

PROCEDURE FOR THE PREPARATION OF 0.08 SIMULATOR EXTERNAL STANDARD SOLUTION FOR USE WITH A BREATH TEST INSTRUMENT

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A. Introduction:

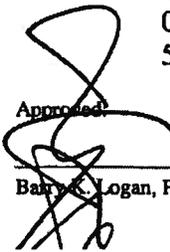
1. The BAC Datamaster breath test instrument is equipped with a Guth Breath Alcohol Simulator. This device produces a predictable, known vapor concentration by passing air through a heated aqueous solution of known alcohol concentration.

B. Principle and Purpose:

1. The simulator external standard solution is a water and ethanol mixture formulated to provide a standard ethanol vapor concentration when used in a breath alcohol simulator at 34 ± 0.2 degrees Centigrade, of between 0.072 and 0.088 grams of ethanol per 210 liters of air, inclusive. To allow for depletion of alcohol from the solution during its use, the target starting concentration is 0.082 g/210 L.

The aqueous ethanol concentration is determined as follows. The water/air partition ratio at 34 degrees Centigrade is 2585.8 (Jones, 1983). The water/alcohol concentration required to produce a 0.082 g/210 L of vapor equivalent, should be 0.101 g/100 mL. For convenience, the simulator solution batches are prepared in a 52 L container, requiring 54.5 grams of ethanol. The density of absolute ethanol at

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room temperature is 0.79 g/mL, therefore a volume of 66.5 mL of ethanol in 52 L of water is required.

The preparation is carried out at room temperature.

The reference vapor concentration used is the average value of the solution concentration (rounded to four decimal places) divided by 1.23 (Jones 1983, Dubowski 1983) and rounded to four decimal places to give the alcohol concentration in grams per 210 liters of vapor.

C. Equipment:

Agilent (Hewlett Packard) Headspace Autosampler or equivalent
Agilent (Hewlett Packard) 6890 or 6890N gas chromatograph; one equipped with a J&W DBALC1 megabore (0.53 mm) 30 meter capillary column and/or J&W DBALC2 megabore (0.53 mm) 30 meter capillary column or equivalent. (For information on the columns, see Headspace Protocol)
Computer System equipped with HP GC Chem Station
Compressed gases; air, nitrogen, hydrogen, helium
Autosampler vials
Cap crimper
Hamilton Automatic Diluter
Volumetric glassware
10 mL, 5 mL, 2 mL, 1 mL volumetric pipette, grade A
1 mL pipette
Mechanical mixer and stir rod
Calibrated 52 L container
Appropriate plastic 500 mL containers and caps
Tamper evident tape or tamper evident caps
Plastic storage bottles

D. Reagents:

200 proof absolute ethanol (USP Grade) (used within 6 months of the date first opened)
Laboratory Grade deionized water

E. Controls:

Commercially prepared controls are included in the run.

F. Preparation:

1. Fill the 52 L vessel to approximately 80% of the 52 L mark with deionized water.

2. In a 1 L flask, add approximately 900 mL deionized water and using volumetric glassware, add precisely 66.5 mL absolute ethanol into the flask. Stopper the flask

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and mix well by inverting several times and add the contents of the flask to the mixing vessel. Rinse the flask with approximately 1 L deionized water and add this to the mixing vessel. Fill the mixing vessel to the 52 L mark with deionized water. Mix the solution by applying mechanical mixing for a minimum of two hours.

3. Assign a batch number to the solution. The first two digits of the batch number represent the year in which the solution was made, followed by a sequential three-digit number, beginning with 001. Therefore, the first batch of 2007 would be 07001.
4. Remove approximately 50 mL of the mixed solution for testing.

