What Really Works in Alcohol Monitoring

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Director of Business Development
Smart Start Wisconsin

MADD & NHTSA Statistics

- An average drunk driver has driven drunk 80 times before first arrest
- 50-75% of convicted drunk drivers continue to drive on a suspended license
- Almost every 90 seconds, a person is injured in a drunk driving crash
- Every day in America, another 28 people die as a result of drunk driving crashes
- In 2012, 10,322 people died in drunk driving crashes - one every 51 minutes

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Effects of Drugs & Alcohol

Agenda

- Comparison of Alcohol Monitoring Technology
  - BrAC - Breath detection
  - TAC - Sweat detection
  - EtG - Urine detection

"Start with the assumption that the best way to do something is not the way it's being done right now."

- Aaron Levie, CEO of Box

Alcohol Detection

BrAC
TAC
ETG

What Are You Looking For?

- Is a drink or two once in a while allowed?
- How soon do you want to know about a drinking event?
- Is differentiating contaminants from consumed alcohol necessary?
- How important is the cost?

Breath Alcohol Monitor

ALCOHOL CONSUMPTION
WINDOW OF DETECTION
CONFIRMATION

Blood Alcohol Concentration (BAC)

Consumption

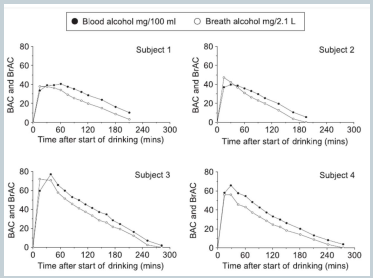
- Absorption Rate:
  - Increase for 30 min to 2 hrs.
- Elimination Rate:
  - Average .020% per hour

https://www.responsibility.org/end-impaired-driving/solutions/prevention/08-bac-legal-limit/

BAC vs BrAC

Detection

- After 15-30 min, blood is higher than breath
- Breath monitors alveolar air



Breath Alcohol Device

<u>Detection</u>

- Fuel Cell
  - BrAC .000 to .600
    - +/- 0.005
  - Breath Volume
  - Temperature
  - Humidity

Breath Alcohol Device

<u>Detection</u>

- Features
  - Battery
  - Camera
  - Cell modem

Breath Alcohol Device

<u>Detection</u>

- Programming
  - Up to 10 tests per day
  - Vary test frequency
  - Custom settings
    - Retest
    - Zero Tolerance

Contaminants

	Listerine Deeper Clean - Mouthwash	Colgate Total Adv. ALCOHOL FREE - Mouthwash	Listerine Freshburst - Strip	Scope Outlast - Breath Mist	Listerine - Pocketmist	Martinelli Cider - ALCOHOL FREE	Monster - Zero Ultra	Monster - Ultra Blue	Red Bull	5 Hour Xtra Strength Berry	Testemme Xtra Firm - NON-AEROSOL	Testemme Xtra Firm - AEROSOL
Wait time after product use	30 sec	0	1 minute	30 sec	30 sec	0	0	0	0	0	0	0
BrAC test result	0.189	0.000	0.000	0.103	0.025	0.000	0.000	0.000	0.000	0.000	0.019	0.015
Rinse mouth	no			no	no						no	no
Time between tests	3 min			3 min	2 min						2 min	3 min
BrAC test result	0.125			0.000	0.000						0.000	0.000
Rinse mouth	no											
BrAC test result	0.000											

If you rinse & retest, contaminants disappear.

Wait ti												n
BrAC test result	0.000	0.019	0.000	0.000	0.000	0.000	0.000	0.000	0.009	0.006	0.048	0.189
Rinse mouth		no		no	no	no	no	no	no	no	yes	no
Time between tests		3 min		1 min	1 min	0 min	1 min	4 min, 3 swallow	3 min	2 min	2 min	2 min
BrAC test result		0.000		0.000	0.000	0.000	0.000	0.006	0.000	0.000	0.000	0.024
Rinse mouth				no	no	no	no	No				no
retest				1 min	1 min	1 min	< 1 min	2 min				4 min
BrAC test result				0.000	0.000	0.000	0.000	0.000				0.000

