The Use of EtG & EtS Monitoring in Drug Court

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Current alcohol testing issues:

- “legal” drug - without prescription
- screening tests specific for ethanol, ethyl alcohol
- urine, blood, saliva or breath
- positive results indicate presence alcohol
- alcohol is rapidly cleared from the body
- negative results don’t necessarily document abstinence
- detection time = hours
- transdermal detection - SCRAM

Problems Associated with Monitoring Clients for Alcohol

- short detection window (hours)
- current specimens:
  - blood (invasive)
  - urine (tampering issues)
  - breath/saliva (for best results requires on-site field visits)
- urine - fermentation

Promise of EtG/EtS Testing

Alcohol is the most commonly abused substance by drug court clients yet the most difficult substance to detect via abstinence monitoring when attempting to detect alcohol.

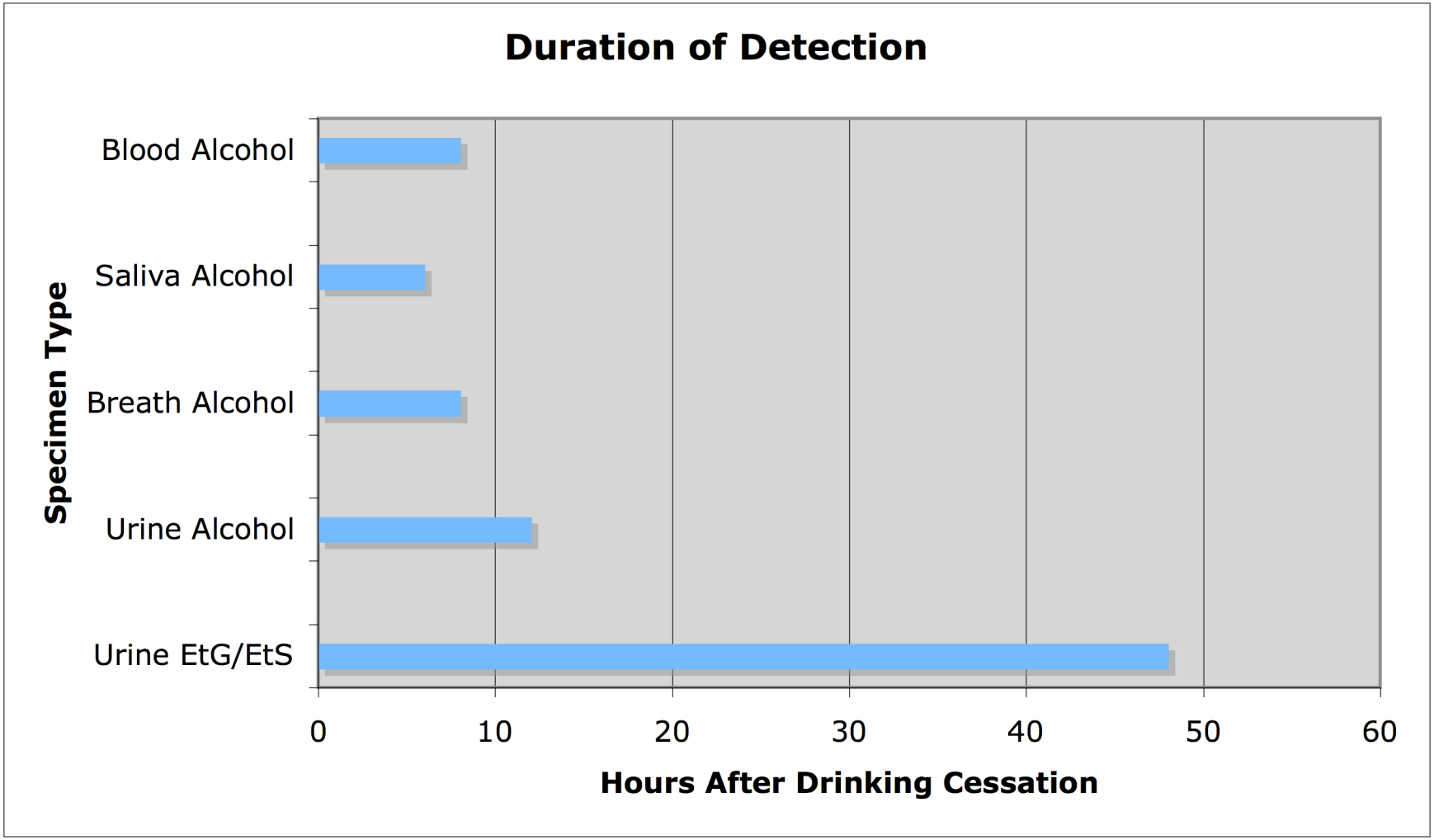
EtG = ethyl glucuronide

EtS = ethyl sulfate

Advantages of EtG & EtS

- unique biological marker of alcohol use (no false positives)
- direct marker indicating recent use
- longer detection window than alcohol
- stable in stored specimens (non-volatile)
- is not formed by fermentation
- is not detected in the urine of abstinent subjects

Extending the detection window



EtG/EtS Testing is Specific

- numerous types of “alcohol”
- isopropanol, isopropyl alcohol (“rubbing alcohol”)
- methanol, methyl alcohol
- acetone (nail polish remover)
- beverage alcohol is ethyl alcohol (ethanol)
- EtG/EtS testing is specific for the alcohol in alcoholic beverages

