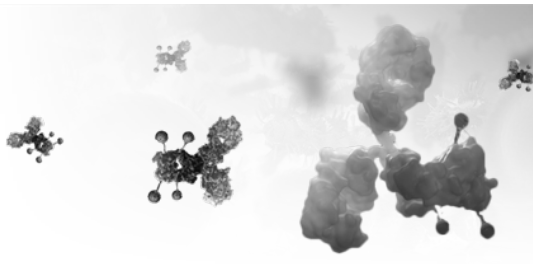

Ethyl Glucuronide Rapid Test (DTS-H089)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Intended Use

The EtG Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative presumptive detection of Ethyl Glucuronide in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-Off (ng/mL)
EtG	Ethyl Glucuronide	500

This assay provides only a preliminary result and is intended for professional use only. Clinical consideration and professional judgment must be applied particularly when evaluating a positive result. In order to obtain a confirmed analytical result a more specific alternate chemical method is needed. Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmation method.

General Description

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid. Alcohol in urine is normally detected for only a few hours, whereas EtG can be detected up to several days even after complete elimination of alcohol from the body. Therefore, EtG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.

Ethanol can be produced in vitro due to fermentation of urine samples containing sugars (diabetes), bacteria or yeast when samples are exposed to warm temperatures. In such cases, EtG test can be used, as a confirmatory test to determine if the alcohol in the sample is due to consumption of alcohol or it is formed in vitro as a result of fermentation. Currently EtG is monitored by GC/MS and LC/MS/MS.

Ethyl glucuronide (EtG) is a minor non-oxidative metabolite of ethyl alcohol formed by the in vivo conjugation of ethanol with glucuronic acid with UDP glucuronosyl transferase. ETG is a product of metabolic process of Ingested alcohol (ethanol) rapidly metabolized in the body, which is excreted in the blood, hair and urine. By using the ETG Rapid Test Device EtG can be detected in urine, confirming the consumption of alcohol. The EtG metabolite remains in the body longer and therefore has a more useful window of detection of 8 to 80 hours. EtG testing is an excellent option for zero-tolerance alcohol consumption or for rehabilitation programs.

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Reagents And Materials Provided	Reagents Each test consists of a reagent strip mounted in a plastic housing. The amount of each antigen and/or antibody coated on the strip 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 Provided 25 individually wrapped test devices. The test device consists of a test cassette containing a reagent test strip. Each reagent strip contains a membrane with two attached absorbent pads. The upper pad acts as a reservoir for the specimen after it migrates through the membrane.
Materials Required But Not Supplied	1. Timer. 2. Specimen collection container. 3. External positive and negative controls.
Storage	1. The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch. 2. The test must remain in the sealed pouch until use. 3. Do not freeze. 4. Kits should be kept out of direct sunlight.
Specimen Collection And Preparation	1. The EtG Rapid Test Device (Urine) is intended for use with human urine specimens only. 2. Urine collected at any time of the day may be used. 3. Urine specimens must be collected in clean, dry containers. 4. Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing. 5. 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. 6. 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. 7. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
Assay Procedure	1. Bring tests, specimens, and/or controls to room temperature (15-30°C) before use. 2. Do not open test device pouch until ready to perform the test 3. Remove the device from it sealed pouch label the test with patient or control identification and then remove the cap to expose the sampling tip. 4. Immerse the sampling tip in the urine specimen for about 15 seconds and then place the device on a flat surface with the cap on. 5. If all lines have formed (drug and control lines) the test results may be interpreted. Interpret the test results according to the description in section "Interpretation of test results". If all lines have formed, i.e. both test valid lines and all drug lines, the test results may be interpreted as negative. If one or more of the drug lines have not formed, read the results in the 5th minute. Results are stable for 2 hours.

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.