Breath Alcohol Device

Detection Summary

- Fuel Cell
  - Quantitative
- Temp & Humidity Sensor
  - Accuracy
- Camera
  - Facial Detection
- Cellular Modem
  - On Board
- Robust Programming
  - Qualitative

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Breath Alcohol Monitoring

Confirmation

- BrAC
  - Exact reading, closely related to BAC
  - Current state of impairment
  - Automatic re-test after fail
- Zero Tolerance
  - 63% of our violations over a 1 week period were consistent with consumed drinking <.020 BAC
- Metabolic Rate
  - Consumed vs Contaminant

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Breath Alcohol Summary

- Alcohol Consumption Levels
  - 30 min to 2 hours after consumption
  - Elimination of .020% per hour
- Window of Detection
  - From .000 to .600 with ±.005 accuracy
  - Multiple tests per day
- Confirmation
  - Repeat tests during event
  - Average fail rate .02, Smart Start Wisconsin is .005

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Transdermal Alcohol Monitor

ALCOHOL CONSUMPTION
WINDOW OF DETECTION
CONFIRMATION

Transdermal Alcohol Monitoring

- Fuel Cell
  - Monitors perspired alcohol,
  - Transdermal Alcohol Concentration (TAC)
- Worn by user
  - No camera or facial detection software needed
- Tests every 30 min
  - No test windows needed
- Pair with base to send data
  - Base unit is not portable
- Battery operated
  - Replace 30-60 days

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Transdermal Alcohol Monitoring

Alcohol Consumption

Table 2. TAC-Based and AMS Criteria for the Detection of Drinking Events

	Males					Females					
Beers (units) consumed	1 (0.92)	2 (1.84)	3 (2.76)	4 (3.68)	5 (4.60)	1 (0.92)	2 (1.84)	3 (2.76)	4 (3.68)	5 (4.60)	Total
Total *n*	32	32	32	32	32	29	29	29	29	17	293
Exceed 0, *n* (%)	20 (62.5)	30 (93.8)	32 (100)	32 (100)	32 (100)	17 (58.6)	28 (96.6)	29 (100)	29 (100)	17 (100)	266 (90.8)
Exceed 0.02, *n* (%)	0 (0)	8 (25.0)	24 (75.0)	31 (96.9)	32 (100)	0 (0)	17 (58.6)	23 (79.3)	29 (100)	17 (100)	161 (61.8)
Exceed 0.03, *n* (%)	0 (0)	4 (12.5)	15 (46.9)	29 (90.6)	32 (100)	0 (0)	11 (37.9)	21 (72.4)	28 (96.6)	17 (100)	157 (53.6)
AMS resolved, *n* (%)	0 (0)	8 (25.0)	19 (59.4)	30 (93.8)	32 (100)	0 (0)	13 (44.8)	19 (65.5)	29 (100)	17 (100)	167 (56.9)
AMS confirmed, *n* (%)	0 (0)	8 (25.0)	16 (50.0)	27 (84.4)	31 (96.9)	0 (0)	11 (37.9)	18 (62.1)	28 (96.6)	17 (100)	156 (53.2)

AMS, Alcohol Monitoring Systems; TAC, transdermal alcohol concentration.
Displayed are the number of subjects and the percentage of 32 males and 29 females whose TAC levels were greater than (exceed) various criteria for detection after drinking the designated number of beers (no. beers). Shown also are the number of standard drinks (no. units) contained in each no. beers.

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(2015) Using Transdermal Alcohol Monitoring to Detect Low-Level Drinking. *Alcoholism: Clinical & Experimental Research*, 39(7), 1120–1127. https://doi.org/10.1111/acer.12750

Transdermal Alcohol Monitoring

Alcohol Consumption

- 1 beer = missed 100%
  - TAC for 62.5% of males exceeded zero
  - TAC for 58.6% of females exceeded zero
  - **0% Exceeded .02 g/ml & 0% confirmed**
- 2 beers = missed 68.5%
  - TAC for 93.8% of males exceeded zero
  - TAC for 96.6% of females exceeded zero
  - **41.8% Exceeded .02 g/ml & 31.5% confirmed**
- 3 beers = missed 43.9%
  - TAC for 100% of all exceeded zero
  - **77.2% Exceeded .02 g/ml & 56.1% confirmed**

45.9% of all occasions of drinking 1 to 3 beers were NOT detected.