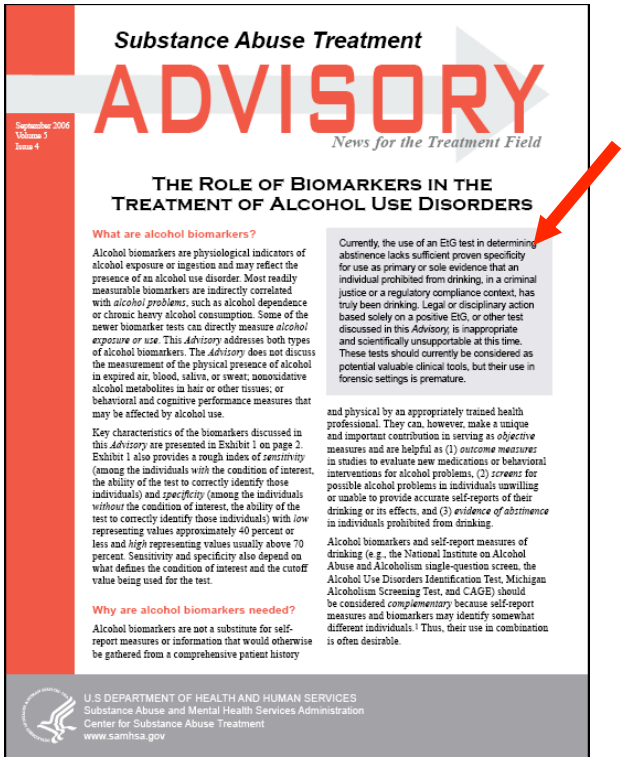
Disadvantages of Ethyl Glucuronide

- testing available at relatively few laboratories
- EtG/EtS testing more costly than abused drugs
  - expensive LC/MS/MS technology
- not a quantitative determination

- most significant concern – casual, inadvertent, environmental alcohol exposure causing positive results

A bit of history:

September 25, 2006, the U.S. Department of Health and Human Services released an advisory from the Center for Substance Abuse Treatment (CSAT) entitled:
The Role of Biomarkers in the Treatment of Alcohol Use Disorders



Substance Abuse Treatment

ADVISORY

News for the Treatment Field

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THE ROLE OF BIOMARKERS IN THE TREATMENT OF ALCOHOL USE DISORDERS

What are alcohol biomarkers?

Alcohol biomarkers are physiological indicators of alcohol exposure or ingestion and may reflect the presence of an alcohol use disorder. Most readily measurable biomarkers are indirectly correlated with *alcohol problems*, such as alcohol dependence or chronic heavy alcohol consumption. Some of the newer biomarker tests can directly measure *alcohol exposure or use*. This *Advisory* addresses both types of alcohol biomarkers. The *Advisory* does not discuss the measurement of the physical presence of alcohol in expired air, blood, saliva, or sweat; nonoxidative alcohol metabolites in hair or other tissues; or behavioral and cognitive performance measures that may be affected by alcohol use.

Key characteristics of the biomarkers discussed in this *Advisory* are presented in Exhibit 1 on page 2. Exhibit 1 also provides a rough index of *sensitivity* (among the individuals *with* the condition of interest, the ability of the test to correctly identify those individuals) and *specificity* (among the individuals *without* the condition of interest, the ability of the test to correctly identify those individuals) with *low* representing values approximately 40 percent or less and *high* representing values usually above 70 percent. Sensitivity and specificity also depend on what defines the condition of interest and the cutoff value being used for the test.

Why are alcohol biomarkers needed?

Alcohol biomarkers are not a substitute for self-report measures or information that would otherwise be gathered from a comprehensive patient history

Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this *Advisory*, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature.

and physical by an appropriately trained health professional. They can, however, make a unique and important contribution in serving as *objective* measures and are helpful as (1) *outcome measures* in studies to evaluate new medications or behavioral interventions for alcohol problems, (2) *screens* for possible alcohol problems in individuals unwilling or unable to provide accurate self-reports of their drinking or its effects, and (3) *evidence of abstinence* in individuals prohibited from drinking.

Alcohol biomarkers and self-report measures of drinking (e.g., the National Institute on Alcohol Abuse and Alcoholism single-question screen, the Alcohol Use Disorders Identification Test, Michigan Alcoholism Screening Test, and CAGE) should be considered *complementary* because self-report measures and biomarkers may identify somewhat different individuals.[1] Thus, their use in combination is often desirable.

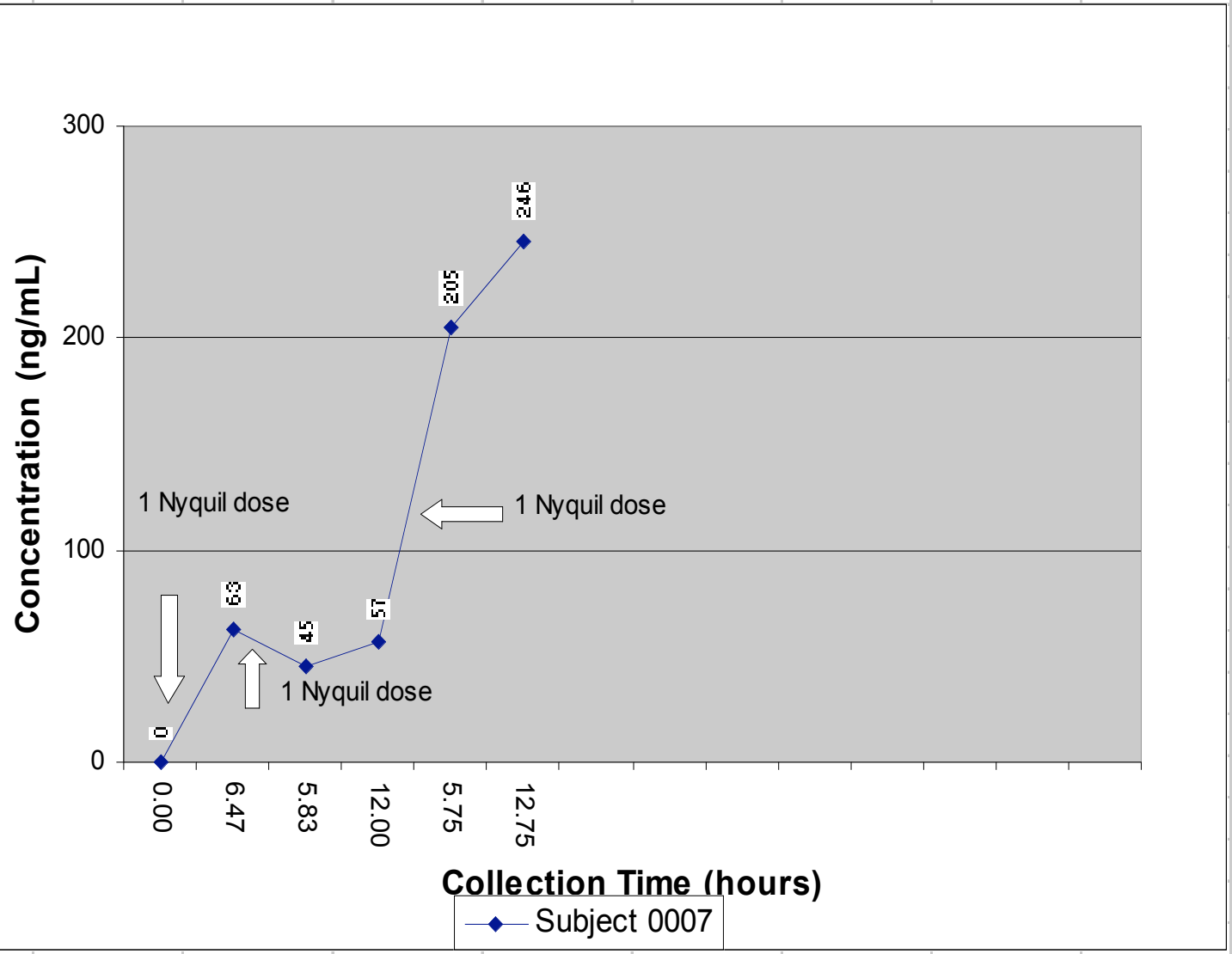
U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

"Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this Advisory, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature."

Sources of "Incidental" Alcohol Exposure

- OTC medications (Nyquil, Vicks 44) ←
- mouthwashes (Listermint, Scope, Cepacol)
- herbal/homeopathic medications (i.e., tincture of gingko biloba - memory)
- foods containing alcohol (such as vanilla extract, baked Alaska, cherries jubilee, etc.)
- "non-alcoholic" beers (O'Doul's, Sharps)
- colognes & body sprays
- insecticides (DEET)
- alcohol-based hand sanitizers (Purell, GermX)

Nyquil Dosing Study



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The Mouthwash Studies:

- mouthwash study (whole bottle) - highest EtG = one sample over 300 ng/mL - total of 39 samples
- mouthwash study (30 seconds, 3X per day, five days) - no EtG over 120 ng/mL - total of 55 samples
- mouthwash study (30 seconds, every hour for 8 hours) - highest EtG = 336 ng/mL EtS = 73 ng/mL
- mouthwash 27% (Listerine “original”) - 4 times daily - 4 days - highest EtG = 173 ng/mL, highest EtS = 104 ng/mL

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Alcohol in Food - Cook's Illustrated Study (2005) "A Few Sobering Thoughts"

- beef burgundy - three hours in oven, lid on, 40% alcohol retained

- flambé recipes - igniting brandy over high heat 29% alcohol retained - igniting brandy in cold pan 57% alcohol retained

Sources of "Incidental" Alcohol Exposure

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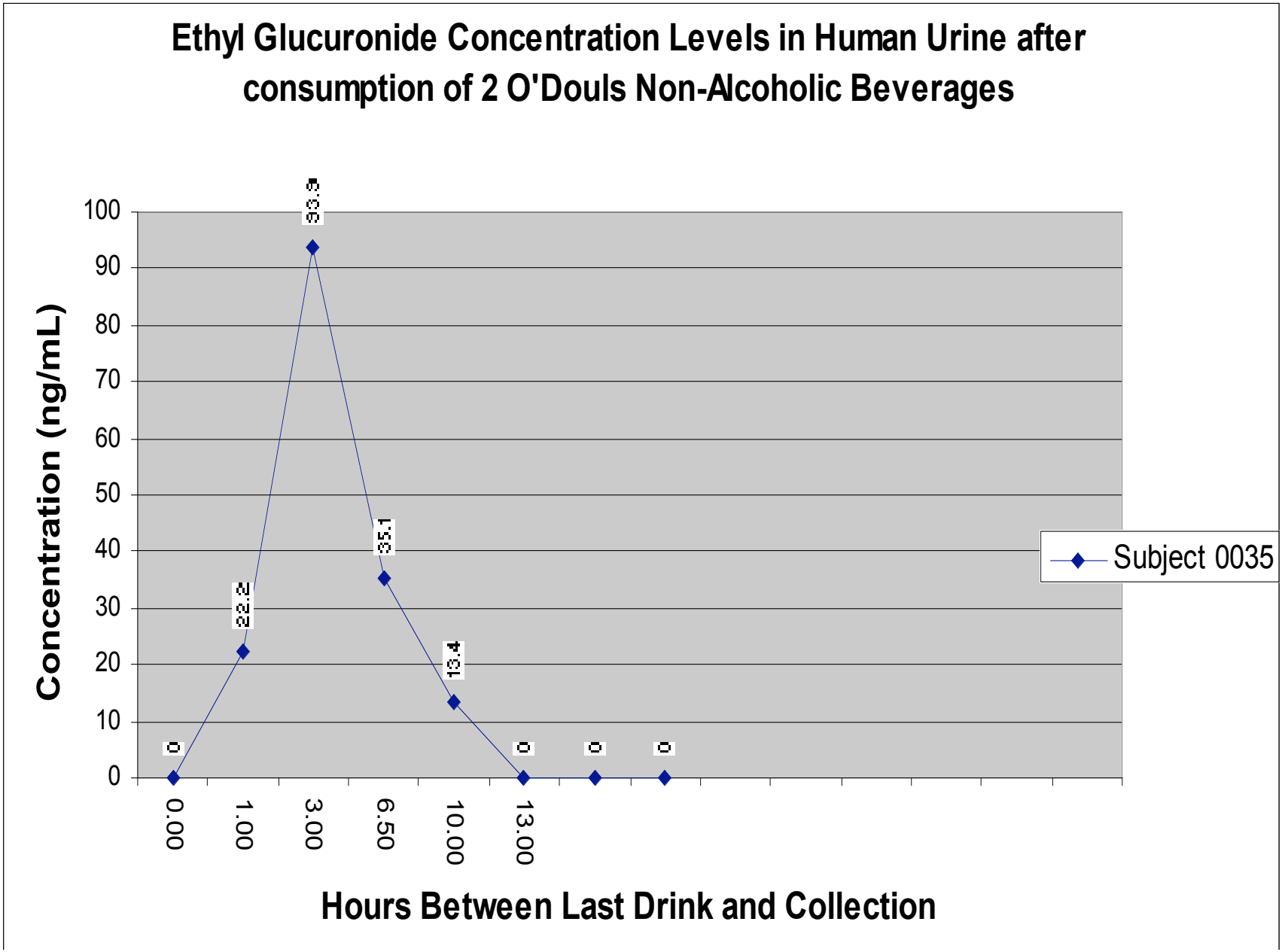
- "non-alcoholic" beers (O'Doul's, Sharps) ←
- colognes & body sprays
- insecticides (DEET)
- alcohol-based hand sanitizers (Purell, GermX)

