D-ETG-12 ETG Test Dip Card (Urine)

INTENDED USE

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

Parameter	Calibrator	Cut-off (ng/mL)
ETG(Ethylglucoronide)	Ethylglucoronide	500

INTRODUCTION

Ethylglucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidationfollowing exposure to ethanol, such as by drinking alcoholic beverages. It is used as a biomarker to test for ethanol use and to monitor to document alcohol abstinence in situations where drinking is prohibited, such as by the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, liver transplant clinics, or in recovering alcoholic patients. In addition to its use to monitor abstinence and detect drinking ETG also has potential for monitoring amount of alcohol use over time because it can be detected in hair and nails.

PRINCIPLE

The ETG Rapid Test Dip Card (Urine) has been designed to detect ETG through visual interpretation of color development in the Dip Card. The membrane was immobilized with ETG conjugates on the test region, and the sample pad was pre-coated with colored anti-ETG antibodies colloidal gold conjugates. After specimens were added, the gold-conjugates move along the membrane chromatographically by capillary action and antibodies get to the test region. If there is no drug molecule in the urine the antibody gold conjugate would attach to the drug conjugate to form a visible line. Therefore, the formation of a visible precipitant in the test region occurs when the urine is negative for the drug. If ETG are present in the urine, the drug antigen competes with the immobilized drug conjugate on the test region for limited antibody sites. In case of sufficient concentration of the drug, it fills the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug conjugate zone on the test region. Therefore, absence of the colored band on the test region indicates a positive result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test consists of a reagent mounted in a plastic housing. The amount of each antigen and/or antibody coated on the Dip Card 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

Materials Provided

- Test Dip card
- Package insert

Materials Required but Not provided

- Positive and negative controls
- Timer
- Centrifuge

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch or canister is damaged. Do not reuse tests.
- 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).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30℃ until the expiry date printed on the sealed pouch or canister.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

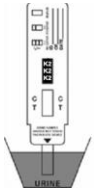
- The ETG Rapid Test Dip Card (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant 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℃ for up to 2 days. For long term storage, specimens should be kept below -20℃.
- 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.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30℃) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strip(s) of the test card vertically in the urine specimen for at least 10-15 seconds. Do not pass the arrow(s) on the test panel when immersing the panel. See the illustration below.
3. Place the test card on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T). A positive result indicates that the drug concentration exceeds the detectable level .

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). A negative result indicates that the drug concentration is below the detectable level .

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. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

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.

LIMITATIONS OF THE TEST

1. The ETG Rapid Test Dip Card (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of ETG.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a ETG only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of ETG in urine, as they may be present below the minimum detection level of the test.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the ETG Rapid Test Dip Card (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

B. Reproducibility

The reproducibility of the ETG Rapid Test Dip Card (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 positive results.

D. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the ETG Rapid Test Dip Card (Urine) identified positive results at 5 minutes.

ETG related compounds	Concentration (ng/ml)
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500

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

Acetaminophen	Digoxin	(+)-Naproxen
Acetophenetidine	Dihydrocodeine	Nifedipine
Acetylcodeine	(+)-cis-Diltiazem	Nimesulide
Acetylsalicylic acid	Dimenhydrinate	Nitrazepam
Alprazolam	4-Dimethylaminoantipyrine	Olanzapine
Amikacin	Diphenhydramine	Opipramol
Aminopyrine	DL-Tryptophan	Oxalic acid
Amitriptyline	DL-Tyrosine	Oxazepam
Amoxicilline	Dopamine	Oxymetazoline
Amphetamine	Doxepin	Pennicilline G
Ampicilline	Doxylamine	Perphenazine
Apomorphine	d-Propoxyphene	Pheniramine
Ascorbic acid	Ecgonine HCl	Phenothiazine
Aspartame	Ecgonine methylester	Phentermine
Atropine	Ephedrine	(+/-) Phenylpropanolamine
Baclofen	(+/-)Epinephrine	beta-phenylethylamine
Benzocaine	Erythromycine	Prednisolone
Bilirubin	Estron 3 sulfate	Prednisone
Bromazepam	Ethylmorphine	Phencyclidine
Buprenorphine	Etodolac	Procaine
Caffeine	Fenfluramine	Promazine
Cannabidiol	Fentanyl	Promethazine
Cannabinol	Flupentixol	Prothipendyl
Carbamazepine	Fluoxetine	Protriptyline
Chloramphenicol	Furosemide	Quetiapine
Chlordiazepoxide	Gastrozepin	Quinidine
Chloroquine	Gentamicin	Ranitidine
Chlorpheniramine	Gentisic acid	Rifampicine
Chlorprothixene	Guaiacol Glyceryl Ether	Risperidone
Cholesterol	Hemoglobin	Salbutamol
Chorptothixene	Hydralazine	Salicylic acid
Cimetidine	Hydrochlorothiazide	Secobarbital
Ciprofloxacin	Hydrocortisone	Sertraline
Citalopram	Ibuprofen	Spironolactone
Clindamycin	Imipramine	Sulfamethoxazole

Clobazam	(-)Isoproterenol	Sulindac
Clomipramine	Ketamine	Temazepam
Clonazepam	Ketoprofen	Thebaine
Clonidine	L - Thyroxine	Theophylline
Clorazepate	Lincomycin	Thiamine
Clozapine	Lidocaine	Thioridazine
Cocain	Loperamide	Tobramycin
Codein	L-Phenylephrine	Triamterene
(-)Cotinine	Maprotiline	Trimethoprim
Creatinine	Meperidine	Trimipramine
Cyclobenzaprine	Mephentermine hemisulfate salt	Tyramine
Delorazepam	Methadone	Vancomycin
Desipramine HCl	Methamphetamine	Venlafaxine
Dexamethasone	3,4-Methylenedioxyamphetamine	Verapamil
Dextromethorphan	3,4-Methylenedioxy-methamphetamine	Zolpidem
Diacetylmorphine	N-Methylephedrine	
Diazepam	Metoclopramide	
Diclofenac	Metoprolol	
Dicumarol	Metronidazole	
Diflunisal	MOR-3-Beta-D Glucuronide	
DL-Propanolol	Nalorphine	

LITERATURE REFERENCES

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4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical Dip Card		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE making according to IVD Medical Directive 98/97/EC		

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