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(2015) Using Transdermal Alcohol Monitoring to Detect Low-Level Drinking. *Alcoholism: Clinical & Experimental Research*, 39(7), 1120–1127. https://doi.org/10.1111/acer.12750

Transdermal Alcohol Monitoring

Alcohol Consumption

- 4 beer = missed 9.5%
  - TAC for 100% of all exceeded zero
  - **98.5% Exceeded .02 g/ml & 90.5% confirmed**
- 5 beers = missed 1.5%
  - TAC for 100% of all exceeded zero
  - **100% Exceeded .02 g/ml & 98.5% confirmed**

Only reliably detects heavy drinking levels of approx. 4 standard drinks for females & 5 for males when consumed in <3 hours.

SMART START WISCONSIN

(2015) Using Transdermal Alcohol Monitoring to Detect Low-Level Drinking. *Alcoholism: Clinical & Experimental Research*, 39(7), 1120–1127. https://doi.org/10.1111/acer.12750

Transdermal Alcohol Monitoring

Other Alcohol Consumption Studies:

- 2014 Predictors of Detection of Alcohol Use Episodes Using a Transdermal Alcohol Sensor
  - The SCRAM sensor is very good at detecting five or more drinks
- 2019 Processing transdermal alcohol concentration (TAC) data to detect low-level drinking
  - Reliance upon the AMS criteria for alcohol detection affords a high specificity for detection of heavy drinking but is a poor indicator of abstinence rates.
- 2020 Wearable Transdermal Alcohol Monitors: A Systematic Review of Detection Validity, Relationship Between Transdermal and Breath Alcohol Concentration and Influencing Factors
  - SCRAM seems unable to detect low to moderate drinking levels using the thresholds and criteria set by the manufacturer.

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Transdermal Alcohol Monitoring

Window of Detection

- Approx. 1-2 Hour Delay After Detectable in BAC
- Pairing Required for Data Upload
  - Not real time detection

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Transdermal Alcohol Monitoring

Accuracy & Sensitivity

- Water
- Environmental
- Hygiene Products
- Cold Skin (slows vapor loss)
- Hydration Levels
- Individual Characteristics
  - Sweat rate
  - Skin thickness

NHTSA determined that "a TAC reading of 0.02 g/dl produced a 12.34% false-positive rate with SCRAM devices."

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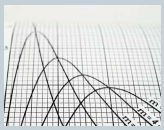
Transdermal Alcohol Monitoring

Confirmation

- Algorithm
  - Confirmed TAC >.02 g/dL
  - May require 3 TAC reading of .02 or higher
  - Different absorption & elimination rate based on peak TAC
  - Avoids contaminates and low BAC events
- Spiky at Times
  - Water affects accuracy
  - Misclassify rapid rise in BAC as an external interferent



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TAC Summary

- Alcohol Consumption
  - Best for high drinking (5 drinks or more)
  - >0.020 BAC
- Detection
  - 1 hr after BAC
  - Sample every 30 min
  - Sends when paired
- Confirmation
  - Algorithm
  - Testimony at .02 or .04 depending on vendor

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Transdermal Vs Breath Alcohol Monitoring

Transdermal	Breath

Accuracy
• .020 g/dL
• Algorithm to Determine BAC
• Contaminants Effect Reading
  ○ Also Effected by
  ▪ Water
  ▪ Cold skin (slows vapor loss
	Accuracy
	• .005 BAC
	• BrAC Directly Related to BAC
	• Retest Clears Contaminants
	  ○ Immediate retest after fail

Delayed Detection • 1 hr after BAC • Sample Every 30 Min	Immediate Detection • 30 Min to 2 Hrs Post Drinking • Scheduled Test Windows
Pairing Required for Data Upload	All-In-One Unit • Real-time Reports ○ GPS Location of Tests

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EtG

ALCOHOL CONSUMPTION LEVELS
WINDOW OF DETECTION
CONFIRMATION

Ethyl Glucuronide (EtG)

- Alcohol Metabolite Found in Urine
- Simple Collection
  - Instant test (POCT) or lab screen
  - Sample can be screened for multiple drugs
- Everyone is Able to Provide
- Lab Confirmation of EtS

