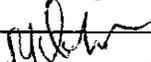




Title: Ethanol Simulator Solution Preparation		Page 1 of 5	
Doc. No. P-Alc-204	Revision No. 0	Approved by:  Date: 3/18/09 Owner: Toxicology Program Chief	Date Effective: 3/17/09

## 1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used for the preparation of aqueous ethanol solutions intended for use in calibration, certification and to act as a control sample during subject testing for DataMaster infrared breath testing instruments.

## 2.0 Responsibility

- 2.1 All staff having the responsibility for preparation of ethanol simulator solutions are responsible for following this procedure. The need for any revisions must be brought as soon as possible to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology program staff. Necessary revisions will be made at that time or when there is an identified need to change this written procedure to be compatible with changing needs in the analytical process.

## 3.0 Precautions and Safety Directives

- 3.1 Absolute ethanol is highly flammable. It must be kept from heat and flame. In case of fire it can be extinguished with water or by proper use of any class of fire extinguisher.
- 3.2 Absolute ethanol is toxic. Do not ingest. Avoid prolonged inhalation of vapors or skin contact.
- 3.3 MSDS sheet for absolute ethanol are available in the yellow MSDS wall-basket located in the middle of the second floor hallway, toxicology wing.
- 3.4 See VDHL Chemical Hygiene Plan & Laboratory Safety Manual (D-AD-003) located in the Toxicology Program Chief's office for further guidelines.

## 4.0 Procedure

### 4.1 Materials and Supplies

- 4.1.1 All supplies located in Room 207 unless otherwise specified.
- 4.1.2 Absolute ethanol (EtOH) (200 proof, anhydrous) by Pharmco or equivalent.
- 4.1.2 Volumetric Pipettes.
- 4.1.3 Graduated cylinders. (2<sup>nd</sup> floor hallway)
- 4.1.4 Class A Volumetric flasks. (2<sup>nd</sup> floor hallway)
- 4.1.5 Lab pure (e.g., MiliQ) water, organic volatile-free. (room 205)
- 4.1.6 Plastic Carboy with spigot (20L, 50L).

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Doc. No. P-Alc- 204	Revision No. 0	Approved by:  Owner: Toxicology Program Chief	Date: 3/18/09 Date Effective: 3/17/09

4.1.7 Copper Sulfate crystals (ACS Reagent Grade) by Fisher or equivalent.

4.1.8 Boston round plastic bottles (500 ml) (Room 124).

4.1.9 Parafilm.

#### 4.2 Stock Aqueous Ethanol Solution

4.2.1 Using volumetric pipettes, transfer 77.0 mL of absolute ethanol into a 1L volumetric flask to which about 500 mL of laboratory pure water has been added. Cap the flask and invert to mix thoroughly. Add water to the mark on the volumetric flask.

4.2.2 Transfer the solution into two glass screw-cap bottles, attach the solution identification label and seal with Parafilm. This solution has a shelf life of 1 year. The label should include the concentration of the solution, the purpose, the preparation date and preparer's initials as well as the expiration date.

4.2.3 Record all preparation information in the Alcohol Solutions logbook (Alc 666).

#### 4.3 Calibration and Certification Solutions

4.3.1 The following table describes the volume of Stock Aqueous Ethanol Solution required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Ethanol Stock Soln.	Final volume
0.02 g/210L	8.0 mL	2L
0.05 g/210L	20.0 mL	2 L
0.08 g/210L	32.0 mL	2 L
0.10 g/210L	40.0 mL	2L
0.16 g/210L	64.0 ml	2L
0.40 g/210L	160.0 mL	2L

4.3.2 Pipet the appropriate amount of Stock Aqueous Ethanol Solution into a volumetric flask which is filled to approximately 1/2 volume with laboratory pure water. Invert to mix.

