

# Ethanol-Based Hand Sanitizing Gel Vapor Causes Positive Alcohol Marker, Ethylglucuronide (EtG), and Positive Breathalyzer

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## Abstract (Word count 298)

Context: Ethylglucuronide (EtG), a minor metabolite of alcohol, is an important new marker that can detect alcohol use for several days or more after alcohol itself leaves the body. The test has rapidly gained widespread use where alcohol abstinence is desirable (e.g. in health professional monitoring programs, alcohol treatment programs, high schools, criminal justice settings, liver transplant clinics etc). As with any new test, it is important to understand its limitations, especially, it turns out, regarding non-beverage sources of alcohol that can affect EtG levels. We describe a case and follow-up studies in which ethanol-based hand sanitizing gel (EthGel) caused elevated EtG levels for a pharmacist who disputed disciplinary actions by her licensing board.

Objective: To document that EthGel causes elevated EtG levels and to identify the route of absorption. Design, Setting, Participants:

Following discovery of the index case in 2004, twenty-four subjects were tested for EtG before and 30min and 6 hours after exposure to EthGel in four groups: controls, skin exposure only, vapor exposure only, and both skin and vapor exposure. Breathalyzer was used to measure breath alcohol levels. Results: EthGel caused elevated EtG and breathalyzer primarily from alcohol vapor. For "Skin Only", "Vapor Only", and "Both" Groups the mean EtG levels at 30 min were 42ng/ml (range 0-102ng/ml), 106ng/ml (18-328ng/ml), and 176ng/ml (0-348ng/ml) respectively. Breathalyzer levels of .01-.02gm% persisted for up to 40-60min in subjects with who had high EtG levels.

Conclusion: EthGel exposure, particularly inhalation of fumes, caused positive EtG levels. Subjects being monitored with EtG testing should be warned to avoid products containing alcohol, including fumes from EthGel and similar compounds. Further studies should be conducted to

better quantitate the amount of ethanol absorbed from EthGel to determine if frequent use, particularly in poorly ventilated areas, might cause toxicity, especially for fetuses, where zero tolerance to alcohol is desirable.

#### Introduction:

Ethylglucuronide (EtG) is a non-oxidative metabolite of ethyl alcohol that has recently gained widespread use in monitoring alcohol abstinence. Depending on the amount of alcohol consumed, EtG can detect alcohol use for several days or more after alcohol leaves the body. It has rapidly gained widespread use in professional monitoring programs, alcohol treatment programs, schools, criminal justice settings, liver transplant clinics and other situations where alcohol abstinence is desirable. Shortly after the test became commercially available in the United States in 2003, concerns arose regarding "false positive" tests due to incidental exposure to non-beverage alcohol. The situation is similar to that of poppy seeds that can cause positive tests for morphine. As with any new test, it is important to understand its limitations and identify non-beverage sources of alcohol (e.g. mouthwash, foods, over-the-counter cough and cold meds, etc) that might cause positive EtG levels.

In 2004 two of the authors (Skipper and Liepman) were contacted by health professionals who claimed they'd tested positive in the absence of alcohol consumption, suspecting their positive EtG tests had resulted from frequent use of ethanol-based hand sanitizing gel (EthGel) at work. One of the health professionals, a pharmacist, was willing to undergo testing and was admitted to an addiction treatment center for a trial exposure to EthGel.

EthGels have become ubiquitous in hospitals, homes, schools, prisons, nursing homes, daycare centers, and even gas stations or grocery stores. The frequent use of EthGel is strongly encouraged by agencies such as the US Center for Disease Control to prevent spread of infections.<sup>1</sup> A search of the internet showed 14 name brand EthGel products containing 60% or higher content of ethanol. Surprisingly, little has been reported about potential absorption, abuse, or possible toxicity from these products.

Acceptance of the use of EthGels has been remarkable. One hospital report describes a 4% to 29% increase in the use of EthGel for hand cleansing between 2001 and 2004.<sup>2</sup> According to another report, 440,000 uses of the gel were counted in the first year of its

introduction alone.<sup>3</sup> Some nurses, particularly those in neonatal intensive care units, report using EthGels up to 50 or more times per shift.<sup>4</sup> Numerous studies demonstrate the popularity<sup>5,6</sup> of EthGel use. It is well tolerated<sup>7</sup> and leads to lower infection rates in hospitals,<sup>8</sup> extended care facilities,<sup>9</sup> acute care facilities,<sup>10</sup> and has been correlated with decreased transmission of illness in homes,<sup>11</sup> less absenteeism in elementary schools,<sup>12</sup> and fewer upper respiratory-illness and absenteeism in university residence halls.<sup>13</sup> The only hazard mentioned in literature from regulatory agencies regarding these products relate to their flammability and fire hazard (Joint Commission and CDC).<sup>14, 15</sup> A recent study designed to assess possible human toxicity from EthGels concluded that such an occurrence was highly unlikely.<sup>16</sup> Unfortunately, they neglected to test for alcohol markers and did not specifically examine skin vs inhalation exposure.