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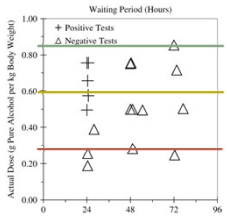
OXFORD UNIVERSITY PRESS

Alcohol Consumption

From: **Sensitivity of commercial ethyl glucuronide (ETG) testing in screening for alcohol abstinence**

Alcohol Alcohol. 2007;42(4):317-320. doi:10.1093/alcalc/agm014



High Dose Group
Dose 0.66 to 0.85 = up to 6.4 drinks
= 0.031 to .109 BAC

Medium Dose Group
Dose 0.39 to 0.58 = up to 3.4 drinks
= .032 to .087 BAC

Low Dose Group
Dose of 0.19 to 0.28 = up to 2.4 drinks
=.028 to .034 BAC

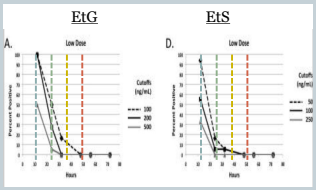
- Individual test results by actual dosage and actual waiting period.
- 100 ng/ml EtG

Date of download: 3/8/2017

Ethyl Glucuronide (ETG)

Alcohol Detection
500 ng/ml

- 12 hrs
  - 50% low dose
- 24 hrs
  - 5% low dose
- 36 hours
  - 0% low dose
- 48 hours
  - 0% low dose



Actual BAC: Low Dose = .028% (20 mg/dl)

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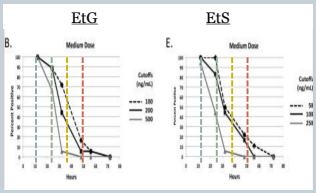
(2014). Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials. *Alcoholism: Clinical & Experimental Research, 38*(7), 2056–2065.

Ethyl Glucuronide (ETG)

Alcohol Detection
500 ng/ml

- 12 hrs
  - 100% med dose
- 24 hrs
  - 65% med dose
- 36 hours
  - 5% med dose
- 48 hours
  - 0% med dose



Actual BAC: Med Dose = .093% (80 mg/dl)

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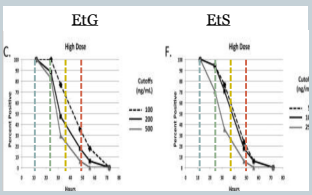
(2014). Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials. *Alcoholism: Clinical & Experimental Research, 38*(7), 2056–2065.

Ethyl Glucuronide (ETG)

Alcohol Detection
500 ng/ml

- 12 hrs
  - 100% high dose
- 24 hrs
  - 80% high dose
- 36 hours
  - 25% high dose
- 48 hours
  - 5% high dose



Actual BAC: High Dose = .138% (120 mg/dl)

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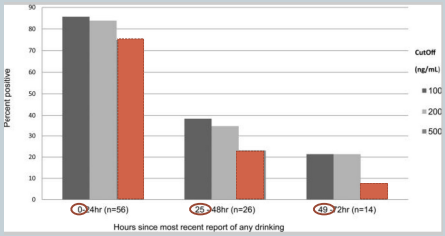
(2014). Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials. *Alcoholism: Clinical & Experimental Research, 38*(7), 2056–2065.

Ethyl Glucuronide (ETG)

Alcohol Detection

Graph shows percent positive for EtG



(2014). Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials. *Alcoholism: Clinical & Experimental Research, 38*(7), 2056–2065.

EtG Lowered Sensitivity

Alcohol Detection

- Effected by Contaminants
  - Medications
  - Hand Sanitizers
  - Hygiene products
  - Antiperspirant
  - Banana (within 3.5 hrs)
  - Sauerkraut (within 5 hrs)
- Bacterial UTI
  - False-positive & false-negative results

Confirmation with EtS

Alcohol Detection

- Few Discrepancies between EtG and EtS

(2014) Ethyl Glucuronide and Ethyl Sulfate Assays in Clinical Trials, Interpretation, and Limitations: Results of a Dose Ranging Alcohol Challenge Study and 2 Clinical Trials

SAMHSA ADVISORY

- EtS provides a slightly greater sensitivity to alcohol

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

ALCOHOLISM CLINICAL & EXPERIMENTAL RESEARCH

EtG Summary

- Alcohol Consumption
  - Good for medium to high drinking
- Detection
  - Best within 24 hrs
- Confirmation
  - EtS