4.3.3 Fill to the mark on the volumetric flask with laboratory pure water and cap. Invert to mix thoroughly.

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- 4.3.4 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :
- 4.3.4.1 YY = The last two digits of the fiscal year in which the solution was made;
- 4.3.4.2 NN= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;
- 4.3.4.3 XXX = The target concentration expressed to three decimal places.
- 4.3.5 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.
- 4.3.6 Add several crystals of copper sulfate to the flask and swirl until all crystals are dissolved. The solution should have a faint blue color when held to the light.
- 4.3.7 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.
- 4.3.8 Upon solution certification, transfer the solution(s) to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

#### 4.4 Check Sample Preparation

- 4.4.1 Large batches of simulator solutions are requested for use as a check sample on subject tests in DataMaster instruments in the field.
- 4.4.2 In December and May, one 50 L and one 20 L batch are made for Routine Performance check shipments to DataMaster agencies.
- 4.4.3 The following table describes the volume of absolute ethanol (200 proof anhydrous) required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Absolute EtOH.	Final volume
0.10 g/210L	32 mL	20L
0.10 g/210L	80 mL	50L

- 4.4.4 Fill the carboy approximately half way with MilliQ water.
- 4.4.5 Add the appropriate amount of absolute ethanol to the carboy.
- 4.4.6 Continue filling the carboy to the fill line and shake well.

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- 4.4.7 Decant a portion of the solution into a flask and add approximately half a gram of copper sulfate to it. Shake the flask until the copper sulfate is dissolved and add back to the carboy.
- 4.4.8 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :
- 4.4.8.1 YY = The last two digits of the calendar year in which the solution was made;
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- 4.4.10 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.
- 4.4.11 Upon solution certification, transfer the solution to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

## 5.0 Emergency or High Priority Situations

- 5.1 In the case where there are no unopened bottles of solution remaining, a request to prepare solution may be made as an emergency. This request should be done in person to the individual assigned to prepare simulator solutions and should be expressed as an emergency. Solution preparation will be expedited.

## 6.0 Quality Control and Corrective Action

- 6.1 Solutions not meeting acceptance criteria must be adjusted or remade and then certified as stated in P-Alc-203.
- 6.2 The concentration characterization is confirmed during the data review portion of the simulator solution analytical procedure (P-Alc-203).
- 6.3 The analyst will confirm that the information on the storage bottle labels (lot #, concentration) matches the information in the simulator solution log book.

## 7.0 Preventive Maintenance and Backup

- 7.1 If the simulator solution cannot be prepared and characterized in-house, certified simulator solution of similar concentration levels will be purchased from Guth Laboratories or an equivalent vendor.

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Doc. No. P-Alc-204	Revision No. 0	Approved by:  Owner: Toxicology Program Chief	Date: 3/18/09 Date Effective: 3/17/09

- 7.2 Solutions should be requested via email or by recording them on the white board outside of room 209 when one unopened bottle of solution remains to ensure that a new lot is available when needed.

## 8.0 References and Appendices

- 8.1 Simulator Solution Certification SOP (P-Alc- 203)
- 8.2 Dubowski , K.M.; " Breath-Alcohol Simulators: Scientific Basis and Actual Performance", Journal of Analytical Toxicology, vol. 3 , Sept./Oct. 1979, pp 177-182.
- 8.3 Appendix A: Alcohol Solutions Logbook (Alc 666)
- 8.4 Appendix B: Simulator Solution Preparation Log, (Chem 642)

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# APPENDIX A



Toxicology Program  
Solutions for Headspace Analysis Logbook

Solution Name \_\_\_\_\_ Lot #: \_\_\_\_\_ Analyst: \_\_\_\_\_

Preparation Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Compound	Weight/Volume Used	Manufacturer & Lot #	Final Volume

Solution Name \_\_\_\_\_ Lot #: \_\_\_\_\_ Analyst: \_\_\_\_\_

Preparation Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Compound	Weight/Vol Used	Manufacturer & Lot #	Final Volume

Solution Name \_\_\_\_\_ Lot #: \_\_\_\_\_ Analyst: \_\_\_\_\_

Preparation Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Compound	Weight/Vol Used	Manufacturer & Lot #	Final Volume

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# APPENDIX B

### SIMULATOR SOLUTION PREPARATION LOG

Prep. Date	Manufacturer & Lot identification	Volume prepared	Solution Components	Target Concentration	Prepared by	GC assay Results	Analyst	Intended use
							Date of analysis	