AVERAGE ALCOHOL AND CALORIE CONTENT OF REGULAR, LIGHT, AND NON-ALCOHOLIC BEER

Product	No. samples	% Alcohol per 100 ml	Calories
Regular	163	5.0 [2.0-9.5]	43 [26-83]
Light	26	4.1 [2.4-5.4]	32 [19-43]
Non-alcoholic	13	**0.3 [0.1-0.7]**	17 [13-30]


Ethyl Glucuronide Concentration Levels in Human Urine after consumption of 2 O'Douls Non-Alcoholic Beverages
Concentration (ng/mL)
100
90
80
70
60
50
40
30
20
10
0
0
22.2
93.9
35.1
13.4
0
0
0
0.00
1.00
3.00
6.50
10.00
13.00
Hours Between Last Drink and Collection
Subject 0035

Sources of "Incidental" Alcohol Exposure

- OTC medications (Nyquil, Vicks 44)
- mouthwashes (Listermint, Scope, Cepacol)
- herbal/homeopathic medications (i.e., tincture of gingko biloba - memory)
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- "non-alcoholic" beers (O'Doul's, Sharps)
- colognes & body sprays
- insecticides (DEET)
- alcohol-based hand sanitizers (Purell, GermX)

The Hand Sanitizer Studies:

- hand sanitizer study (every 15 minutes , 8 hours) - highest EtG = 62 ng/mL
  - In closed room - one subject = 350 ng/mL of EtG
- hand sanitizer study (1X, every 8 hours) - highest EtG = 103 ng/mL EtS = 51 ng/mL
- NOTE: 11 subjects, 62% alcohol, every 5 minutes, for ten hours, for 3 consecutive days - highest EtG = 2001 ng/mL, EtS = 84 ng/mL

The Inhalation Study:

- 50 mL of ethanol into beaker, the beaker was swirled to wet the sides and promote vaporization, the beaker was held up to the nose and 1 deep respiration of vapor was performed
- every five minutes for one hour (X 12)
- inhalation study - highest EtG = 124 ng/mL EtS = 13 ng/mL

On May 20, 2012 . . .

Substance Abuse and Mental Health Services Administration

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Behavioral Health Is Essential To Health • Prevention Works • Treatment Is Effective • People Recover

The Role of Biomarkers in the Treatment of Alcohol Use Disorders, 2012 Revision

This *Advisory* is a revision of the 2006 *Substance Abuse Treatment Advisory,* The Role of Biomarkers in the Treatment of Alcohol Use Disorders. The revision was necessitated by increased scientific knowledge about alcohol biomarkers and requests from clinical and judicial professionals for greater clarification on the use of biomarkers. This *Advisory* reviews recent scientific biomarker data and discusses their relevance for clinical, medical, and forensic purposes. Potential strategies for the use and interpretation of biomarkers in varying circumstances such as clinical, criminal justice, and impaired healthcare provider settings are discussed. This *Advisory* does not discuss the measurement of the physical presence of alcohol in expired air, blood, or saliva; nonoxidative alcohol metabolites in hair or other tissues; or behavioral and cognitive performance measures that may be affected by alcohol use.

What are alcohol biomarkers?

Alcohol biomarkers are physiological indicators of alcohol exposure or ingestion and may reflect the presence of chronic and/or high level of use of alcohol. Most readily measurable biomarkers are indirectly correlated with *alcohol problems*, such as alcohol dependence. Some of the newer biomarker tests can directly measure *alcohol exposure or use*. Key characteristics of the biomarkers discussed in this *Advisory* are presented in Exhibit 1 (see page 2). Exhibit 1 also provides a rough index of *sensitivity* (the ability of the test to correctly identify those individuals *with* the condition of interest when used on an affected population) and *specificity* (the ability of the test to correctly identify those individuals among the individuals *without* the condition of interest). *Low* represents values approximately 40 percent or less and *high* represents values usually above 70 percent. Sensitivity and specificity also depend on what defines the condition of interest and the cutoff value being used for the test.

Why are alcohol biomarkers needed?

Alcohol biomarkers are not a substitute for self-report measures or information that would otherwise be gathered from a comprehensive patient history and physical by an appropriately trained health professional. They can, however, make a unique and important contribution in serving as *objective* measures and are helpful as (1) *outcome measures* in studies to evaluate new medications or behavioral interventions for alcohol problems; (2) *screens* for possible alcohol problems in individuals unwilling or unable to provide accurate self-reports of their drinking or its effects; and (3) *evidence of abstinence* in individuals prohibited from drinking.

Alcohol biomarkers and self-report measures of drinking, such as the National Institute on Alcohol Abuse and Alcoholism[1] single-question screen; Alcohol Use Disorders Identification Test;[2] Michigan Alcoholism Screening Test;[3] and CAGE[4] should be considered *complementary* because self-report measures and biomarkers may identify somewhat different individuals.[5] Thus, their use in combination is often desirable.

What are the categories of alcohol biomarkers?

