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Ethyl Glucuronide (ETG) Rapid Test Kit

QBL/ETG IFU/RPT_068

The Ethyl Glucuronide (ETG) Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Ethyl Glucuronide (ETG) in human Urine specimens.

CLINICAL SIGNIFICANCE

Ethyl Glucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidation following exposure to ethanol, such as by drinking alcoholic beverages. It is used as a biomarker to test for ethanol use and to monitor alcohol abstinence in situations where drinking is prohibited, such as in the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, in liver transplant clinics, or in recovering alcoholic patients. ETG can be measured in urine up to approximately 80 hours after ethanol is ingested. ETG is a more accurate indicator of the recent exposure to alcohol than measuring for the presence of ethanol itself.

The Ethyl Glucuronide 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 Rapid Test Strip (Urine) yields a positive result when the Ethyl Glucuronide in urine exceeds 500 ng/mL.

PRINCIPLE

The ETG Rapid Test (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.

KIT COMPONENTS

• Test Cassettes • Droppers • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

- The Ethyl Glucuronide (ETG) Test 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**.** Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. Hold the dropper vertically and transfer 2-3 drops of Urine using the dropper provided.
4. Wait for the colored line(s) to appear. Read results at 5 minutes. **Note**: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive Result	
Negative Result	

1) Positive
The control line is the only visible line on the test device. This is indicative of presence of ETG above 500 ng/ml

2) Negative
The control line and Test line is visible line on the test device. This no ETG detected or ETG below 500 ng/ml

3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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 ETG Rapid Test (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 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
Cutt off Value
The Ethyl Glucuronide (ETG) Test Kit can detect ETG as low as 500ng/ml.

Diagnostic Performance
A total of 140 normal human urine specimens were collected from human subjects and 4 positive control samples tested by Ethyl Glucuronide (ETG) Test Kit. These specimens were confirmed by commercially available kit. Comparison for all subjects is showed in the following table.

Commercial ETG Rapid Test Results	ETG Rapid Test		Total
	Positive	Negative	
Positive	4	0	4
Negative	2	138	140
Total	06	138	144

Relative sensitivity: 100%, Relative Specificity: 98.0%, Overall agreement: 98.57%

Precision
Between-run precision has been determined by 3 independent assays on the same 2 specimens: Three different lots of the ETG Rapid Test have been tested over a 3-days period using negative and positive specimens. The specimens were correctly identified >99% of the time

Specificity and cross-reactivity
The following substances were tested and confirmed did not interfere with Ethyl Glucuronide (ETG) Test at the listed concentrations.

Substances	Concentration
Glucose	2000 mg/dl
Human Albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/d

To evaluate the analog cross-reactivity of the devices, the target drug, drug metabolites and the same class compounds that may cross-react with the target drugs are tested by ETG rapid test.
All the compounds are added to drug-free urine at three different concentration levels. The final results are as following table. It displays the limits of detection for the specified drugs or their analog. Below these levels, the analog drugs show no cross-reactivity to target drugs.

Drugs	Concentration (ng/ml)
Oxazepam	300
Alprazolam	200
Hydroxyalprazolam	1,500
Bromazepam	1,500

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

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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