Due to the growing use of EtG testing and concerns regarding “false accusations of drinking” the Substance Abuse and Mental Health Services Administration published an advisory in 2006 warning against over-reliance on positive tests as proof of drinking, especially if disciplinary or punitive action is being considered.<sup>17</sup>

It is known that ethanol is not readily absorbed through adult skin,<sup>18</sup> however, there is a case report of a 1-month old Italian infant who became lethargic and was found to have a blood alcohol of 0.362 g/dl following application of an umbilical cord stump dressing soaked in methylated alcohol (95% ethanol/5% methanol).<sup>19</sup> There is a single report of a subject who had a slightly elevated EtG following use of EthGel.<sup>20</sup> Another study showed no significant blood alcohol levels following use of EthGel.<sup>21</sup> One study, reported examining the effect of heavy exposure to EthGel (30 times per hr) and detected alcohol on the breath of 6 of 20 subjects (0.001 to 0.0025%) at 1 to 2 minutes post exposure and in the serum of 2 subjects 5 to 7 minutes post exposure. Another study demonstrated EtG levels as high as 713ng/ml following 8 uses of EthGel over an 8-hour period.<sup>22</sup> None of these studies, however, controlled for skin versus vapor exposure.<sup>23</sup>

Even minimal ethanol absorption, especially if recurrent, could present a concern for certain individuals. The Surgeon General’s Advisory on Alcohol Use in Pregnancy states, “No amount of alcohol can be considered safe during pregnancy.”<sup>24</sup> No warnings, however, have been issued for pregnant women to avoid use or exposure to EthGel.

## Method:

Testing Methods: Determination of EtG was performed by liquid chromatography-tandem mass spectrometry (LC-ESI-tandem MS) method by NW Toxicology. The breathalyzer was an Intoximeter™ Breathalyzer with lower level of detection at 0.001gm%.

Index Case: The index case, a pharmacist, was admitted to a secure residential alcohol treatment program where her possessions were searched and all potential items containing alcohol (hairspray, etc) were removed. On the first day, she was instructed to apply two squirts of 62% EthGel to her hands and forearms every hour for eight hours and on the following day every half hour for eight hours. Urine for EtG was obtained prior to beginning testing and at 7pm and 7am both days of exposure. Neither blood alcohol nor breathalyzer was tested.

Exposure study: A study was subsequently carried out, following IRB approval, utilizing 24 volunteer subjects, (inclusion/exclusion criteria: Age > 21, BMI < 25, not pregnant or lactating, had not consumed alcoholic beverages in the last 5 days, no skin lesions on hands, not sensitive to alcohol, and no history of alcoholism or drug addiction). Subjects were divided into 4 groups of 6 each including: controls (unexposed to EthGel), skin only exposure (EthGel on hands but inside a plexiglass box), vapor only exposure (subjects stood in bathroom with "both vapor & skin" exposure subjects but did not touch EthGel themselves), and "both vapor/skin" exposure (EthGel on skin with no recommendation regarding location of hands relative to face, in a 6x10x8, 540ft<sup>3</sup>, bathroom, a relatively closed space where vapor would be inhaled). All subjects using EthGel applied two squirts on their hands every 4 minutes for one hour. Blood alcohol concentrations, BAC, were measured by an Intoximeter™ Breathalyzer at baseline, 20, 40, and 60 and at 90 minutes after completion of exposure. Urine samples for EtG were collected at baseline, 30 minutes and 6 hours post exposure. All EtG results were from urine and were corrected to U100Creatinine standard to minimize the effect of variations in hydration ( $U100Creatinine EtG = 100 /Urine creatinine \times Urine EtG$ ). All urine samples were test for urine alcohol using an enzymatic test.

## Results:

Index Case: The pre-exposure EtG upon admission to the treatment program was negative (100ng/ml cutoff). Post exposure EtG levels

were positive: day 1, 7pm = 225ng/ml, and day 2, 7am = 441ng/ml and 7pm = 770ng/ml.

Exposure study: For this study, the lab provided EtG levels to the lower limit of detection. All urine alcohol tests were negative. The control group had negligible EtG levels throughout. All handgel exposed groups showed significant intersubject variability. "Both" and "Vapor only" group EtG levels were significantly higher than controls at 30 min ( $p=0.0044$ ) and at 6 hours post ( $p=0.0049$ ) exposure. (See Charts 1-4 for details)

Breathalyzer registered zero in controls and .01 in one subject in the "skin only" group at 20min, otherwise the "skin only" group registered zero throughout. All but one of the "Vapor Only" group registered .01 persisting for 40min post exposure and then returned to zero. One subject in the "Both" group registered .02 and the other five registered .01 that persisted for 40min otherwise all six of the "Both" Group subjects registered .01 persisting for 60min before returning to zero by 90min.