*M.P.*

**Vermont Department of Health Laboratory**  
**Procedure and Document Review Coversheet**

Document Title: Ethanol Simulator Solution Preparation	
Document #: P-ALC-### (To replace P-ALC 201 & 202)	Revision #: 0
File Name: 204	
Author or Editor: Darcy Richardson	Owner: Bob Drawbaugh
Start Date: 6/10/08	Due Date:

Name and Title of Reviewers	Signature	Comments? Y/N *	Date of Signature	Control Copy #
Amanda Bolduc	<i>ABolduc</i>	Y <input type="checkbox"/>	6/16	
Hillary Boucher	<i>H. Boucher</i>	N <input type="checkbox"/>	6/16/08	
Marie Sawyer	<i>Marie Sawyer</i>	N <input type="checkbox"/>	6/17/08	
Bob Drawbaugh	<i>BD</i>	<input type="checkbox"/>	8/4/08	
Ed Luce	<i>Edmund P. Luce</i>	Y <input type="checkbox"/>	8/5/08	
Stella Celotti	<i>Mary Cefati</i>	N <input type="checkbox"/>	8/28/08	
		<input type="checkbox"/>		

\* ( ✓ ) in checkbox indicates reviewer comments have been discussed and incorporated if applicable.

Title: Ethanol Simulator Solution Preparation			Page 1 of 6
Doc. No. P-AIc- 204	Revision No. 0	Approved by: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

## 1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used for the preparation of aqueous ethanol solutions intended for use in calibration, certification and to act as a control sample during subject testing for DataMaster infrared breath testing instruments.

## 2.0 Responsibility

- 2.1 All staff having the responsibility for preparation of ethanol simulator solutions are responsible for following this procedure. The need for any revisions must be brought as soon as possible to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology program staff. Necessary revisions will be made at that time or when there is an identified need to change this written procedure to be compatible with changing needs in the analytical process.

## 3.0 Precautions and Safety Directives

- 3.1 Absolute ethanol is highly flammable. It must be kept from heat and flame. In case of fire it can be extinguished with water or by proper use of any class of fire extinguisher.
- 3.2 Absolute ethanol is toxic. Do not ingest. Avoid prolonged inhalation of vapors or skin contact.
- 3.3 MSDS sheet for absolute ethanol are available in the yellow MSDS wall-basket located in the middle of the second floor hallway, toxicology wing.
- 3.4 See VDHL Chemical Hygiene Plan & Laboratory Safety Manual (D-AD-003) located in the Toxicology Program Chief's office for further guidelines.

## 4.0 Procedure

### 4.1 Materials and Supplies

- 4.1.1 All supplies located in Room 207 unless otherwise specified.
- 4.1.2 Absolute ethanol (EtOH) (200 proof, anhydrous) by Pharmco or equivalent.
- 4.1.2 Volumetric Pipettes.
- 4.1.3 Graduated cylinders. (2<sup>nd</sup> floor hallway)
- 4.1.4 Class A Volumetric flasks. (2<sup>nd</sup> floor hallway)
- 4.1.5 Lab pure (e.g., MiliQ) water, organic volatile-free. (room 205)
- 4.1.6 Plastic Carboy with spigot (20L, 50L).

Title: Ethanol Simulator Solution Preparation		Page 2 of 6
Doc. No. P-Alc- 204	Revision No. 0	Approved by: _____ Date: _____ Owner: Toxicology Program Chief
		Date Effective:

4.1.7 Copper Sulfate crystals (ACS Reagent Grade) by Fisher or equivalent.

4.1.8 Boston round plastic bottles (500 ml) (Room 124).

4.1.9 Parafilm.

## 4.2 Stock Aqueous Ethanol Solution

4.2.1 Using volumetric pipettes, transfer 77.0 mL of absolute ethanol into a 1L volumetric flask to which about 500 mL of laboratory pure water has been added. Cap the flask and invert to mix thoroughly. Add water to the mark on the volumetric flask.

