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: 900 ng/mL
  - Minimum detection level: 200 ng/mL
  - Maximum detection level: 5000 ng/mL

STORAGE AND STABILITY
- **Material Required But Not Provided**
  - Urine collection cup
  - Timer or clock
  - Storage and Stability
    - Store at 4°C–30°C (40°F–86°F) in the sealed pouch up to the expiration date.
    - Keep away from direct sunlight, moisture and heat.
    - Do not freeze.

CONTENT OF THE KIT
- 1. Test devices, one test in one pouch. One pouch containing a test and a desiccant.
- **Leaflet with instructions for use.**
  - Timer or clock
  - Test devices, one test in one pouch. One pouch containing a test and a desiccant.
  - 1. Store at 4ºC-30ºC (40ºF-86ºF) in the sealed pouch up to the expiration date.
  - 2. Bring frozen or refrigerated samples to room temperature before testing. Previously
  - 3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure
  - 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.

WHAT IS A FALSE POSITIVE TEST?
The definition of a false positive test is that the alcohol intake is present but isn’t detected

WHAT IS A FALSE NEGATIVE TEST?
The definition of a false negative test is that the alcohol intake is present but isn’t detected

TEST LIMITATIONS
- 1. This test has been developed for testing urine samples only. No other fluids have
- 2. Adlerutuated urine samples may produce erroneous results. Strong oxidizing agents
- 3. This test is a qualitative screening assay. It is not designed to determine

WARNINGs AND PRECAUTIONS
- 1. This kit is for external use only. Do not swallow.
- 2. Discard after first use. The test cannot be reused more than once.
- 3. Do not use test kit beyond expiration date.
- 4. Do not use the test 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 test is for in vitro diagnostic use.

MATERIAL REQUIRED BUT NOT PROVIDED
- **Urine collection cup**
- **Timer or clock**

SPECIMEN COLLECTION AND PREPARATION
**HOW TO COLLECT URINE?**
- 1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at
- 2. Bring frozen or refrigerated samples to room temperature before testing. Previously
- 3. Use only clear aliquots for testing.

READ THE RESULTS

- **Preliminary Positive (+)**
  - A rose-pink band is visible in the control region. No color band appears in the test region. It
  - **Negative (-)**
  - A rose-pink band is visible in the control region and the test region. It indicates that the
  - **Invalid**
  - If a color band is not visible in the control region or a color band is only visible in the

TEST PROCEDURE
- 1. Open the sealed pouch by tearing along the notch. Remove the test device from the
- 2. Hold the one side of the device with one hand. Use the other hand to pull out the
e and expose the absorbent end.
- 3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure
- 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.

QUALITY CONTROL
Users should follow the appropriate federal, state, and local guidelines concerning the

PERFORMANCE CHARACTERISTICS

Accuracy
- Eighty clinical urine specimens were analyzed by GC-MS and by the One Step Ethyl Glucuronide (EtG) Urine Test. Each test was read by three viewers. Samples were diluted, if necessary, before testing. GC-MS, less than half the cutoff.

SUMMARY
Ethyl Glucuronide (EtG) is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol 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 can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EIG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EIG 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

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

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

4. Lay the device flat on a clean, dry, non-absorbent surface.
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1. Open the sealed pouch by tearing along the notch. Remove the test device from the

<table>
<thead>
<tr>
<th>Result</th>
<th>EtG-free</th>
<th>Less than half the cutoff concentration by GC/MS analysis</th>
<th>Near Cutoff Negative (Between the cutoff and 50% above the cutoff concentration)</th>
<th>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</th>
<th>High Positive (greater than 50% above the cutoff concentration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>Negative</td>
<td>30</td>
<td>30</td>
<td>29</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

% agreement among positives is 95.3% (95% Confidence Interval 91.24% - 100%)
% agreement among negatives is 97.8% (95% Confidence Interval 91.72% - 99.56%)

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

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3. Use only clear aliquots for testing.

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The average negative agreement is 98.5% and the average positive agreement is 97.7%.

From the results of the above tables, the total results are showed as below:

- % agreement among negatives is 98.9% (95% Confidence Interval 87.12% - 99.56%)
- A total of 50 determinations per concentration per lot.
- 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.
- All concentrations were confirmed with GC-MS. The study was performed 2 runs/day and varied ranges of urinary specific gravity range is at 1.005-1.025.
- 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 SIG at 50% below and 50% above cutoff levels. 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 SIG 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 SIG at 50% below and 50% above cutoff levels. The One Step Ethyl Glucuronide (EtG) Urine Test was tested in duplicate. The results demonstrate 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 ng/mL:

- Adefovir
- Aplidine
- Amantadine
- Amodiaquine
- Aripiprazole
- Asparagine
- Atazanavir
- Atorvastatin calcium
- Azathioprine
- Baricitinib
- Bazedoxifene
- Benazepril
- Benzydamine
- Benzhexol
- Benzlohydroxocaine
- Benznidazole
- Betaxolol
- Betamethasone
- Betaxolol hydrochloride
- Bilirubin
- Bimatoprost
- Biric定
- Blisatide
- Bromocriptine
- Buprenorphine
- Busulfan
- Butorphanol tartrate
- Cabazitaxel
- Cabergoline
- Caffeine
- Calcitonin
- Calcipotriol
- Calcipotriol B 0.005%
- Calcipotriol B 0.05%
- Calcipotriol B 0.5%
- Calcipotriol B 1%
- Calcipotriol B 5%
- Calcipotriol B 10%
- Calcipotriol B 20%
- Calcipotriol B 50%
- Calcipotriol B 100%
- Calcipotriol B 200%
- Calcipotriol B 500%
- Calcipotriol B 1000%
- Calcipotriol B 2000%
- Calcipotriol B 5000%
- Calcipotriol B 10000%
- Calcipotriol B 20000%
- Calcipotriol B 50000%
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