Rapid Ethylglucuronide (ETG) Test Cartridge Instruction Insert

Please read all the information in this Insert before performing the test.

Instruction of use for testing of Ethylglucuronide (ETG).
Rapid Ethylglucuronide (ETG) Test Cartridge is a rapid, screening test for the qualitative detection of Ethylglucuronide (ETG) in human urine at the cut off of 300ng/ml.
For in vitro diagnostic use only.
For Forensic use only.

INTENDED USE

Rapid Ethylglucuronide (ETG) Test Cartridge is an immuno-chromato graphic assay for the qualitative determination of the presence of Ethylglucuronide (ETG) at *the cut off of 300ng/ml.* . This assay provides only a preliminary analytical test 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 indicated.

SUMMARY

Ethyl Glucuronide (ETG)
Ethyl Glucuronide (ETG) is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of ETG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, ETG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The ETG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

PRINCIPLE

Rapid Ethylglucuronide (ETG) Test Cartridge is a competitive immunoassay that is used to screen for the presence of Ethylglucuronide (ETG) in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test Cartridge by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test cartridge. This produces a colored Test line in the Test Region (T) of the cartridge, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each cartridge, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Immunoassay for *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test Cartridge should remain in the sealed pouch until use.
- The used test Cartridge should be discarded according to local regulations.

CONTENTS OF THE KITS

- Drug Test Cartridge.
- Desiccant .
- Leaflet with instruction for use.

ADDITIONAL REQUIREMENTS

- A clean, dry, plastic or glass container to collect the urine.
- Timer (watch or clock)
- External controls

STORAGE AND STABILITY

- Store at 39 ~ 86 ºF (4 ~ 30 ºC) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

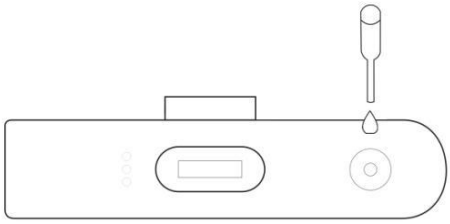
- Collect urine sample with a clean, dry container. Urine collected at any time of the day may be used.
- For best results, test specimens immediately following collection.
- Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
- Bring frozen or refrigerated samples to room temperature before testing.

HOW TO PERFORM THE TEST?

Test must be in room temperature (15°C to 30ºC)
1. Remove a Testing Device from the foil pouch by tearing at the notch and place it on a level surface.

2. Holding a sample dropper vertically, add 3 drops of the urine specimen to the sample well (with an arrow marked).

3. Read the result in five minutes. Positive results may sometimes appear as early as one minute but you should wait the full 5 minutes before determining a negative result.

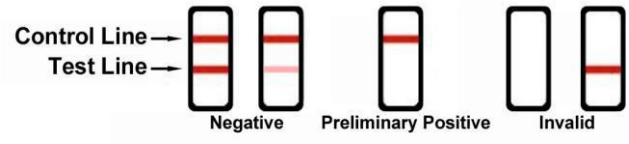


READING THE RESULTS

Preliminary positive (+)
A rose-pink band is visible in each control region. If no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.

Negative (-)
If a rose-pink band is visible in each control region and the appropriate test "T" region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid
If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid. Another test should opened and run to re -evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.



Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.
Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST "T" REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEAGATIVE RESULT.

***IMPORTANT*:** This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?
The definition of a false positive test would be an instance where a substance is identified incorrectly by Rapid Ethylglucuronide (ETG) Test Cartridge. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?
The definition of a false negative test is that the initial drug is present but isn't detected by Rapid Ethylglucuronide (ETG) Test Cartridge. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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.

QUALITY CONTROL

A procedural control is included in the test. A 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 practice to confirm the test procedure and to verify proper test performance. Quality control should be run with each new lot, and every 30 days to check storage stability. Positive and negative control should give the expected results.
Users can commercially obtain control materials (For example from Sigma-Aldrich Corporation).The concentration of drug(s) in positive and negative controls are approximately 50% above and below the cutoff concentration of the assay.

PERFORMANCE CHARACTERISTICS

Specificity and cross reactivity
To test the cross reactivity of the test, Rapid Ethylglucuronide (ETG) Test Cartridge was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Ethylglucuronide (ETG)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300

Interfering substances
Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine or drug positive urine containing ETG with the concentration 50% below the cutoff and the concentration 50% above the cutoff, respectively. All potential interfering substances were added at a concentration of 100μg/mL. The urine specimens were tested with Rapid Ethylglucuronide (ETG) Test Cartridge. None of the urine samples showed any deviation from the expected results.

Acetaminophen	Estrone-3-sulfate	Oxolinic acid
Acetophenetidin	Ethyl-p-aminobenzoate	Oxymetazoline
Amoxicillin	Erythromycin	Oxytetracycline
Ampicillin	Fenoprofen	Papaverine
Aspirin	Flucloxacillin	Penicillin-G
Atenolol	Fluoxetine	Pentazocine
Atorvastatin	Furosemide	Perphenazine
Azlocillin	Gentisic acid	Phenelzine
Benzilic acid	Hemoglobin	Prednisolone
Benzylpenicillin	Hydralazine	Prednisone
Benzoic acid	Hydrochlorothiazide	d,l-Propanolol
Bilirubin	Hydrocortisone	d-Pseudoephedrine
Benzydamine	o-Hydroxyhippuric acid	Quinacrine
Caffeine	p-Hydroxytyramine	Quinine
Carbamazepine	Ibuprofen	Quindine
Cephalexin	Indomethacin	Ranitidine
Chloralhydrate	Iproniazid	Salicylic acid
Chloramphenicol	d,l-Isoproterenol	Serotonin
Chlorothiazide	Isoxsuprine	Sulfamethazine
Chlorpheniramine	Ketamine	Sulindac
d,l-Chlorpromazine	Ketoprofen	Tetracycline
Cholesterol	Labetalol	Tetrahydrozoline
Clonidine	Lisinopril	Thiamine
Cimetidine	Loperamide	Thioridazine
Citalopram	Meperidine	d, l-Thyroxine
Cortisone	Meprobamate	Tolbutamine
Creatinine	Methoxyphenamine	Tolbutamide
Deoxycorticosterone	Methylphenidate	Trifluoperazine
Dexamethasone	Nadolol	Tryptamine
Dextromethorphan	Nalidixic acid	Uric acid
Diclofenac	Naproxen	Verapamil
Diflunisal	Niacinamide	Zomepirac
Digoxin	Nifedipine	
Diphenhydramine	Norethindrone	
Ephedrine	d,l-Octopamine	
β -Estradiol	Oxalic acid	

Effect of Urinary Specific Gravity
The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine containing ETG at 50% below and 50% above cutoff level. Each sample was tested by Rapid Ethylglucuronide (ETG) Test Cartridge. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary pH
The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with ETG at 50% below and 50% above cutoff levels. Each sample was tested by Rapid Ethylglucuronide (ETG) Test Cartridge. The result demonstrate that varying ranged of pH do not interfere with the performance of the test.

APPLICABLE STANDARDS

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002, EN ISO 13640:2002.

MANUFACTURED For

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INDEX OF SYMBOLS

	Consult instructions for use		Keep away from sunlight
	In vitro diagnostic for use		Keep dry
	Store between 4 ~ 30 ºC		Do not reuse

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