4.2.2 Transfer the solution into two glass screw-cap bottles, attach the solution identification label and seal with Parafilm. This solution has a shelf life of 1 year. The label should include the concentration of the solution, the purpose, the preparation date and preparer's initials as well as the expiration date.

4.2.3 Record all preparation information in the Alcohol Solutions logbook (Alc 666).

## 4.3 Calibration and Certification Solutions

4.3.1 The following table describes the volume of Stock Aqueous Ethanol Solution required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Ethanol Stock Soln.	Final volume
0.02 g/210L	8.0 mL	2L
0.05 g/210L	20.0 mL	2 L
0.08 g/210L	32.0 mL	2 L
0.10 g/210L	40.0 mL	2L
0.16 g/210L	64.0 ml	2L
0.40 g/210L	160.0 mL	2L

4.3.2 Pipet the appropriate amount of Stock Aqueous Ethanol Solution into a volumetric flask which is filled to approximately 1/2 volume with laboratory pure water. Invert to mix.

4.3.3 Fill to the mark on the volumetric flask with laboratory pure water and cap. Invert to mix thoroughly.

Title: Ethanol Simulator Solution Preparation		Page 3 of 6
Doc. No. <b>P-Alc- 204</b>	Revision No. 0	Approved by: _____ Date: _____ Owner: Toxicology Program Chief
		Date Effective:

- 4.3.4 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :
- 4.3.4.1 YY = The last two digits of the fiscal year in which the solution was made;
- 4.3.4.2 NN= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;
- 4.3.4.3 XXX = The target concentration expressed to three decimal places.
- 4.3.5 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.
- 4.3.6 Add several crystals of copper sulfate to the flask and swirl until all crystals are dissolved. The solution should have a faint blue color when held to the light.
- 4.3.7 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.
- 4.3.8 Upon solution certification, transfer the solution(s) to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

#### 4.4 Check Sample Preparation

- 4.4.1 Large batches of simulator solutions are requested for use as a check sample on subject tests in DataMaster instruments in the field.
- 4.4.2 In December and May, one 50 L and one 20 L batch are made for Routine Performance check shipments to DataMaster agencies.
- 4.4.3 The following table describes the volume of absolute ethanol (200 proof anhydrous) required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Absolute EtOH.	Final volume
0.10 g/210L	32 mL	20L
0.10 g/210L	80 mL	50L

- 4.4.4 Fill the carboy approximately half way with MilliQ water.
- 4.4.5 Add the appropriate amount of absolute ethanol to the carboy.
- 4.4.6 Continue filling the carboy to the fill line and shake well.

Title: Ethanol Simulator Solution Preparation			Page 4 of 6
Doc. No. P-Alc- 204	Revision No. 0	Approved by: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

- 4.4.7 Decant a portion of the solution into a flask and add approximately half a gram of copper sulfate to it. Shake the flask until the copper sulfate is dissolved and add back to the carboy.
- 4.4.8 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :
- 4.4.8.1 YY = The last two digits of the calendar year in which the solution was made;
- 4.4.8.2 NN= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;
- 4.4.8.3 XXX = The target concentration expressed to three decimal places.
- 4.4.9 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.
- 4.4.10 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.
- 4.4.11 Upon solution certification, transfer the solution to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

## 5.0 Emergency or High Priority Situations

- 5.1 In the case where there are no unopened bottles of solution remaining, a request to prepare solution may be made as an emergency. This request should be done in person to the individual assigned to prepare simulator solutions and should be expressed as an emergency. Solution preparation will be expedited.

## 6.0 Quality Control and Corrective Action

- 6.1 Solutions not meeting acceptance criteria must be adjusted or remade and then certified as stated in P-Alc-203.
- 6.2 The concentration characterization is confirmed during the data review portion of the simulator solution analytical procedure (P-Alc-203).
- 6.3 The analyst will confirm that the information on the storage bottle labels (lot #, concentration) matches the information in the simulator solution log book.

## 7.0 Preventive Maintenance and Backup

- 7.1 If the simulator solution cannot be prepared and characterized in-house, certified simulator solution of similar concentration levels will be purchased from Guth Laboratories or an equivalent vendor.

