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 though 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 $\pm$ 0.3 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 52.5 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 66.5 mL absolute ethanol into the flask. Stopper the flask and mix well by inverting 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. After mixing is completed, an aliquot (approximately 50 mL) of the mixed solution is removed for testing.

3. The preparer will 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. Open the Solution Certification Database, and create a new entry for the batch. Enter the batch number and the date of preparation (the date the alcohol and water were added), create labels for the batch (if an external standard field solution) and prepare a folder marked with the batch number to store all results and documents. Enter the control lot# and expiration date for the external control.

G. Certification:

1. Multiple analysts will analyze five separate aliquots of the simulator solution, by headspace gas chromatography. Each analyst must have a valid Legal Blood Alcohol Analyst permit issued by the State Toxicologist.

2. A minimum of three (3) analysts must test the solution before the average solution concentration can be calculated and the solution certified.

3. 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).

4. The solution meets the standards required by the state toxicologist if:

   i. The average solution concentration is between 0.098 and 0.108 g/100mL inclusive.

   ii. The CV is 5% or less.

5. The reference vapor concentration is calculated by dividing the solution concentration by 1.23 and rounding to four decimal places.

6. A solution is valid for use for a period of one year from the date of preparation.

H. Documentation

1. The preparer of the solution shall record on the solution preparation log, the batch number of the solution, the date of preparation (the date when the alcohol and water were added), the preparer's name, and the lot number of the absolute ethanol reagent and the date it was opened. Verify that the date of preparation is the same as that recorded in the Solution Certification Database.

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2. Upon completion of their testing, each analyst will enter into the Solution Certification Database the results of all five tests, the control result, and the date of testing. In the event that a sequence is started on one day and completes after midnight, the date the sequence began shall be the date of testing. Ensure that the dates of preparation (preparer) and testing (analysts) are correct. Double check the data from the chromatograms against the data entered in the database. Place the chromatograms in the batch file.

3. Once the last analyst has entered their data, the Solution Certification Database sheet will be printed. Each analyst will check the results from their chromatograms against the results as they appear on the printed Solution Certification Database sheet before signing. The analyst will initial their chromatograms to indicate this review was completed.

4. Each analyst will sign on the corresponding signature line on the Solution Certification Database sheet, and their signature will reflect that the results are the results of tests that they personally performed.

5. The preparer of the batch and at least the first two analysts (three in total) will complete an affidavit as described in CrRLJ 6.13(c)(1), certification of simulator solution.

6. The batch file will be forwarded to a supervisor or manager for final review. The batch file should contain:
    i. A copy of the simulator solution database printout, signed and dated by each analyst.
    ii. Chromatograms (initialed) for each result that appears on the printout.
    iii. Notation or printout identifying the calibration used.
    iv. Copies of affidavits for at least the first three analysts who tested the solution.

7. The reviewer will initial and date the bottom of the Solution Certification Database sheet, indicating that the file is complete and has been reviewed.

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.

J. References:

Approved:

Barry K. Logan, Ph.D.

Date (prepared October 5, 2007):

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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.

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.

Date: 10/5/2007

Barry K. Logan Ph.D.
Washington State Toxicologist

Approved:

Barry K. Logan, Ph.D.

Date (prepared October 5, 2007):

10/5/2007

Simulator Solution Preparation Log

Batch #	*QA/Ext Std*	*Date Prepared*	*Prepared by*	*USP Ethanol Lot #*	*Date Opened*

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: Brianne P. Akers Date: 10-8-2007

Reviewed By: Lisa Noble Date: 10-9-07

Reviewed By: Carl Oleby Date: 10-9-07

Reviewed By: [signature] Date: 2007 Oct 09

Reviewed By: Brian Lynn Date: 10.9.07

Reviewed By: [signature] Date: 10-11-07

Reviewed By: Brianna Peterson Date: 10.11.07

Reviewed By: [signature] Date: 10/11/07

Reviewed By: [signature] Date: 10/11/07

Reviewed By: [signature] Date: 10-11-07

Reviewed By: Brittany Ball Date: 10/11/07

Reviewed By: [signature] Date: 10/12/07

Reviewed By: [signature] Date: 10/12/07

Reviewed By: [signature] Date: 10-13-2007

Reviewed By: [signature] Date: 10/31/07

Approved: [signature]

Barry K. Logan, Ph.D.

Date (prepared October 5, 2007): 10/5/2007

Reviewed By: Dwight Ackerman Date: 10/31/07

Reviewed By: [signature] Date: 11/1/2007

Reviewed By: _____ Date: _____

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Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

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Approved:

Barry K. Logan, Ph.D.

Date (prepared October 5, 2007):

10/5/2007