Traditional alcohol biomarkers have generally been of an *indirect* nature because they suggest heavy alcohol consumption by detecting the toxic effects that alcohol may have had on organ systems or body chemistry.[6] Included in this class are the blood-based measures of gamma glutamyl transferase (GGT), aspartate amino transferase (AST), alanine amino transferase (ALT), and mean corpuscular volume (MCV). The first three are serum enzymes produced by the liver. GGT elevation is caused by liver enzyme induction by alcohol, liver damage, or many drugs including prescription

Spring 2012 • Volume 11 • Issue 2

What This Advisory Is and Isn't

- not revolutionary
- is incremental progress report state of the science
- is tempered versus strident
- is *clinically*-oriented: word "patient" used 14 times
- "forensic" "legal" "criminal" "justice" do not appear

What This Advisory Is and Isn't

- not a legal/forensic document
- is treatment document
- legal justification for EtG/EtS testing - case law, evidential hearings & judicial rulings
- new advisory adds support for the use of EtG/EtS as a recovery tool
- *not* a roadblock to current drug court policies & practices

Exhibit 1. Characteristics of Several Alcohol Biomarkers[6,7,8,9,10,11]

Biomarker	Type of Drinking Characterized	Sensitivity/ Specificity	Examples of Possible Sources of False Positives	General Comments
Aspartate Amino Transferase (AST), Alanine Amino Transferase (ALT)	Unknown, but heavy and lasting for several weeks	Moderate/Moderate (somewhat lower sensitivity than GGT as screen for heavy drinking)	See GGT. Excessive coffee consumption can lower values.	Primarily reflects liver damage that is often related to alcohol. ALT seems less sensitive than AST. Ratios of AST to ALT greater than 2 may suggest liver damage that is alcohol related. Performs best in adults ages 30 to 60 years.
Carbohydrate-Deficient Transferrin (CDT)	Probably at least 5 drinks/day for approximately 2 weeks	Moderate/High (as screen for alcohol dependence)	Rare genetic transferring variant, primary biliary cirrhosis, chronic end-stage liver disease, fulminant hepatitis C. Values are also altered due to smoking or obesity.	Equal to, or possibly slightly better than, GGT, but much more specific. Biomarker of relapse to heavy drinking following a period of abstinence. Likely less sensitive for women and younger people.
Ethyl Glucuronide (EtG), Ethyl Sulfate (EtS)	Perhaps as little as a single drink	High/High (as indicator of relapse)	Extraneous alcohol exposure, such as alcohol in medications, hygiene products, cosmetics, foods, etc., can elevate values of biomarkers.	As direct analytes of nonoxidative breakdown of alcohol, highly sensitive. Probably little gender, age, or ethnicity effect. New, but promising biomarkers; more research is warranted.
Gamma Glutamyl Transferase (GGT)	Probably at least 5 drinks/ day for several weeks	Moderate/Moderate (as screen for heavy drinking)	Liver and biliary disease, smoking, obesity, diabetes, and medications inducing microsomal enzymes.	Most commonly used traditional biomarker. Primarily reflects liver damage that is often related to alcohol consumption. Performs best in adults ages 30 to 60 years.
Mean Corpuscular Volume (MCV)	Unknown, but heavy and lasting up to several months	Moderate/Moderate (sensitivity somewhat below GGT as screen for heavy drinking)	Hemolysis, bleeding disorders, anemia, folate deficiency, hypothyroidism, hyperglycemia, and medications reducing folate.	Poor biomarker for relapse because of sluggish response to drinking. Higher sensitivity in women than men. Performs best in adults ages 30 to 60 years.
Phosphatidyl Ethanol (PEth)	Possibly 3 or 4 drinks/day for several days	High/High (additional research is needed)	None likely but still unknown due to paucity of research.	Probably little gender, age, or ethnicity effect. Linear dose–response relationship with recent drinking levels. A new but promising biomarker; more research is warranted.

The EtG/EtS Cutoff Issue

EtG Cutoff Carnival:

- EtG cutoffs of 100 - 250 ng/mL likely to low for criminal justice
- EtG cutoff of 2000 ng/mL likely to high for effective abstinence monitoring
- Goldilocks cutoff for EtG is 500 ng/mL - just right!
  - up to 48 hour detection window
  - avoids sources of "incidental" exposure
  - consistent with “preponderance of the evidence” admissibility standard

2012 Advisory EtG Cutoff levels

- Jatlow & O'Malley (2010) "Clinical (non forensic) Application of EtG Measurement"
- > 1000 ng/mL "heavy drinking" prior 48 hours
- 500 - 1000 ng/mL
  - previous heavy drinking (1 - 3 days)
  - recent light drinking (prior 24 hours)
  - recent *intense* "extraneous" exposure (within 24 hours)

2012 Advisory EtG Cutoff levels

- 100 - 500 ng/mL
  - previous heavy drinking (1 - 3 days)
  - previous light drinking (12 - 36 hours)
  - recent “extraneous” exposure
- consensus EtG cutoff level currently used by most drug courts 500 ng/mL
- no inconsistency with revised Advisory based upon “preponderance” standard
- admissibility enhanced with addition of EtS and client contract

Forensic Cutoff:

- EtG minimum of 500 ng/mL
- EtS minimum of 100 ng/mL

Positive EtG/EtS Result (500/100 ng/mL):

- is consistent with the recent ingestion of alcohol-containing products (1-2 days prior to specimen collection) by a monitored client
- studies examining "extraneous" exposure widely conclude that results in excess of the 500/100 ng/mL cutoffs are <u>not</u> associated with "environment" alcohol sources
- meets "preponderance of the evidence" standard

Negative EtG/EtS Result (500/100 ng/mL):

- a result reported as EtG negative is indicative of a client who has not ingested beverage alcohol within 1-2 days prior to specimen collection
- a negative result is <u>not</u> proof of abstinence

