Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine)
Package Insert

REF DET-102	English

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

【INTENDED USE】

The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Ethyl Glucuronide in human urine. The Ethyl Glucuronide detected by the test includes, but are not limited to, the metabolites of Ethanol.

This assay provides only a preliminary 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】

Ethyl Glucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body byglucuronidation following exposure to ethanol, such as by drinking alcoholic beverages. Itis used as a biomarker to test for ethanol use and to monitor alcohol abstinence in situationswhere drinking is prohibited, such as in the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, inliver transplant clinics, or in recovering alcoholic patients. ETG can be measured in urine by Traditional laboratory methods (GC/MS or LC/MS) upto approximately 80 hours after ethanol is ingested (greatly dependent on the amount of alcoholic and non-alcoholic drinks). ETG is a more accurate indicator of therecent exposure to alcohol than measuring for the presence of ethanol itself.

The Ethyl Glucuronide (ETG) Rapid Test Cassette (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 ethyl glucuronide in human urine. The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) yields a positive result when the Ethyl Glucuronide in urine exceeds 500 ng/mL.

【PRINCIPLE】

The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Ethyl Glucuronide, if present in the urine specimen below 500ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized Ethyl Glucuronide 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 Ethyl Glucuronide level exceeds 500ng/mL because it will saturate all the binding sites of anti-Ethyl Glucuronide antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, 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 cassette contains mouse monoclonal anti-ethyl glucuronide antibody-coupled particles and ethyl glucuronide-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. The test 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

ETG is not very stable in urine. After the urine is collected, the ETG will gradually degrade. The urine specimen containing ETG should be tested as soon as possible. In general, the specimen should be tested within 2 hours, and it must not be stored beyond 8 hours. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing. If you intend to send specimens for quantitative follow-up testing into the lab you should stabilize the urine (e.g. boric acid) beforehand. Do not use the stabilized specimen for the rapid test.

【MATERIALS】

Materials Provided

- Test cassettes
- Droppers
- Package insert

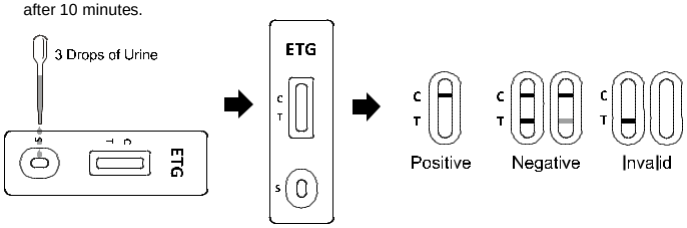
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx 120 μL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. 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 colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A negative result indicates that the Ethyl Glucuronide concentration is below the detectable level (500ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it 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). A positive result indicates that the Ethyl Glucuronide concentration exceeds the detectable level (500ng/mL).

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. If the problem persists, discontinue using the lot 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】

1. The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2]
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 ETG but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate ETG-free urine. Negative results can be obtained when ETG is present but below the cut-off level of the test.
6. Test does not distinguish between legal or illicit use of alcohol.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
Ethyl Glucuronide (ETG) Rapid Test Cassette	Results	Positive	Negative	
	Positive	83	1	84
	Negative	2	164	166
Total Results		85	165	250
% Agreement		97.6%	99.4%	98.8%

Analytical Sensitivity

A drug-free urine pool was spiked with ETG at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL, 750 ng/mL and 1,500 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Ethyl Glucuronide Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
250	-50%	30	30	0
375	-25%	30	26	4
500	Cut-off	30	15	15
625	+25%	30	3	27
750	+50%	30	0	30
1500	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Ethyl-β-D-Glucuronide	500
Propyl β-D-glucuronide	50,000
Morphine 3β-glucuronide	100,000
Morphine 6β-glucuronide	100,000
Glucuronic Acid	100,000
Ethanol	>100,000
Methanol	>100,000

Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Ethyl Glucuronide, 25% Ethyl Glucuronide above and below the cut-off, and 50% Ethyl Glucuronide above and below the 500ng/mL cut-off was provided to each site. The following results were tabulated:

Ethyl Glucuronide Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	8	2	9	1
625	10	1	9	2	8	2	8
750	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high and low specific gravity ranges were spiked with 250ng/mL and 750ng/mL of Ethyl Glucuronide. The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity (1.005-1.045) 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 4 to 9 in 1 pH unit increments and spiked with Ethyl Glucuronide to 250ng/mL and 750ng/mL. The spiked, pH-adjusted urine was tested with the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) in duplicate. The results demonstrated 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 Ethyl Glucuronide positive urine. The following compounds show no cross-reactivity when tested with the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) at a concentration of 100μg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Procaine
Acetone	Diphenhydramine	Meperidine	Promazine
Acetophenetidin	5,5-Diphenylhydantoin	Meprobamate	Promethazine
N-Acetylprocainamide	Disopyramide	d-Methamphetamine	l-Propoxyphene
Acetylsalicylic acid	Doxylamine	l-Methamphetamine	d,l-Propranolol
Albumin	Ecgonine	Methadone	d-Pseudoephedrine
Amitriptyline	Ecgoninemethylester	Methoxyphenamine	Quinacrine
Amobarbital	EMDP	(+)-3,4-Methylendioxy-	Quinidine
Amoxapine	Ephedrine	Methylphenidate	Quinine
Amoxicillin	l-Ephedrine	Mephentermine	Ranitidine
Ampicillin	l-Epinephrine	Metoprolol	Riboflavin
Ascorbic acid	(±)-Epinephrine	Meprobamate	Salicylic acid
Aminopyrine	Erythromycin	Morphine sulfate	Serotonin
Apomorphine	β-Estradiol	Methyprylon	(5-Hydroxytryptamine)
Aspartame	Estrone-3-sulfate	Nalidixic acid	Sodium chloride
Atropine	5,5-Diphenylhydantoin	Nalorphine	Sulfamethazine
Benzilic acid	Ethyl-p-aminobenzoate	Naloxone	Sulindac
Benzoic acid	Etodolac	Naltrexone	Sustiva (Efavirenz)
Benzphetamine	Famprofazone	α-Naphthaleneacetic acid	Temazepam
Bilirubin	Fentanyl	Naproxen	Tetracycline
Brompheniramine	Fluoxetine	Niacinamide	Tetrahydrocortexolone
Buspirone	Furosemide	Nifedipine	Tetrahydrocortisone,
Cannabinol	Gentisic acid	Nimesulide	3-acetate
Cimetidine	d-Glucose	Norcodeine	Tetrahydrozoline
Chloral hydrate	Guaiacolglyceryl ether	Norethindrone	Thebaine
Chloramphenicol	Hemoglobin	d-Norpropoxyphene	Thiamine
Chlordiazepoxide	Hydralazine	Noscapine	Thioridazine
Chloroquine	Hydrochlorothiazide	d,l-Octopamine	l-Thyroxine
Chlorothiazide	Hydrocortisone	Orphenadrine	Tolbutamide
(+)-Chlorpheniramine	o-Hydroxyhippuric acid	Oxalic acid	cis-Tramadol
(±)-Chlorpheniramine	p-Hydroxymethamphetamine	Oxazepam	trans-2-
Chlorpromazine	3-Hydroxytyramine	Oxolinic acid	Phenylcyclopropylamine
Chlorprothixene	(Dopamine)	Oxycodone	Trazodone
Cholesterol	Hydroxyzine	Oxymetazoline	Trimethobenzamide
Clomipramine	Ibuprofen	Oxymorphone	Triamterene
Codeine	Imipramine	Papaverine	Trifluoperazine
Cortisone	Iproniazide	Pemoline	Trimethoprim
(-)-Cotinine	(-)-Isoproterenol	Penicillin-G	Trimipramine
Creatinine	Isoxsuprine	Pentazocine	Tryptamine
Cyclobarbital	Kanamycin	Perphenazine	d,l-Tryptophan
Cyclobenzaprine	Ketamine	Phencyclidine	Tyramine
Deoxycorticosterone	Ketoprofen	Phenelzine	d,l-Tyrosine
R (-)Deprenyl	Labetalol	Pheniramine	Uric acid

Dextromethorphan	Levorphanol	Phenobarbital	Verapamil
Diazepam	Lidocaine	Phenothiazine	Digoxin
Diclofenac	Lindane	Phentermine	Lithium carbonate
Dicyclomine	(Hexachlorocyclohexane)	Prednisolone	l-Phenylephrine
Diflunisal	Loperamide	Prednisone	Procaine
4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Promazine
Acetone	Diphenhydramine	Meperidine	Promethazine
Acetophenetidin			

【BIBLIOGRAPHY】

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
2. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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