

PROCEDURE FOR THE PREPARATION OF QUALITY ASSURANCE SOLUTIONS FOR USE WITH A BREATH TEST INSTRUMENT

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A. Introduction:

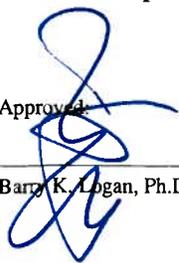
1. The BAC Datamaster breath test instrument is equipped with a Guth Breath Alcohol Simulator. This device produces a predictable, known vapor concentration by passing air through a heated aqueous solution of known alcohol concentration.

B. Principle and Purpose:

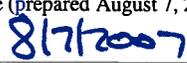
1. The quality assurance simulator solutions are a mixture of water and ethanol formulated to provide a standard ethanol vapor concentration when used in a breath alcohol simulator at 34 ± 0.2 degrees Centigrade. The solutions are used to verify the accuracy and precision of the BAC Verifier DataMaster Quality Assurance Program of the Washington State Patrol Breath Test Section. The 0.100 g/210 L solution may also be used to calibrate the BAC DataMaster.

The preparation is carried out at room temperature using deionized water and 200 proof, absolute ethanol.

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The water/air partition ratio at 34 degrees Centigrade is 2585.8 (Jones, 1983). 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 (Jones 1983, Dubowski 1983).

The quality assurance program operated by the Washington State Patrol Breath Test Section requires vapor concentrations of approximately 0.08, 0.10, 0.15 and 0.20 g/210 L vapor. Other solutions required periodically for instrument evaluation will produce vapor concentrations of 0.04 and 0.30 g/210 L vapor. The exact concentration of a given solution is measured by gas chromatography.

C. Equipment:

Agilent (Hewlett Packard) 7694 Headspace Autosampler or equivalent
Agilent (Hewlett Packard) 6890 gas chromatograph; equipped with a J&W DBALC1 megabore (0.53 mm) 30 meter capillary column and/or with a 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
100 mL Buret
Mechanical mixer and stir rod
Calibrated 18 L containers
Tamper evident Tape or tamper evident caps
Plastic storage bottles

D. Reagents:

200 proof absolute ethanol (USP Grade) (Used within 90 days of opening)
Laboratory Grade deionized water

E. Controls:

Commercially prepared controls are included in run.

F. Preparation:

1. Fill the 18 L vessel to approximately 80% of the 18 L mark with deionized water.
2. Use the values in Table 1 to prepare each solution.

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Table 1:

Vapor Concentration	Solution Concentration	Acceptable Range	Ethanol/Water Dilution Factor
0.04	0.049	0.047 - 0.052	11.1 mL/18 L
0.08	0.098	0.092 - 0.102	22.2 mL/18 L
0.10	0.127	0.123 - 0.133	28.9 mL/18 L
0.15	0.185	0.176 - 0.194	42.3 mL/18 L
0.2	0.246	0.234 - 0.258	56.1 mL/18 L
0.3	0.368	0.350 - 0.385	84.6 mL/18 L

- In a 1 L volumetric flask, add approximately 900 mL deionized water. Using volumetric glassware, add precisely the appropriate volume as indicated in Table 1 of absolute ethanol. Stopper the flask and mix well by inverting several times and add the contents of the flask to the 18 L vessel. Rinse the flask with approximately 1 L deionized water and add this to the 18 L vessel. Fill the vessel to the 18 L mark with deionized water and tighten the cap. Mix the solution by applying mechanical mixing for a minimum of 30 minutes.
- 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.
- Remove approximately 10 mL of the mixed solution for testing.

G. Certification:

- 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.
- Record the results of the testing in the solution certification database, including the date and the results of the contemporary external control.
- A minimum of two (2) analysts must certify the solution prior to its certification.
- 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 and al., 1978).
- The solution is acceptable for use and therefore certified if it meets the following criteria. The solution concentration must meet the criteria in Table 1. The CV must be 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 following its preparation.
8. The solution is acceptable for use in establishing linearity, precision and accuracy on the Quality Assurance program of the Washington State Patrol Breath Test Section.

H. Documentation:

1. Upon completion of their testing, each analyst will complete the simulator solution 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.
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 provided to breath test technicians of the Washington State Patrol in containers of convenient size.
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:

AW 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.

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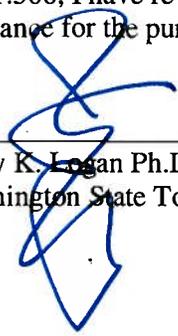
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STATEMENT OF STATE TOXICOLOGIST --

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: 8/7/2007

Approved:


Barry K. Logan, Ph.D.

Date (prepared August 7, 2007):

8/7/2007

The following toxicologists have read the Quality Assurance 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: [Signature] Date: 8/8/07

Reviewed By: [Signature] Date: 8-8-07

Reviewed By: Brittany Ball Date: 8/8/07

Reviewed By: [Signature] Date: 8/8/07

Reviewed By: [Signature] Date: 2007 08 08

Reviewed By: Brianna Peterson Date: 8/8/07

Reviewed By: [Signature] Date: 8-8-07

Reviewed By: Brianne Akers Date: 8.8.07

Reviewed By: [Signature] Date: 8-8-07

Reviewed By: [Signature] Date: 8-8-07

Reviewed By: [Signature] Date: 8/8/07

Reviewed By: [Signature] Date: 8/8/07

Reviewed By: [Signature] Date: 080807

Reviewed By: [Signature] Date: 8/8/07

Reviewed By: _____ Date: _____

Approved: [Signature]
Barry K. Logan, Ph.D.

Date (prepared August 7, 2007):

8/7/2007

Reviewed By: _____

Date: _____

Approved: 

Barry K. Logan, Ph.D.

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

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