G. Certification:

1. An individual with a valid Blood Analyst Permit, authorized by the State Toxicologist, analyzes five separate aliquots of the simulator solution, by headspace gas chromatography.
2. Record the results of the testing in the solution certification database, including the date and the results of the contemporary external control. Enter the control lot number.
3. A minimum of three (3) analysts must certify the solution prior to its certification.
4. The average of the results from all of the analysts are computed (rounded to four decimal places). The standard deviation and relative standard deviation (CV) on all results are computed. (Freedman et al., 1978).
5. The solution is acceptable for use and therefore certified if it meets the following criteria:
 - i. The average solution concentration is between 0.098 and 0.108 g/100 mL inclusive.
 - ii. The CV is 5% or less.
6. The reference vapor concentration is calculated by dividing the solution concentration by 1.23 and rounding to four decimal places.
7. A solution is valid for use for a period of one year from the date of preparation.

H. Documentation

1. Upon completion of their testing, each analyst will complete the simulator certification database, entering the results of all five tests, and the control result.
2. The analyst will sign on the corresponding signature line, and their signature will reflect that the results are the results of tests that they personally performed. The preparer completes the first line.

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3. The preparer of the batch and the first two analysts (three in total) will complete a declaration as described in CrRLJ 6.13(c)(1), certification of simulator solution.

I. Packaging:

1. The solution is dispensed into 500 mL glass or plastic bottles and capped, tightly.
2. Each bottle is labeled with the batch number and its preparation date.
3. The bottles are sealed with tamper evident tape. Alternatively, tamper evident caps may be used in lieu of regular caps with tamper evident tape.
4. Once the solution is certified, it may be provided to the BAC technicians for use with the breath test instruments.

J. References:

A.W. Jones, Determination of Liquid/Air Partition Coefficients for Dilute Solutions of Ethanol in Water, Whole Blood and Plasma. *Journal of Analytical Toxicology*, 7, 1983 pp 193-197.

K.M. Dubowski, Breath Alcohol Simulators: Scientific Basis and Actual Performance. *Journal of Analytical Toxicology*, 3, 1983 pp177-182

G.J. Shugar, R.A. Shugar and L. Bauman, Chemical Technicians Ready Reference Handbook. McGraw-Hill Book Co. 1978.

BAC Verifier DataMaster Operator Instruction Manual, WSP Forensic Laboratories Services Bureau, May 1985, pp27-28.

D. Freedman, R. Pisano and R. Purves, Statistics, W.W. Norton & Co. N.Y. 1978.

STATEMENT OF STATE TOXICOLOGIST -

In my capacity as Washington State Toxicologist, and by my authority outlined in RCW 46.61.506, I have reviewed this protocol and find it to be proper and adequate in form and substance for the purpose it was intended. I, therefore, approve and authorize its use.

Barry K. Logan Ph.D.
Washington State Toxicologist

Date: _____

8/2/07

Approved: _____

Barry K. Logan, Ph.D.

Date (prepared August 6, 2007): _____

8/2/07

The following toxicologists have read the Simulator Solution Protocol and agree to follow this procedure as it is written. Any deviations from the procedure must be documented in writing and approved by the laboratory manager and/or the State Toxicologist.

Reviewed By: Melissa Parker Date: 8/7/07

Reviewed By: Jennifer Date: 8/7/07

Reviewed By: Christy Date: 8-7-07

Reviewed By: John Date: 8/7/07

Reviewed By: Maria Capron Date: 8-7-07

Reviewed By: Ellen Date: 08-07-2007

Reviewed By: John Date: 8-7-07

Reviewed By: Bethany Bab Date: 8/7/07

Reviewed By: Melissa Date: 8/7/07

Reviewed By: Branne Petersen Date: 8/7/07

Reviewed By: Paul Dief Date: 8/7/07

Reviewed By: Brianne Atkins Date: 8/7/07

Reviewed By: Walter Date: 8/7/07

Reviewed By: Christy Date: 8/7/07

Reviewed By: [Signature] Date: 08072007

Approved: [Signature]
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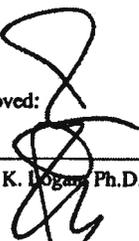
Date (prepared August 6, 2007): 8/7/2007

Reviewed By: 

Date: 2007 08 07

Reviewed By: _____

Date: _____

Approved: 
Barry K. Logan Ph.D.

Date (prepared August 6, 2007): 8/7/2007
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