

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

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A. Introduction:

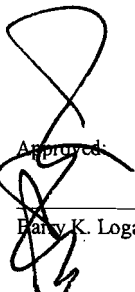
1. The BAC Datamaster breath test instrument is equipped with a Guth Breath Alcohol Simulator. This device produces a predictable, known vapor concentration by passing air through a heated aqueous solution of known alcohol concentration.

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 ± 0.3 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 preparation is carried out at room temperature using deionized water and 200 proof, absolute ethanol.

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

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(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 0.04, 0.08, 0.10 and 0.15 g/210 L vapor. Other solutions required periodically for instrument evaluation will produce vapor concentrations of 0.20 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/flasks
10 mL, 5 mL, 2 mL, 1 mL volumetric pipette, grade A
1 mL pipette
100 mL Buret
Mechanical mixer and stir rod
18 L containers
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 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 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 18 L with deionized water and tighten the cap. Mix the solution by applying mechanical mixing for a minimum of 30 minutes. Once mixing is completed, remove an aliquot (approximately 10 mL) of the mixed solution for testing.
- 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 2008 would be 08001.
- 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), 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:

- 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.
- A minimum of three (3) analysts must test the solution before the average solution concentration can be calculated and the solution certified.
- After obtaining all measurement results the arithmetic mean (rounded to four decimal places) and the standard deviation (rounded to five decimal places) will be determined. For Quality Assurance Procedure solutions (n=15) no measurement result should exceed 3.8 standard deviations. When an outlier value is observed, the value will be removed from the data set and the test for outliers repeated. If there are two outliers then the data will be reviewed for statistical and/or technical causes before being approved. This may result in the solution finally being approved with

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the two values omitted, or it may result in rejection of the batch. If more than two outliers are detected for a batch then the solution will be discarded. When no more than two outliers have been identified and removed, the final arithmetic mean and standard deviation will be determined based on the remaining results found to be in acceptable agreement. The tests for outliers and final solution calculations will be performed by a reviewer independent from the analysts performing the measurements. Each analyst who has results included in the final computation of the mean has certified the batch.

4. The solution meets the standards required by the state toxicologist if:
 - i. The average solution concentration is within the range established in Table 1.
 - 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.
7. The solution is acceptable for use in establishing linearity, precision and accuracy in the Quality Assurance program of the Washington State Patrol Breath Test Section.

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.
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.

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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 provided to breath test technicians of the Washington State Patrol in containers of convenient size.
2. Each container is labeled with the batch number and its preparation date.
3. The containers 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.

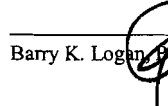
STATEMENT OF STATE TOXICOLOGIST –

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

Approved:



Barry K. Logan Ph.D.

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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: 12/19/07

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Reviewed By: [Signature] Date: 12/19/07

Reviewed By: [Signature] Date: 12/19/07

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Reviewed By: [Signature] Date: 12-20-07

Reviewed By: [Signature] Date: 2007 Dec 20

Reviewed By: [Signature] Date: 12-20-07

Reviewed By: [Signature] Date: 12/20/2007

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Approved: [Signature]
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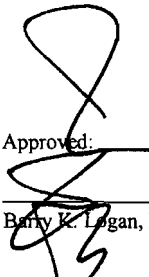
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Approved: 

Barry K. Logan, Ph.D.

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