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Doc. No. P-Alc- 204	Revision No. 0	Approved by: Owner: Toxicology Program Chief	Date: Date Effective:

5.1

Solutions should be requested via email or by recording them on the white board outside of room 209 when one unopened bottle of solution remains to ensure that a new lot is available when needed.

7.1

## 8.0 References and Appendices

- 8.1 Simulator Solution Certification SOP (P-Alc- 203)
- 8.2 Dubowski , K.M.; " Breath-Alcohol Simulators: Scientific Basis and Actual Performance", Journal of Analytical Toxicology, vol. 3 , Sept./Oct. 1979, pp 177-182.
- 8.3 Appendix A: Alcohol Solutions Logbook (Alc 666)
- 8.4 Appendix B: Simulator Solution Preparation Log, (Chem 642)

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Doc. No. P-Alc-###	Revision No. 0	Approved by: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective: _____

**Appendix A**

Alcohol Solutions Logbook pending approval.

**APPENDIX B**

VT Department of Health Laboratory

**SIMULATOR SOLUTION PREPARATION LOG**

Prep. Date	<i>Manufacturer &amp;</i> Lot identification	Volume prepared	Solution Components	Target Concentration	Prepared by	GC assay Results	Analyst <hr/> Date of analysis	Intended use

OFFICE MEMO

Title: Ethanol Simulator Solution Prep

Doc. No. P-Alc- 204 Revision No. 0 Approved by: Owner: Toxicology Progra

TO: Darcy  
FROM: Steele  
DATE: 2/27/09

- APPROVAL  NOTE AND SEE ME  AS REQUESTED
- SIGNATURE  NOTE AND RETURN  FYI
- COMMENT  NOTE AND FILE

1.0 Purpose and Scope

1.1 The purpose of this procedure is to describe ethanol solutions intended for use in calibration during subject testing for DataMaster infrared

2.0 Responsibility

- 2.1 All staff having the responsibility for preparation responsible for following this procedure. The need for any revisions must be brought as soon as possible to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology program staff. Necessary revisions will be made at that time or when there is an identified need to change this written procedure to be compatible with changing needs in the analytical process.

*closed with a few Ed's suggestions that weren't incorporated. Please return for close-out. Thank*

3.0 Precautions and Safety Directives

- 3.1 Absolute ethanol is highly flammable. It must be kept from heat and flame. In case of fire it can be extinguished with water or by proper use of any class of fire extinguisher.
- 3.2 Absolute ethanol is toxic. Do not ingest. Avoid prolonged inhalation of vapors or skin contact.
- 3.3 MSDS sheet for absolute ethanol are available in the yellow MSDS wall-basket located in the middle of the second floor hallway, toxicology wing.
- 3.4 See VDHL Chemical Hygiene Plan & Laboratory Safety Manual (D-AD-003) located in the Toxicology Program Chief's office for further guidelines.

4.0 Procedure

4.1 Materials and Supplies *Location needed*

- 4.1.1 Absolute ethanol (EtOH) (200 proof, anhydrous). *Current manufacturer + Cat # (per Ed's suggestion) needed*
- 4.1.2 Class A volumetric pipet.
- 4.1.3 Safety bulb for 4.1.2.
- 4.1.4 Class A Volumetric flasks.
- 4.1.5 Lab pure (e.g., MilliQ) water, organic volatile-free.
- 4.1.6 Plastic Carboy with spigot (20L, 50L)
- 4.1.7 Copper Sulfate crystals (ACS Reagent Grade) *need Manufacturer + Cat # (per Ed's suggestion) Steele*

Title: Ethanol Simulator Solution Preparation			Page 2 of 6
Doc. No. P-Alc- 204	Revision No. 0	Approved by: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

4.1.8 Boston round plastic bottles (500 ml)

4.1.9 Parafilm

## 4.2 Stock Aqueous Ethanol Solution

4.2.1 Using volumetric pipets, transfer 77.0 mL of absolute ethanol into a 1L volumetric flask to which about 500 mL of laboratory pure water has been added. Cap the flask and invert to mix thoroughly. Add water to the mark on the volumetric flask.

