UScreen™+

ETG Dual Use Single Panel Urine Dip

INSTRUCTIONS FOR USE

PLEASE READ ALL THE INFORMATION IN THIS INSERT BEFORE PERFORMING THE TEST.

REF See Box Label

INTENDED USE

ETG Dual Use Single Panel Urine Dip is a rapid urine screening test. It's a lateral flow, one-step immunoassay for the qualitative detection of Ethyl Glucuronide (ETG) in human urine at the cut-off level of 500 ng/mL.

This assay provides only a qualitative, preliminary analytical test result. A more specific analytical method must be used in order to obtain a confirmed 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.

It is intended for forensic use only.

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

ETG Dual Use Single Panel Urine Dip 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 antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When drug level in the sample is zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein 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 drug level in the sample is at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the 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 potentially positive result.

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

PRECAUTIONS

1. 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 result after 10 minutes.
7. The used dip card should be discarded according to local regulations.

STORAGE AND STABILITY

1. Store at 35℉ - 86℉ (2ºC - 30ºC) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. **DO NOT FREEZE.**
4. Preferably open the pouch only shortly before the test.

MATERIALS AND COMPONENTS

REAGENTS AND MATERIALS SUPPLIED

- ETG Dual Use Single Panel Urine Dip
- Instructions for use

MATERIALS NOT PROVIDED

- Dropper
- Urine collection cup
- Timer or stopwatch

SPECIMEN COLLECTION AND PREPARATION

Collect urine specimen with a urine collection cup. Urine specimens may be refrigerated at 35℉ - 46℉ (2ºC - 8ºC) and stored up to forty-eight hours. For longer storage, freeze the specimens at -4℉(-20°C) or below.
Bring frozen or refrigerated specimens to room temperature before testing. Use only clear aliquots for testing.

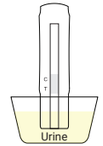
TEST PROCEDURE

Test must be in room temperature (59℉- 86℉ / 15°C - 30°C).

2 WAYS TO TEST:

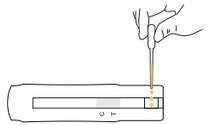
- Test as a dipcard:

1. Remove the ETG Dual Use Single Panel Urine Dip from the pouch and use it within the first hour after opening.
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. Dip the absorbent end into the urine specimen for about 10 seconds. Make sure that the urine level does not touch the plastic device.
4. Start the timer.
5. Re-cap and lay the device flat on a clean, dry, non-absorbent surface.
6. Read the result at 5 minutes. **Do not read after 10 minutes.**



- Test as a cassette:

1. Remove the ETG Dual Use Single Panel Urine Dip from the pouch and use it within the first hour after opening.
2. Place the device on a clean and level surface. Hold the dropper (not included in the box) vertically and transfer 3 drops of urine (approx. 80 µL) to the specimen well of the device.
3. Read the result at 5 minutes. **Do not read after 10 minutes.**



INTERPRETATION OF RESULTS

Preliminary Positive (+)
A color band is visible in the control region (C). No color band appears in the test region. It indicates the concentration of ethyl glucuronide is equal to or higher than the detection limit.

Negative (-)
A color band is visible in both the control region (C) and the test region (T). It indicates that the concentration of ethyl glucuronide is zero or below the detection limit.

Invalid
If a color band is not visible in the control region (C) or a color band is only visible in the test region (T), the test is invalid. Another test should be run to re-evaluate the specimen.

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

QUALITY CONTROL

Though there is an internal procedural control line in the test device of 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 control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug 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 drugs or the level of intoxication.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.

PERFORMANCE CHARACTERISTICS

A. Precision and Sensitivity

To investigate the precision and sensitivity, each drug samples were analyzed at the following concentrations: +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cutoff and -100% cutoff. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding drug of abuse test. Totally 3 operators participated in the study of the corresponding drug of abuse test. 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 of the corresponding drug of abuse test.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
ETG 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	15/35	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
ETG 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	13/37	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0

B. Specificity

The following table lists the concentration of compounds (ng/mL) above which the ETG Dual Use Single Panel Urine Dip identified positive results at a read time of 5 minutes.

