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

Introduction:

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 though a heated aqueous solution of known alcohol concentration.

Principle and Purpose

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 $\pm$ 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/210L.

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/210L of vapor equivalent, should be 0.101 g/100 mL. For convenience, the simulator solution batches are prepared in a 52L container, requiring 52.5 grams of ethanol. The density of absolute ethanol at room temperature is 0.79 g/mL, therefore a volume of 66.5 mL of ethanol in 52L 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.

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 crimpier
Hamilton Automatic Diluter
50mL volumetric flask, grade A
10mL, 5mL, 2mL, 1 mL volumetric pipette, grade A
1mL pipette
Mechanical mixer and stir rod
Calibrated 52L container

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Glass or appropriate plastic 500mL containers and caps
Tamper evident Tape or tamper evident caps
Plastic storage bottles

Reagents:

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

Controls:

Commercially prepared controls are included in run.

Preparation:

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

2) In a 1L flask, add approximately 900mL deionized water and using volumetric glassware, add precisely 66.5 mL absolute ethanol into the flask. Stopper the flask and mix well by inverting several times and add the contents of the flask to the mixing vessel. Rinse the flask with approximately 1L deionized water and add this to the mixing vessel. Fill the mixing vessel to the 52L 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 2006 would be 06001.

4) Remove approximately 50 mL of the mixed solution for testing.

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:

   a. The average solution concentration is between 0.098 and 0.108g/100mL inclusive.
   b. The CV is 5% or less.

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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.

Packaging:

1) The solution is dispensed into 500mL glass or appropriate plastic bottles and capped, tightly.

2) Each bottle is labeled with the batch number and its expiration 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.

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 Verifeer 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. This supplements the simulator solution protocol dated 10/23/04, which remains in effect.

Barry K. Logan Ph.D.
Washington State Toxicologist

12/1/05
Date

Approved:

Barry K. Logan, PhD

Date:
12/1/05

Reviewed By: _____ Date: 12-1-05
Ann Marie Gordon
Laboratory Manager

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: _____ Date: 12/1/05
Edward Formoso
Supervisor

Reviewed By: _____ Date: 12-1-05
Melissa Pemberton
Supervisor

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12/1/05

Reviewed By: _____ Date: 12012005

Reviewed By: _____ Date: 12-01-05

Reviewed By: _____ Date: 12-01-05

Approved: _____ Date: 12/1/05
Barry K. Logan, PhD

Reviewed By: Kari Grundell Date: 12/1/05

Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

Approved: _____ Date: 12/1/05

Barry K. Logan, PhD