4.2.2 Transfer the solution into two glass screw-cap bottles, attach the solution identification label and seal with Parafilm. This solution has a shelf life of 1 year. The label should include the concentration of the solution, the purpose, the preparation date and preparer's initials as well as the expiration date.

4.2.3 Record all preparation information in the Alcohol Solutions logbook (Alc 666).

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Title: Ethanol Simulator Solution Preparation			Page 3 of 6
Doc. No. P-Alc- 204	Revision No. 0	Approved by: Owner: Toxicology Program Chief	Date: Date Effective:

- 4.3.4 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :
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- 4.3.4.3 XXX = The target concentration expressed to three decimal places.
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- 4.3.6 Add several crystals of copper sulfate to the flask and swirl until all crystals are dissolved. The solution should have a faint blue color when held to the light.
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Title: Ethanol Simulator Solution Preparation			Page 5 of 6
Doc. No. P-Alc- 204	Revision No. 0	Approved by: Owner: Toxicology Program Chief	Date: Date Effective:

- 5.1  
7.1
- Solutions should be requested via email or by recording them on the white board outside of room 209 when one unopened bottle of solution remains to ensure that a new lot is available when needed.

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- 8.1 Simulator Solution Certification SOP (P-Alc- 203)
- 8.2 Dubowski , K.M.; " Breath-Alcohol Simulators: Scientific Basis and Actual Performance", Journal of Analytical Toxicology, vol. 3 , Sept./Oct. 1979, pp 177-182.
- 8.3 Appendix A: Alcohol Solutions Logbook (Alc 666)
- 8.4 Appendix B: Simulator Solution Preparation Log, (Chem 642)

Title: Ethanol Simulator Solution Preparation		Page 1 of 7	
Doc. No. P-Alc- ###	Revision No. 0	Approved by: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

## 1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used for the preparation of aqueous ethanol solutions intended for use in calibration, certification and to act as a control sample during subject testing for DataMaster infrared breath testing instruments.

## 2.0 Responsibility

- 2.1 All staff having the responsibility for preparation of ethanol simulator solutions are responsible for following this procedure. The need for any revisions must be brought as soon as possible to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology program staff. Necessary revisions will be made at that time or when there is an identified need to change this written procedure to be compatible with changing needs in the analytical process.

## 3.0 Precautions and Safety Directives

- 3.1 Absolute ethanol is highly flammable. It must be kept from heat and flame. In case of fire it can be extinguished with water or by proper use of any class of fire extinguisher.
- 3.2 Absolute ethanol is toxic. Do not ingest. Avoid prolonged inhalation of vapors or skin contact.

4.0 **Procedure** *MSDS Sheet for Absolute ethanol are available in the yellow MSDS wall-basket located in middle of second floor hallway,*

### 4.1 Materials and Supplies

- 4.1.1 Absolute ethanol (EtOH) (200 proof, anhydrous).  
*Current Manufacturer & Cat #*
- 4.1.2 Class A volumetric pipet.
- 4.1.3 Safety bulb for 4.1.2.
- 4.1.4 Class A Volumetric flasks.
- 4.1.5 Lab pure (e.g., MiliQ) water, organic volatile-free.
- 4.1.6 Plastic Carboy with spigot (20L, 50L)
- 4.1.7 Copper Sulfate crystals (ACS Reagent Grade)  
*Manufacturer & Cat #*
- 4.1.8 Boston round plastic bottles (500 ml)
- 4.1.9 Parafilm

*Chemistry wing.*

*3.4. See 'VDHL Chemical Hygiene Plan & Laboratory Safety Manual (D-AD-003) located in Toxicology Program Chief's office, for further guidelines.*

## 4.2 Stock Aqueous Ethanol Solution

4.2.1 Using volumetric pipets, transfer 77.0 mL of absolute ethanol into a 1L volumetric flask to which about 500 mL of laboratory pure water has been added. Cap the flask and invert to mix thoroughly. Add water to the mark on the volumetric flask.