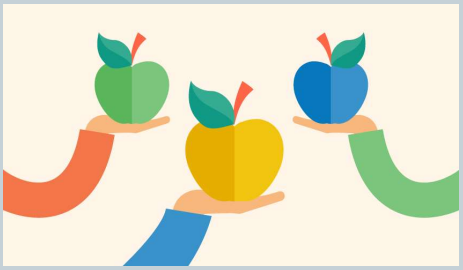
EtG vs Breath Alcohol Monitoring

EtG	Breath

Accuracy
• Detection varies
• EtS needed to confirm
  ○ 24-48 hrs to confirm
• Contaminants cannot be cleared
	Accuracy
	• .005 BAC
	• BrAC directly related to BAC
	• Repeated test for Confirm
	  ○ Immediate provided
	• Contaminants can be cleared

Minimal Detection • 48 hrs or less	Quick Detection • 30 min BrAC after drinking
Limited Availability • Test at facility	Test anywhere, Anytime • Real-time reports • GPS Location of tests

Review of Technologies



EtG vs TAC vs BrAC Monitoring

EtG

Accuracy
- Detection varies
- EtS needed to confirm
  - 24-48 hrs to confirm
- Contaminants cannot be cleared

Minimal Detection
- 48 hrs or less

Limited Availability
- Test at facility

Transdermal

Accuracy
- .020 g/dL
- Algorithm to Determine BAC
- Contaminants Effect Reading
  - Also Effected by
    - Water
    - Cold skin (slows vapor loss

Delayed Detection
- 1 hr after BAC
- Sample Every 30 Min

Pairing Required for Data Upload

Breath

Accuracy
- .005 BAC
- BrAC directly related to BAC
- Repeated test for Confirm
- Contaminants can be cleared

Quick Detection
- 30 min BrAC after drinking

Test anywhere, Anytime
- Real-time reports
- GPS Location of tests

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Cost of Alcohol Monitoring Program

EtG
- $4-5 Per Test, Every Other Day
  - $18-25 at a drug testing facility
- EtS/Confirmation is Extra ($20+)

Transdermal
- $9-12 Per Day + Enrollment

Breath
- $2.50-$6.50 Per Day + Enrollment
  - Breath Check $2.50 Per Day
  - SMART Mobile $6.50 Per Day
  - Cellular IID $4.30 Per Day

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Comparison

BREATH

Accuracy
- .005 BAC
- BrAC Related to BAC
- Clear Contaminants

Immediate Detection
- ½ - 2 hour Post Drinking
- Regular Test Windows

All-In-One Unit
- Real-time Reports
  - GPS Location of Tests

TRANSDERMAL

Accuracy
- .020 g/dL
- Algorithm to Determine BAC
- Effected by Contaminants, Water & Cold Skin

Delayed Detection
- 1 hr after BAC
- Sample Every 30 Min

Pairing Required for Data Upload

EtG

Accuracy
- Detection varies
- EtS needed to confirm
  - 24-48 hrs to confirm
- Contaminants cannot be cleared

Minimal Detection
- 48 hrs or less

Limited Availability
- Test at facility

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Suggested Use For Each Technology

- Transdermal (TAC)
  - Phase 1: when heavy drinking is more likely
  - Sanction
- Breath (BrAC)
  - Long term or regular sobriety monitoring
  - Phase 1-4
- Urine (EtG)
  - Random or in addition to drug panel
  - Last Phase

1st 90 days:
Transdermal
or Breath

Throughout Treatment:
Breath

Random:
Urine

What Are You Looking For?

- Is a drink or two once in a while allowed?
  - No? Then a Zero Tolerance program is needed.
  - Breath is best technology for this program.
- How soon do you want to know about a drinking event?
  - Now? Then Real-time Alerts are necessary.
  - Breath is best technology for this program.
- Is differentiating contaminants from consumed alcohol necessary?
  - Yes? Then back to back BAC readings are necessary.
  - Breath is best technology for this program.
- How important is the cost?
  - Breath & EtG are lowest cost.
  - EtG require confirmation which can be costly.

Thank you for your time!

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