One Step Ethyl Glucuronide (EtG) Urine Test

Catalog No. See Pouch Label

The One Step Ethyl Glucuronide (EtG) Urine Test is a rapid test for the qualitative detection of Ethyl Glucuronide in human urine at specified cut-off level.

For in vitro diagnostic use only. For forensic use only.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Calibrator	Cut-off level	Minimum detection time	Maximum detection time
EtG	500 ng/mL	2 hours	80 hours

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is only for storage purposes, and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

1. Store at 4ºC-30ºC (40ºF-86ºF) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

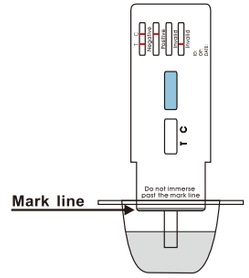
HOW TO COLLECT URINE?

1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at 2ºC-8°C (36ºF-47ºF) and stored up to forty-eight hours. For longer storage, freeze the samples at -20°C (-4ºF) or below.
2. Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well-mixed before analysis. Cloudy specimens should be centrifuged before analysis.
3. Use only clear aliquots for testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the “MAX” line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. Do not read after 5 minutes.



Note: *Results after more than 5 minutes may be not accurate and should not be read.*

READING THE RESULTS

Preliminary positive (+)

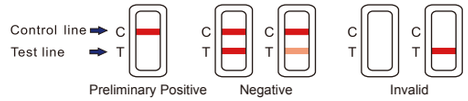
A rose-pink band is visible in the control region. No color band appears in the test region. It indicates a preliminary positive result for the EtG.

Negative (-)

A rose-pink band is visible in the control region and the test region. It indicates that the concentration of EtG is zero or below the detection limit of the test.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.



Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took alcohol and a negative test result does not always mean a person did not take alcohol. There are a number of factors that influence the reliability of EtG test.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample should be tested by a laboratory in order to determine if a EtG positive result is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by the One Step Ethyl Glucuronide (EtG) Urine Test. 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 alcohol intake is present but isn’t detected by the One Step Ethyl Glucuronide (EtG) Urine Test. If the sample is diluted, or the sample is adulterated that may cause 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 anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize the analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of EtG or the level of intoxication.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any EtG test result, particularly when the preliminary result is positive.

SUMMARY

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

The One Step Ethyl Glucuronide (EtG) Urine Test is a competitive immunoassay that is used to screen for the presence of ethyl glucuronide in urine. It is chromatographic absorbent device in which ethyl glucuronide in a sample competitively combined to a limited number of anti-EtG monoclonal antibody (mouse) conjugate binding sites.

When the test is activate, the urine is absorbed into the device by capillary action, mixes with the EtG monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample EtG levels are at zero or below the target cut off (the detection sensitivity of the test), anti-EtG monoclonal antibody (mouse) conjugate binds to the DTG-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample EtG levels are at or above the target cutoff, the free EtG in the sample binds to the EtG monoclonal antibody conjugate preventing the EtG monoclonal antibody conjugate from binding to the EtG-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 potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even though there is an internal procedural control line in the test device in the Control Region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the One Step Ethyl Glucuronide (EtG) Urine Test dip card. Each test was read by three viewers. Samples were divided by concentration into five categories: EtG-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	EtG-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	28	30
Negative	30	30	29	2	0

% agreement among positives is 98.3% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.8% (95% Confidence Interval 87.12% - 99.56%)

Viewer B:

Result	EtG-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	1	29	30
Negative	30	30	29	1	0

% agreement among positives is 98.3% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 98.9% (95% Confidence Interval 87.12% - 99.56%)

Viewer C:

Result	EtG-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)

Positive	0	0	2	29	30
Negative	30	30	28	1	0

% agreement among positives is 96.7% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 98.9% (95% Confidence Interval 87.12% - 99.56%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 97.7%
The average negative agreement is 98.5%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: +100%, +75% +50%, +25%, cut off, -25%, -50%, -75% and -100% of cutoff. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots. Total 3 operators participated in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 2

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	4/46
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 3

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	4/46
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Specificity

To test the specificity of the test, the test device was used to test EtG, alcohol metabolites and other components of the same class that are likely to be present in urine. All the components were added to EtG-free normal human urine. Test result of the One Step Ethyl Glucuronide (EtG) Urine Test is not affected when urinary PH range is at 3.0-8.5 and urinary specific gravity range is at 1.005-1.025.