2006

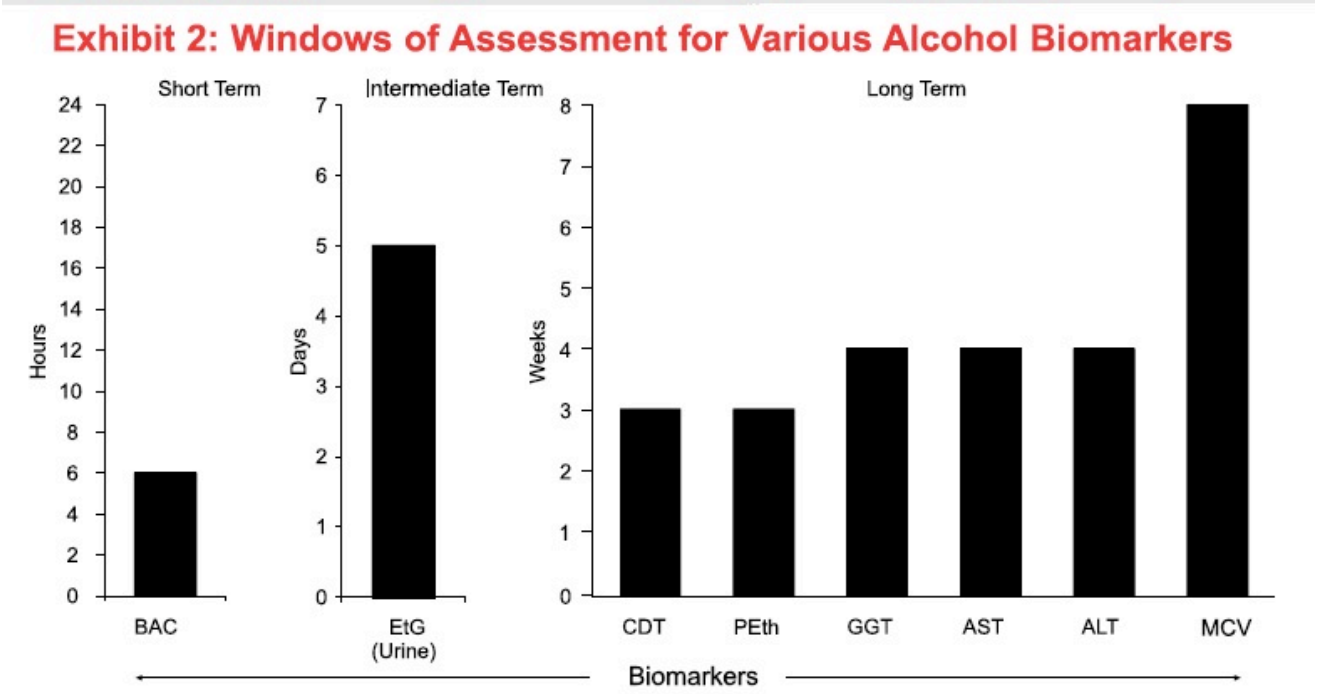
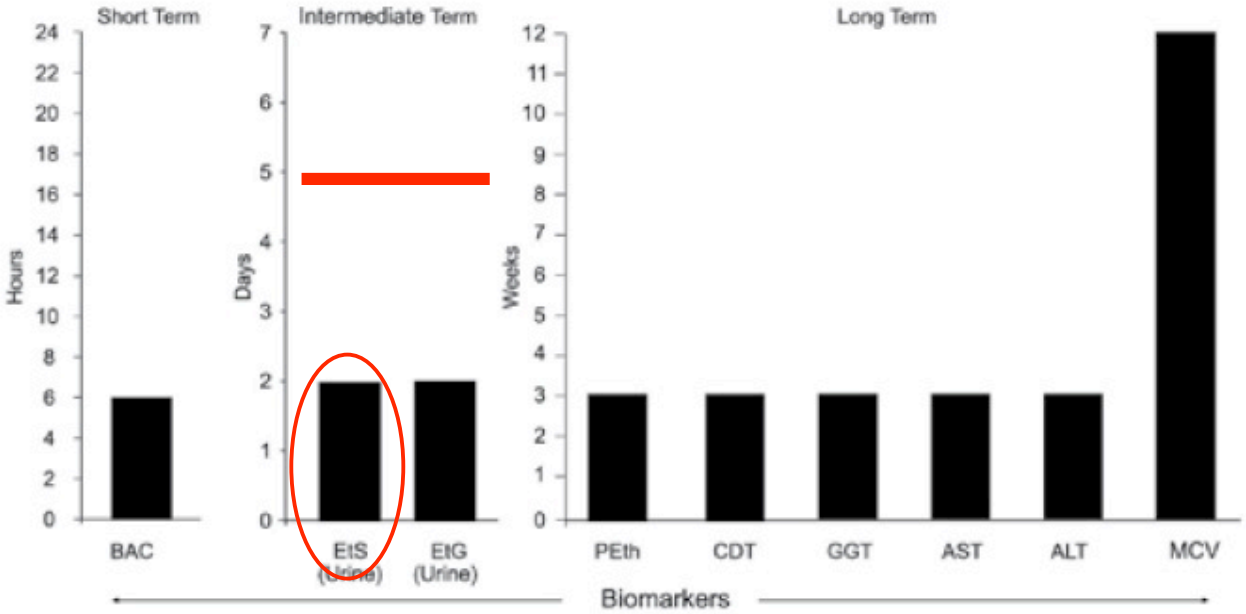


Exhibit 2: Windows of Assessment for Various Alcohol Biomarkers
Short Term
Intermediate Term
Long Term
Hours
Days
Weeks
BAC
EtG (Urine)
CDT
PEth
GGT
AST
ALT
MCV
Biomarkers

2012


Short Term
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Hours
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BAC
EtS (Urine)
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Biomarkers

