PRECISION DX™

For Forensic use Only

Gabapentin Rapid Test (Urine)

INTENDED USE

The GAB Rapid Test Single Panel (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of GAB in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
GAB	Gabapentin	2000

INTRODUCTION

Gabapentin (GAB) marketed under the brand name Neurontin among others, is a medication used to treat epilepsy,neuropathic pain, hot flashes, and restless leg syndrome. 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 indiabetic neuropathy, post-herpetic neuralgia, and central neuropathic pain. The mechanism of the anticonvulsant action of gabapentin has not been fully described. Several possible mechanisms for pain improvement have been discussed. Though similar in structure to the endogenous neurotransmitter GABA, gabapentin has not been shown to bind to GABA receptors at concentrations at or below 1 mM. Gabapentin modulates the action of glutamate decarboxylase (GAD) and branched chain aminotransferase (BCAT), two enzymes involved in GABA biosynthesis. In human and rat studies, gabapentin was found to increase GABA biosynthesis, and to increase non-synaptic GABA neurotransmission in vitro.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. It is unclear if it is safe duringpregnancy or breastfeeding. Lower doses should be used in people with kidney problems. Gabapentin affects the inhibitory neurotransmitter γ-aminobutyric acid (GABA).

PRINCIPLE

The GAB Rapid Test Single Panel (Urine) detects Gabapentin through visual interpretation of color development on the Single Panel. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test consists of a reagent Single Panel mounted in a plastic housing. The amount of each antigen and/or antibody coated on the Single Panel is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.

The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

MATERIALS

Materials Provided

- Test Panel
- Package insert

Materials Required but Not provided

- Positive and negative controls
- Timer
- Centrifuge

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch or canister is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch or canister.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

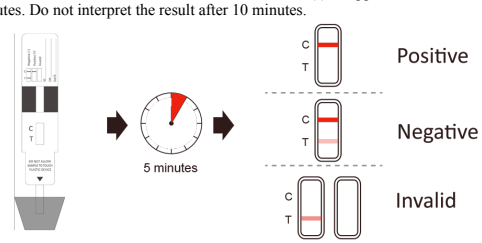
- The GAB Rapid Test Single Panel (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- 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.

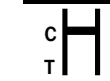
PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use it if the specimens are refrigerated.

1. Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.
2. Hold the Single Panel at the handle with the product name imprints. Do not touch the membrane part of the Single Panel to avoid contamination.
3. Dip the test Single Panel vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test Single Panel when immersing the Single Panel. As the test begins to work, you will see color move across the membrane.
4. Take the Single Panel out of the specimen afterwards and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS



POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T)

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. 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 should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The GAB Rapid Test Single Panel (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Gabapentin.
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) has 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 Gabapentin only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Gabapentin in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Gabapentin and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the GAB Rapid Test Single Panel (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >95.7% in agreement.

B. Reproducibility

The reproducibility of the GAB Rapid Test Single Panel (Urine) was verified by blind tests performed at four different locations. Samples with GAB concentrations at 50% of the cut-off were all determined to be negative, while samples with GAB concentrations at 200% of the cut-off were all determined to be positive.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with GAB concentrations at 50% of the cut-off yielded negative results, and controls with GAB concentrations at 150% of the cut-off yielded positive results.

D. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the GAB Rapid Test Single Panel (Urine) identified positive results at 5 minutes.

GAB related compounds	Concentration (ng/ml)
Gabapentin	2000
Pregbalin	>100000

The following compounds yielded negative results up to a concentration of 100 µg/mL:

(-)-Ephedrine
(+)-Naproxen
(+/-)-Ephedrine
4-Dimethyllaminoantiyrine
Acetaminophen
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Benzocaine
Bilirubin
b-Phenylethyl-amine
Caffeine
Chloroquine
Chlorpheniramine
Creatine
Dextromethorphan
Dextrorphan tartrate
Dopamine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
Imipramine
Isoproterenol
Lidocaine
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
Procaine
Protonix
Pseudoephedrine
Quinidine
Ranitidine
Sertraline
Tyramine
Vitamin C (Ascorbic Acid)
Trimeprazine
Venlafaxine
Methadone

LITERATURE REFERENCES

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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

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical Single Panel		Use by
	Manufacturer	2	Do not reuse

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