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.005-1.025) are collected and spiked with EtG at 50% below and 50% above cutoff level. The One Step Ethyl Glucuronide (EtG) Urine Test was tested in duplicate. 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 3.0 to 8.5 in 1 pH unit increments and spiked with EtG at 50% below and 50% above cutoff levels. The One Step Ethyl Glucuronide (EtG) Urine Test was tested in duplicate. The result demonstrates that varying range of PH do not interfere with the performance of the test.

Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds show no cross-reactivity when tested with the One Step Ethyl Glucuronide (EtG) Urine Test at a concentration of 100 ug/ml.

Acetaminophen
Acid Reducer
Acyclovir
Advil
Aleve
Amiodarone HCl
Amlodipine mesylate
Amoxicillin
Ampicillin
Aripiprazole
Aspirin
Atorvastatin calcium
Atropine
Benadryl
Captopril
Carbamazepine
Cefaclor
Cephalexin
Cephradine
Ciprofloxacin HCl
Clarithromycin
Clopidogrel bisulfate
Clozapine
Cortisone
CVS
Dextromethorphan HBr
Diclofenac
Digoxin
Diphenoxylate HCl
Dirithromycin
Domperidone
Duloxetine
Enalapril maleate
Epinephrine HCl
Esomeprazole magnesium
Estrogen
Estroven
Fenofibrate
Fluoxetine HCl
Fluvoxamine
Fuel
Gabapentin
Glibenclamide
Gliclazide
Glipizide
Glucose
Haloperidol
Heartburn Relief
Hydrochlorothiazide
I Caps
Isosorbide esters
Ketoconazole
Lamotrigine
Lansoprazole
Levofloxacin
Levonorgestrel
Levothyroxine sodium
Lidocaine HCl
Lisinopril
Lithium Carbonate
Loratadine
Magnesium
Mega-T Plus
Metoprolol tartrate
Mifepristone
Mirtazapine
Montelukast sodium
Mosapride
Nifedipine
Nikethamide
Nimodipine
Nitroglycerin
Noscapine
Olanzapine
Omeprazole
Paliperidone
Papaverine
Paroxetine
Penfluridol
Penicillin V Potassium
Pethidine HCl
Pioglitazone HCl
Piracetam
Pravastatin sodium
Prednisone acetate
Propranolol HCl
Propylthiouracil
Pseudoephedrine HCl
Quetiapine
Ranitidine HCl
Rifampicin
Risperidone
Sertraline HCl
Sildenafil citrate
Simvastatin
Spironolactone
Tetracycline
Topiramate
Trazodone HCl
Triamterene
Valproate
Venlafaxine HCl
Vitamin B1
Vitamin B2
Vitamin C
Zencore Plus2

BIBLIOGRAPHY OF SUGGESTED READING

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Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.

McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

WHO, global status report on alcohol and health, 2014: Ethyl Glucuronide in Human Hair. Skopp, G., Schmiitt, G., Potsch, L., Dronner, P., Adderjan, R., & Mattern, R. (2000). Alcohol and Alcoholism, 35(3), 283-285.

Determination of Ethyl Glucuronide in Human Hair by SPE And LC– MS-MS. Janda, I., Weinmann, W., Kuehnle, T., Lahode, M., & Alt, A. (2002). Forensic Science International, 128, 59-65.

Comparison of Ethyl Glucuronide And Fatty Acid Ethyl Ester Concentrations in Hair of Alcoholics, Social Drinkers And Teetotalers
Yegles, M. (2004). Forensic Science International, 145(2-3), 167-173.
doi: 10.1016/j.forsciint.2004.04.032

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
www.nih.gov/about/almanac/organization/NIAAA.htm 301-496-4000

The National Council on Alcoholism and Drug Dependence www.ncadd.org
1-800-NCA-CALL

World Health Organization
www.who.int 41227912111

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4ºC - 30ºC (40ºF - 86ºF)


Keep dry


Do not re-use

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