#### Discussion:

In 2004 when the index case was discovered, EtG testing was new, used only by a few professional monitoring programs in the USA. As concerns over possible "false positive" results were raised it became increasingly important to understand the effect of different sources of alcohol exposure. This became especially important since labs had asserted, in marketing materials, indisputable reliability of a positive EtG as proof of drinking.

Following documentation of findings in the index case, we proceeded to verify this phenomenon in other subjects and to determine whether absorption was from inhalation of vapor or through skin. It is known that vapor of alcohol can cause elevated ethanol levels. In many animal studies, use of alcohol vapor has been the preferred route of administration, due to the difficulty of orally administering alcohol to animals. In addition, a device for aerosolizing alcohol has been recently marketed for use in bars.<sup>25</sup> What has not been known is that use of EthGel, according to recommendations, produces enough ambient vapor to trigger positive tests for EtG.

This study has demonstrated that the breathing EthGel vapor caused positive EtG tests and elevation of breathalyzer levels for up to 60 minutes. The significantly elevated alcohol markers in urine following exposure to EthGel vapor are of particular concern to individuals in

monitoring programs where positive readings could result in sanctions such as loss or suspension of professional license, loss of child custody, return to jail, or uninsurability.<sup>26</sup>

The highest EtG value noted from EthGel exposure in our study was 770ng/ml in the index case, achieved after EthGel use every 30min for 8 hours. EtG levels appear to vary widely between subjects with similar exposure even when controlled for dilution, suggesting that some individuals either absorb more ethanol or produce more EtG. It is not known whether actively avoiding inhalation of vapor from EthGel (i.e. holding hands away from the face) can prevent positive tests. This might be the case since most absorption appears to be from inhalation rather than skin absorption.

#### Conclusion:

Use of EthGel, in accordance with product literature causes positive urine EtG levels, primarily from inhalation of vapor. Further investigation is warranted to assess the potential public health hazard of frequent or prolonged use of EthGels, as occurs in some professions (e.g. nurses in neonatal intensive care units, etc), especially if exposure involves pregnant women, where repeated small exposures could threaten fetal health and development.

While the maximum achievable levels of EtG from EthGel exposure is unknown, in our study the highest recorded level was 770ng/ml. It will likely prove difficult to establish a clear cutoff that distinguishes between drinking and incidental exposure to alcohol due to the plethora of products containing alcohol and the multiple and highly varied exposures they could produce.

In consideration of the above, it is recommended that EtG be utilized primarily as a screening tool for recent drinking. When used properly the test remains useful and fair. In our experience up to half of all positive EtG tests are associated with the patient's admission of drinking. However, if when confronted the patient denies drinking when confronted it is suggested that one or more of the following be considered: 1. Continue observation and close monitoring. 2. Obtain further intensive evaluation from an addiction medicine provider (potentially involving in-depth history and the questioning of collateral sources of information about the patient's drinking, etc.), 3. Corroborate further drinking episodes by adding an additional "confirmatory" method of alcohol use detection, such as wearing a transcutaneous alcohol sensing device, recently shown to be

accurate,<sup>27</sup> and/or 4. In safety sensitive situations consider administering disulfiram for enhanced prevention of drinking behavior.

While all laboratory tests have potential for false positives and many drug tests the potential for “incidental exposure” (i.e. poppy seeds, hemp oil, coca tea, etc) the presence of ethyl alcohol in so many products presents a dilemma. Patients being monitored using EtG should be warned to avoid incidental alcohol exposure, and should be provided a list of products to avoid.<sup>28</sup> Because of the multitude of products containing alcohol, it is unrealistic, however, to expect monitoring program participants to completely avoid all incidental exposure to alcohol

While EtG testing remains a valuable tool for early detection and deterrence of drinking it is important to be cautious by acknowledging its limitations, especially in forensic settings where a positive test can have serious consequences. Further naturalistic studies in larger populations are urgently needed to better understand the reliability of EtG and similar tests and produce better guidelines for their proper use.