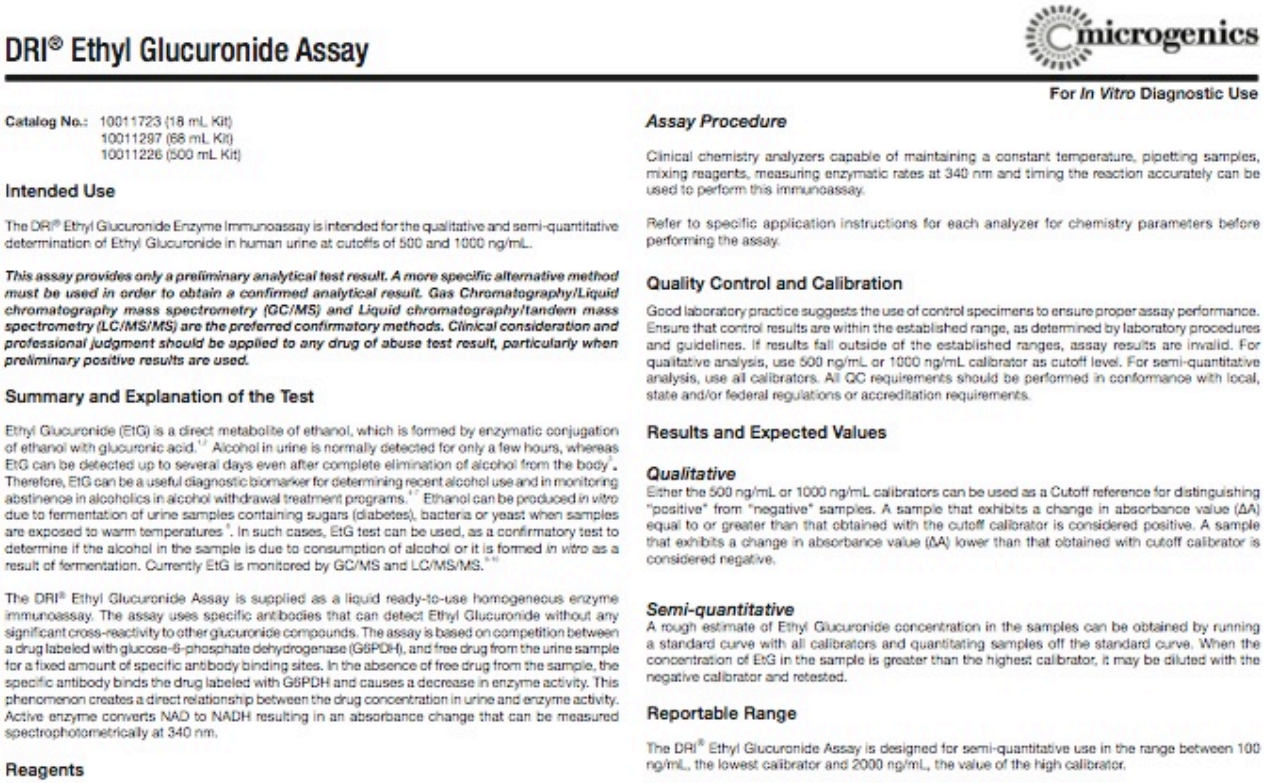
2012 Advisory EtG/EtS Testing Methodologies

- no on-site testing devices – “rapid” or “instant” tests
- LC/MS/MS - recognized reference method
- GC/MS also recommended
- automated method for use on auto-analyzers and other drug testing instrumentation
  - no EtS testing
  - confirmation ?

Advisory's Stance on Testing Methods

- EtG/EtS best measured in urine
- hair & nail testing problematic (undefined detection window)
- recommends GC/MS or LC/MS/MS
- immunoassay tests may produce "false positives" results
- confirm results of positive screening tests

If your court is using an EtG "screening" test (enzyme-immunoassay) - confirm positive results using the LC/MS/MS.



DRI® Ethyl Glucuronide Assay

microgenics

For *In Vitro* Diagnostic Use

Catalog No.: 10011723 (18 mL Kit)
10011297 (68 mL Kit)
10011226 (500 mL Kit)

Intended Use

The DRI® Ethyl Glucuronide Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of Ethyl Glucuronide in human urine at cutoffs of 500 and 1000 ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternative method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Liquid chromatography mass spectrometry (GC/MS) and Liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid.[1,2] Alcohol in urine is normally detected for only a few hours, whereas EtG can be detected up to several days even after complete elimination of alcohol from the body[3]. Therefore, EtG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.[4-7] Ethanol can be produced *in vitro* due to fermentation of urine samples containing sugars (diabetes), bacteria or yeast when samples are exposed to warm temperatures[8]. In such cases, EtG test can be used, as a confirmatory test to determine if the alcohol in the sample is due to consumption of alcohol or it is formed *in vitro* as a result of fermentation. Currently EtG is monitored by GC/MS and LC/MS/MS.[9-11]

The DRI® Ethyl Glucuronide Assay is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect Ethyl Glucuronide without any significant cross-reactivity to other glucuronide compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. Active enzyme converts NAD to NADH resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

Reagents

Assay Procedure

Clinical chemistry analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this immunoassay.

Refer to specific application instructions for each analyzer for chemistry parameters before performing the assay.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Ensure that control results are within the established range, as determined by laboratory procedures and guidelines. If results fall outside of the established ranges, assay results are invalid. For qualitative analysis, use 500 ng/mL or 1000 ng/mL calibrator as cutoff level. For semi-quantitative analysis, use all calibrators. All QC requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Results and Expected Values

Qualitative

Either the 500 ng/mL or 1000 ng/mL calibrators can be used as a Cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value (ΔA) equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value (ΔA) lower than that obtained with cutoff calibrator is considered negative.

Semi-quantitative

A rough estimate of Ethyl Glucuronide concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve. When the concentration of EtG in the sample is greater than the highest calibrator, it may be diluted with the negative calibrator and retested.

Reportable Range

The DRI® Ethyl Glucuronide Assay is designed for semi-quantitative use in the range between 100 ng/mL, the lowest calibrator and 2000 ng/mL, the value of the high calibrator.

Why Drug Courts Should Use EtG/EtS

Exhibit 3. Summary Table of Alcohol Biomarkers by Particular Use[6]

Biomarker	Screening for Heavy Drinking	Identify Relapse, Especially to Heavy Drinking	Time To Return to Normal With Abstinence	Monitoring Abstinence
CDT	✓	✓	2–3 weeks	
EtG, EtS		✓	1–3 days	✓
GGT	✓		2–4 weeks	
MCV	✓		Up to several months	
PEth		✓	2–4 weeks	
Sensor Device		✓	Continual	
SGOT/AST*	✓		2–4 weeks	
SGPT/ALT**	✓		2–4 weeks	

* Serum glutamic-oxaloacetic transaminase/aspartate transaminase

** Serum glutamic pyruvic transaminase/alanine aminotransferas

More Research

- define & establish cutoffs
- identify influencing factors (genetics, age, gender, ethnic groups, disease, etc.)
- how detection window effected by varying levels of alcohol use
- establish reliability of laboratory testing
- determine commercial product influence

Best Practices for EtG/EtS Testing:

- provide those being monitored with an alcohol use advisory document - EtG/EtS specific contract - mandatory
- use appropriate cutoffs:
  - EtG - 500 ng/mL
  - EtS - 100 ng/mL
- test for EtS (ethyl sulfate) - biomarker of choice

EtG/EtS- Specific Contract:

- outlines the behavioral requirements and compliance standards necessary for continued participation in drug court
- educate, alert and advise drug court clients of the potential (incidental) sources of alcohol that could produce a positive urine EtG/EtS test result
- listing the numerous commercial products that contain ethyl alcohol and provides a list of substances to avoid while in a drug court program

Prohibited Items:

- OTC medications
- non-alcoholic beer & wine
- foods that contain alcohol
- alcohol-based mouthwashes
- alcohol-based hand sanitizers
- alcohol-based hygiene products

When in doubt, don't use, consume or apply!

