophan
Triazolam
Trans-2-phenylcyclopropylamine HCl
DL-Tyrosine
Tyramine
Uric Acid
Verapamil HCl
Valproic Acid
Zomepirac

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