Chart 1: Effect of Handgel on EtG – “Skin Only”  
Group

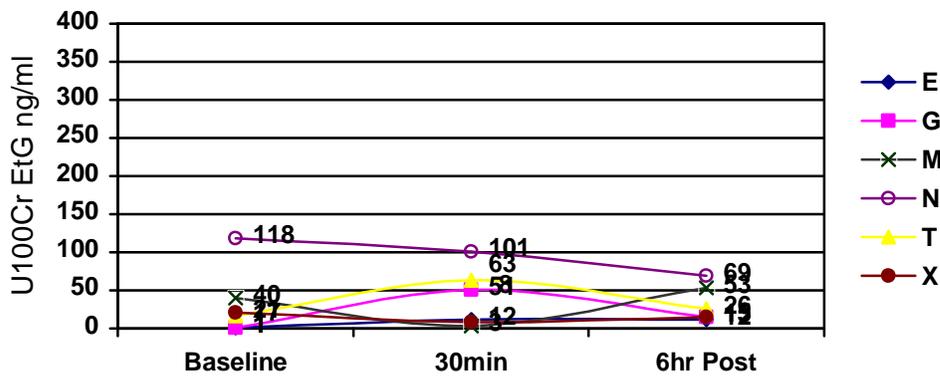


Chart 2: Effect of Handgel on EtG – “Vapor Only”  
Group

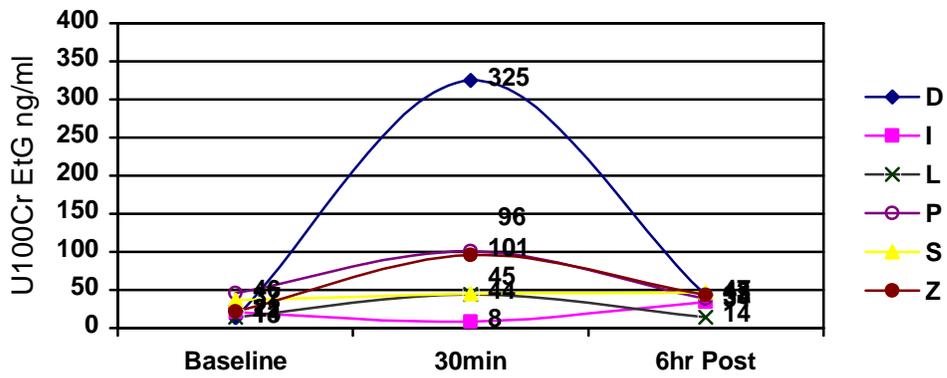


Chart 3: Effect of EthGel on EtG - Both "Skin and Vapor"

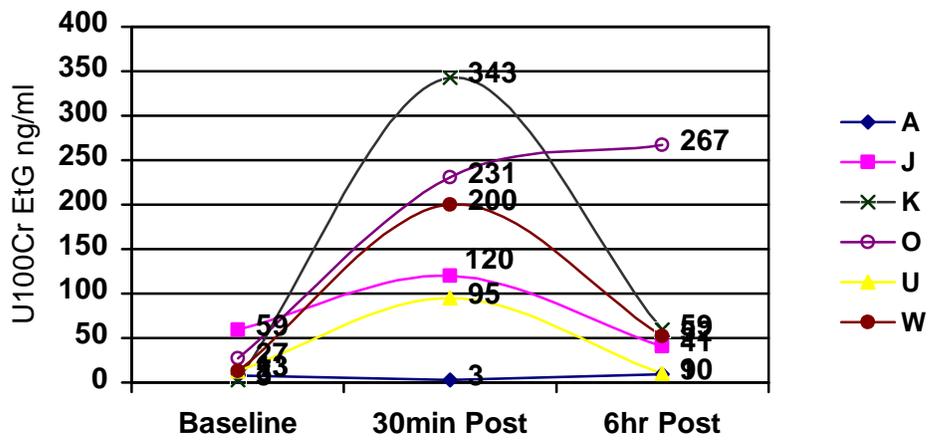
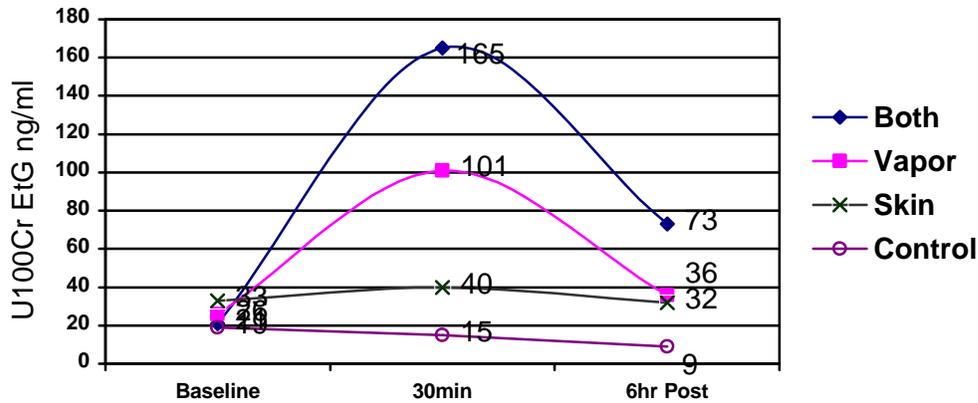


Chart 4: Grouped Mean Data – Effect of Handgel on EtG



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