Best Practices for EtG/EtS Testing:

- provide those being monitored with an alcohol use advisory document - EtG/EtS specific contract - mandatory
- use appropriate cutoffs:
  - EtG - 500 ng/mL
  - EtS - 100 ng/mL
- test for EtS (ethyl sulfate) - biomarker of choice

Is a positive urine EtG/EtS test result a definitive indicator of relapse or prohibited drinking?

Is a positive urine EtG/EtS test result sufficient justification for client sanctioning?

EtG/EtS Admissibility?

- are EtG/EtS results legally admissible
- Kelly-Frye, Daubert, Rule 703
- use of proper cutoffs 500/100 ng/mL
- use of appropriate methodologies (LC/MS/MS for confirmation of positives)
- use client contract
- interpret results correctly
- YES!

EtG Testing Resources / Cases

Kent Lawrence, Judge State Court of Clarke County

U.S. Dept. Health and Human Services, Substance Abuse and Mental Health Services Administration, Substance Abuse Treatment Advisory, Sept. 2006, Volume 5, Issue 4

www.kap.samhsa.gov/products/manuals/advisory/.../0609_biomarkers.pdf

- "Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this *Advisory*, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature."

5 Mod. Sci. Evidence § 41:4 (2010-2011 Edition) Validity of the Underlying Theory or Principle – Tests for Biomarkers

- Review of recent caselaw (included below) regarding EtG testing.

Miller v. Redwood Toxicology Lab., Inc., 2011 U.S. Dist. LEXIS 57014 (D. Minn. May 25, 2011).

- Miller is on probation, ordered not to use/ possess alcohol, and is subject to random alcohol testing. Urine sample given and sent to Redwood lab – positive EtG level of 1130 ng/mL and positive EtS level of 603 ng/mL. Miller denied drinking.
- Redwood expert: "there is considerable discussion concerning what is a good cutoff and whether there truly is one that could absolutely delineate between exposure to secondary products and exposure to only ethanol."
- Miller's expert: "[T]here [i]s no agreed upon or known cutoff level for EtG levels to indicate that someone has been drinking."
- When his probation was not revoked, Miller sued Redwood Lab seeking an injunction enjoining them from communicating consumer statements regarding EtG testing. The Court denied the request because Miller could not show harm.

Murphy v. Board of Parole and Post-Prison Supervision, 241 Or. App. 177; 250 P.3d 13 (Or. Ct. App. 2011).

- Murphy's parole revoked based upon a positive EtG test, odor of alcoholic beverage, bloodshot eyes, and positive breath test. Murphy denied drinking and stated he used Nyquil and Listerine regularly. Murphy appealed the revocation.
- Redwood toxicologist sent letter for parole hearing stating that "EtG serves an excellent 'biomarker' for determining recent use and/or chronic alcoholism."
- The parole board accepted the reliability of the EtG test when supplemented by testimony of those who smelled alcohol on Murphy's breath and observed his bloodshot eyes. The appellate court affirmed the revocation of Murphy's parole.

Fujisawa v. Compass Vision, Inc., 735 F. Supp. 2d 1171 (N.D. Cal., August 13, 2010).

- Plaintiff, a licensed pharmacist, entered a substance abuse rehabilitation program to maintain her licensure. She was terminated from the program due to positive EtG

Client Intervention Strategies

Options for Client Sanctioning:

- positive result - cutoff of at least 500/100 ng/mL

  combined with:

- a client admission of use/relapse
- identification of behavioral indicators
  - alcohol-related arrest or incident
  - alcohol-related job action
  - client seen in bar/tavern
- a violation of EtG-specific contract

Response to Positive WITHOUT self-admission:

- sanction based upon current court policies
- intensify alcohol abstinence monitoring
  - breath testing
  - SCRAM
  - more EtG/EtS
- increase in supervision strategies
- supervised Antabuse (Disulfiram)

Miscellaneous Issues

EtG & Bacteria:

- EtG is a more labile compound than EtS
- recent studies indicate that EtG can be destroyed by certain bacteria resulting in a negative EtG and a positive EtS
- EtS is not susceptible to bacterial degradation
- result indicating a positive EtS is sufficient to document covert alcohol ingestion

Millennium - Synergy

NUTRITION FACTS
Serving Size 8 oz.
Servings Per Container 2
Amount Per Serving
Calories 30
Calories from Fat 0
% Daily Value*

Total Fat 0g	0%
Cholesterol 0mg	0%
Sodium 10mg	1%
Total Carbohydrate 7g (2%)	
Sugars 2g	
Protein 0g	

ADDITIONAL NUTRIENTS (per bottle):

Folic Acid	25%
Vitamin B1	20%
Vitamin B2	20%
Vitamin B3	20%
Vitamin B6	20%
Vitamin B12	20%

PROBIOTIC CONTENT:
Lactobacillus Bacterium: 1 billion organisms
S. Boulardii: 1 billion organisms
ANTIOXIDANTS & ORGANIC ACIDS
EGCG 100mg - Glucuronic Acid 10mg
L(+) Lactic Acid 25mg - Acetic Acid 30mg

- Synergy contains kombucha
- fermented mixture of fungi, bacteria, black tea and sugar
- product contains about 0.5% ethyl alcohol
- similar % to non-alcoholic beer

Current State of EtG/EtS Testing in Drug Courts

- reliable & accurate approach to alcohol abstinence monitoring supported by the science
- EtG/EtS valuable tool for therapeutic intervention - EtS more stable
- provide clients with alcohol avoidance information
- use positive EtG/EtS results to leverage self-admissions
- if using EtG screening - use LC/MS/MS method for confirmation
- employ appropriate cutoff levels
- use results to support recovery

EtG/EtS testing may be the best alcohol abstinence monitoring tool EVER!

Not a silver bullet.

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