Core tests® ETG Test Strip

For Professional Use
Specimen: Urine
Format: Strip

CE

INTENDED USE

ETG Test Strip is a lateral flow, one-step immunoassay for the qualitative detection of Ethyl glucuronide in human urine at a cut-off of 500 ng/mL. This product is used to obtain a visual, qualitative result and is intended for professional use. The assay should not be used without proper supervision and is not intended for over-the-counter sale to lay persons.

This assay provides only a preliminary analytical test result. 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 drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Ethyl glucuronide is a metabolite of ethanol which is formed in the body by glucuronidation following exposure to ethanol, usually from 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.

PRINCIPLE

ETG Test Strip is a one step immunoassay in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine for limited antibody binding sites. The test strip contains a membrane strip which was pre-coated with drug conjugate on the test band. A colored anti-Ethyl glucuronide monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of Ethyl glucuronide in the urine, the solution of colored antibody-colloidal gold conjugate and urine moves upward chromatographically by capillary action across the membrane. This solution then migrates to the immobilized Ethyl glucuronide-protein conjugate zone to form a visible line as the antibody complexes with the Ethyl glucuronide-protein conjugate. Therefore, the formation of a visible precipitant in the test band region occurs when the test urine is negative for the Ethyl glucuronide. When the Ethyl glucuronide is present in the urine, the drug/metabolite antigen competes with the drug-protein conjugate on the test band region for the limited antibody sites on the anti-Ethyl glucuronide antibody-colloidal gold conjugate. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the Ethyl glucuronide-protein conjugate zone on the test band region (T). Therefore, absence of the color band on the test region indicates a positive result.

A control band that has a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug of metabolite. This means that negative urine will produces two colored bands, and positive urine will produce only one band. The presence of this colored band in the control region also serves as verification that 1) sufficient volume has been added, and 2) that proper flow was obtained.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Timer.

STORAGE AND STABILITY

- ETG Test Strip should be stored at temperature 2-30˚C.
- Each strip should remain in its sealed pouch for the duration of the shelf-life.
- Shelf life: 24 months.

PRECAUTIONS

FOR IN-VITRO DIAGNOSTIC USE.
For professional use only.
Urine specimens may be potentially infectious. Proper handing and disposal methods should be established.
Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handing or pretreatment. After the specimen collection, the samples should be tested as soon as possible, preferably during the same day. The specimen may be refrigerated at 2-8˚C for 2 days or frozen at -20˚C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

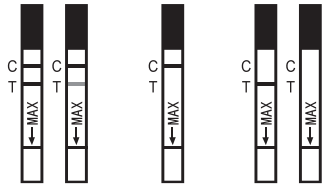
TEST PROCEDURE

Review “Specimen collection” instructions. Test strips, patient’s samples, and controls should be brought to temperature (15-30˚C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test strip from its protective pouch (bring the test to room temperature before opening the pouch to avoid condensation of moisture on the membrane), and label the strip with patient or control number.
2. Immerse the test strip in the urine sample with the arrow end pointing toward the urine. Do not immerse the strip above the printed MAX line. After a minimum of 10 seconds, remove the test strip from the urine and lay flat on a non-absorptive clean surface. Alternatively, the test strip may be left in the test sample, as long as the strip is not immersed above the MAX line. A separate test strip must be for each sample or control.

3. Read result between 3 to 8 minutes after the addition of samples. Do not read result after 10 minutes.

INTERPRETATION OF RESULTS



NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T).

NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

LIMITATIONS OF PROCEDURE

1. The assay is designed for use with human urine only.
2. A positive result with any of the tests indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
3. There is a possibility that technical or procedural errors as well other substances or factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
4. If it is suspected that the samples have been mislabeled or tampered with, a new specimen should be collected and the test should be repeated.

QUALITY CONTROL

Good Laboratory Practice recommends the use of control materials to ensure proper kit performance. Before using a new kit with patient specimens, positive and negative controls should be tested. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A drug-free urine pool was spiked with Ethyl glucuronide at the following concentrations: 0 ng/mL, 50 ng/mL, 250 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL and 1,500 ng/mL. The result demonstrates 100% accuracy at above and below the cut-off concentration. The data are summarized below:

Concentration (ng/mL)	n	Visual Result	
		positive	negative
0	50	0	50
50	50	0	50
250	50	0	50
500	50	50	0
750	50	50	0
1,000	50	50	0
1,500	50	50	0

Reproducibility

The study used three different lots of product. Each lot was tested for the samples of negative and cut-off concentration.The data are summarized below:

Concentration (ng/mL)	Lot A		Lot B		Lot C	
	-	+	-	+	-	+
0	100	0	100	0	100	0
500	0	100	0	100	0	100

Specificity

The specificity for ETG Test Strip was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds were found not to cross-react when tested at concentrations up to 100 μg/mL.

Acetaminophen	Chlorpromazine	Methamphetamine	Promethazine
Amitriptyline	Clonazepam	Methcathinone	Pseudoephedrine
Procaine	Clonidine	Midazolam	Ranitidine
Aspirin	Dezocine	Naloxone	Remifentanil Hydrochloride
Barbital	Diazepam	Naltrexone	
Berberine	Ephedrine	Norfloxacin	Secobarbital
Buprenorphine	Gatifloxacin	Oxazepam	Thebaine
Caffeine	Heroin	Papaverine	Theophylline
Cocaine	Imipramine	Pethidine	Tramadol
Codeine	Ketamine	Phenobarbital	Triazolam
Chloral hydrate	Lidocaine	Phenylpropanolamine	Zolpidem tartrate
Chlordiazepoxide	Morphine	Pholcodine	Methadone
Chlorpheniramine	$\triangle^9$-THC		

INDEX OF SYMBOLS

	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device	LOT	Batch code
2°C 30°C	Store at 2-30℃	CE	CE Mark
	Consult instructions for use		Manufacturer
EC REP	Authorized representative in the European Union		

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