Compound	Concentration (ng/mL)
Ethyl Glucuronide (ETG 300)	
Ethyl Glucuronide	300
Ethanol	>100,000
Glucuronic acid	>100,000
Methanol	>100,000
D-glucose	>100,000
Ethyl Glucuronide (ETG 500)	
Ethyl Glucuronide	500
Ethanol	>100,000
Glucuronic acid	>100,000

Methanol	>100,000
D-glucose	>100,000

C. Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with the following compounds. The following compounds show no cross-reactivity when tested with the ETG Dual Use Single Panel Urine Dip at a concentration of 100 µg/mL.

Aminopyrine	Lofexidine
Amoxicillin	Loperamide
Ampicillin	Maprotiline
Apomorphine	Meperidine
Aspartame	Meprobamate
Aspirin	Methadone
Atropine	Methoxyphenamine
Benadryl	Morphinie-3-b-d-glucuronide
Benzilic acid	N-Acetylprocainamide
Benzoic acid	Nalidixic acid
Benzoylecgonine	Naloxone
Bilirubin	Naltrexone
Cannabidiol	Naproxen
Captopril	Niacinamide
Chloralhydrate	Nifedipine
Chloramphenicol	Nitroglycerin
Chlorothiazide	Norcodeine
Chlorpromazine	Norethindrone
Chloroquine	Noscapine
Cholesterol	O-Hydroxyhippuric acid
Clarithromycin	Omeprazole
Clonidine	Oxalic acid
Codeine	Oxazepam
(-) Cotinine	Oxolinic acid
Cortisone	Oxymetazoline
Creatinine	Papaverine
Deoxycorticosterone	Penicillin V Potassium
Dextromethorphan	Penicillin-G
Diazepam	Pentobarbital
Diclofenac	Perphenazine

Diflunisal	Phencyclidine
Digoxin	Phenelzine
Diphenhydramine	Phenytoin
D L-Tryptophan	Pholcodine
D,L-Isoproterenol	Prednisone
D,L-Octopamine	Procaine
DL-Propranolol	Propranolol HCl
DL-Tyrosine	Quinine
D-Norpropoxyphene	Ranitidine
D-Propoxyphene	Ranitidine HCl
D-Pseudoephedrine	Salicylic acid
Dopamine HCl	Secobarbital
Doxepine	Serotonin (5-Hydroxytyramine)
Doxylamine	Sinus&Allergy
Ecgonine methyl ester	Sulfamethazine
β-Estradiol	Sulindac
Erythromycin	Tetrahydrocortisone3-(β-Dglucuronide)
Estrogen	Tetrahydrocortisone, 3-acetate
Fenoprofen	Tetrahydrozoline
Furosemide	Thiamine
Gentisic acid	Thioridazine
Hydralazine	Triamterene
Hydrochlorothiazide	Trifluoperazine
Hydrocodone	Trimethoprim
3-Hydroxytyramine	Tyramine
Hydrocortisone	Uric acid
I Caps	Venlafaxine HCl
Ibuprofen	Verapamil
Isoxsuprine	Zoloft
Ketamine	Zomepirac
Ketoprofen	

D. 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 or drug positive urine with the concentration at 50% below and 50% above cutoff level. The test device tested each sample. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

E. 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 each drug at 50% below and 50% above cutoff levels. Each sample was tested by the test device. The result demonstrates that varying range of pH do not interfere with the performance of the test.

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ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number ***404-574-6600*** (Monday – Friday 9:00 am – 5:00 pm, EST) or email to ***Sales@uscreentests.com.***

INDEX OF SYMBOL

	Consult instructions for use		Keep dry
	Store at 35℉ - 86℉ (2°C - 30°C)		Keep away from sunlight
	Use-by date	REF	Catalogue number
LOT	Batch code		Do not reuse
	Do not use if package is damaged		

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