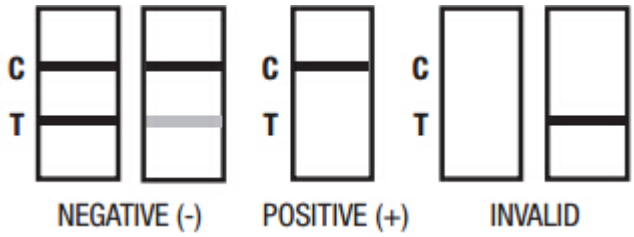
External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

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). Any line, without regard to intensity, colour or size, is a line and indicates a negative result for that drug.

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.



Performance Characteristics

A. Accuracy

The accuracy of the EtG Rapid Test Device was evaluated in comparison to a commercially avaialbe EIA Test. Five Hundred (500) clinical samples were tested. All positive samples were confirmed by Liquid Chromatography/Mass Spectrometry.

Results		Premier Biotech EtG Rapid Test		Total
		Positive	Negative	
Confirmed by EIA	Positive	48	2	50
	Negative	6	444	450
Sensitivity		96% (48/50)		
Specificity		98.67% (444/450)		

B. Reproducibility

The reproducibility of the EtG Rapid Test Device (Urine) was verified by blind tests performed at four different locations. Samples with EtG concentrations at 50% of the cut-off were all determined to be negative, while samples with EtG 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 EtG concentrations at 50% of the cut-off yielded negative results, and controls with EtG concentrations at 150% of the cut-off yielded

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positive results.

D. Cross-reactivity

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

(-)-Ephedrine	Dextromethorphan	Methadone
(+)-Naproxen	Dextrorphan tartrate	Methanol
(+/-)-Ephedrine	Dopamine	Morphin-3-gluc-
4-Dimethyllaminoan-	erumalbumin	uronide
tiyrine	Erythromycin	Norbuprenorphin-
Acetaminophen	Ethanol	glucuronide
Acetone	Ethylenglycol	Oxalic Acid
Albumin	Furosemide	Penicillin-G
Alcohol	Glucose	Pheniramine
Amitriptyline	Glucose	Phenothiazine
Ampicillin	Glyceryl Ether Pseu-	Procaine
Ascorbinsaure	doephedrine	Protonix
Aspartame	Guaiacol	Quinidine
Aspirin	Hamstoff	Ranitidine
Benzocaine	Hemoglobin	Sertraline
Bilirubin	Ibuprofen	Trimeprazine
b-Phenylethyl-amine	Imipramine S	Tyramine
Butanol	Isoproterenol	Venlafaxine
Caffeine	Kochsalz	Vitamin C (Ascorbic
Chloroquine	Koffein	Acid)
Chlorpheniramine	Lidocaine	
Creatinine	Lsopropanol	

Precautions

1. For forensic and professional use only.
2. Follow proper handling and disposal procedures.
3. For best results use a timing device as instructed.
4. Do not use if foil pouch seal is not intact (seal broken, tears, holes, etc.)
5. Do not use if beyond the expiration date printed on the pouch. The expiration date is formatted as YYYY-MM, e.g. 2015 -12, means the kits should not be used after the end of December, 2015.
6. Do not reuse tests.
7. 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).
8. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
9. Read the entire procedure carefully prior to testing.
10. Humidity and temperature can adversely affect results.
11. Used testing materials should be discarded in accordance with local regulations.

References

1. Ethyl Glucuronide: An unusual Ethanol Metabolite in Humans. Synthesis, Analytical Data, and Determination in Serum and Urine. Schmitt G., et al. Journal of Analytical Toxicology. 1995, 19:91-94.
2. Comparison of Urinary Excretion Characteristics of Ethanol and Ethyl Glucuronide. Dahl H., et al. Journal of Analytical Toxicology. 2002, 26:201-204.

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3. Ethyl Glucuronide- the direct ethanol metabolite on the threshold from science to routine use. Wurst FM et al. Addiction. 2003, 98 (S2) 51-61.

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