4.2.2 Transfer the solution into two glass screw-cap bottles, attach the solution identification label and seal with Parafilm. This solution has a shelf life of 1 year.

4.2.3 Record all preparation information in the Alcohol Solutions logbook (Alc 666). PENDING APPROVAL. *Include manufacturer and lot # of absolute ethanol*

## 4.3 Calibration and Certification Solutions

4.3.1 The following table describes the volume of Stock Aqueous Ethanol Solution required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Ethanol Stock Soln.	Final volume
0.02 g/210L	8.0 mL	2L
0.05 g/210L	20.0 mL	2 L
0.08 g/210L	32.0 mL	2 L
0.10 g/210L	40.0 mL	2L
0.16 g/210L	64.0 ml	2L
0.40 g/210L	160.0 mL	2L

4.3.2 Pipet the appropriate amount of Stock Aqueous Ethanol Solution into a volumetric flask which is filled to approximately 1/2 volume with laboratory pure water. Invert to mix.

4.3.3 Fill to the mark on the volumetric flask with laboratory pure water and cap. Invert to mix thoroughly.

4.3.4 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :

4.3.4.1 YY = The last two digits of the fiscal year in which the solution was made;

4.3.4.2 NN= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;

4.3.4.3 XXX = The target concentration expressed to three decimal places.

4.3.5 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.

4.3.6 Add several crystals of copper sulfate to the flask and swirl until all crystals are dissolved. The solution should have a faint blue color when held to the light.

4.3.7 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.

4.3.8 Upon solution certification, transfer the solution(s) to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

#### 4.4 Check Sample Preparation

4.4.1 Large batches of simulator solutions are requested for use as a check sample on subject tests in DataMaster instruments in the field.

4.4.2 In December and May, one 50 L and one 20 L batch are made for Routine Performance check shipments to DataMaster agencies.

4.4.3 The following table describes the volume of absolute ethanol (200 proof anhydrous) required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Absolute EtOH.	Final volume
0.10 g/210L	32 mL	20L
0.10 g/210L	80 mL	50L

4.4.4 Fill the carboy approximately half way with MilliQ water.

4.4.5 Add the appropriate amount of absolute ethanol to the carboy.

4.4.6 Continue filling the carboy to the fill line and shake well.

4.4.7 Decant a portion of the solution into a flask and add approximately half a gram of copper sulfate to it. Shake the flask until the copper sulfate is dissolved and add back to the carboy.

4.4.8 Assign a simulator solution lot number for each solution using the scheme: YY- NN-XXX; where :

4.4.8.1 YY = The last two digits of the calendar year in which the solution was made;

*Note: Record Manufacture & Lot # used to prep cal & cert. stds.*

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4.4.8.2 NN= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;

4.4.8.3 XXX = The target concentration expressed to three decimal places.

4.4.9 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.

4.4.10 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.

4.4.11 Upon solution certification, transfer the solution to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

## 5.0 Emergency or High Priority Situations

5.1 In the case where there are no unopened bottles of solution remaining, a request to prepare solution may be made as an emergency. This request should be done in person to the individual assigned to prepare simulator solutions and should be expressed as an emergency. Solution preparation will be expedited.

## 6.0 Quality Control and Corrective Action

6.1 Solutions not meeting acceptance criteria must be adjusted or remade and then certified as stated in P-Alc-203.

6.2 The concentration characterization is confirmed during the data review portion of the simulator solution analytical procedure (P-Alc-203).

6.3 The analyst will confirm that the information on the storage bottle labels (lot #, concentration) matches the information in the simulator solution log book.

## 7.0 Preventive Maintenance and Backup

7.1 If the simulator solution cannot be prepared and characterized in-house, certified simulator solution of similar concentration levels will be purchased from Guth Laboratories or an equivalent vendor.

5.1 Solutions should be requested via email or by recording them on the white board outside of room 209 when one unopened bottle of solution remains to ensure that a new lot is available when needed.

## 8.0 References and Appendices

8.1 Simulator Solution Certification SOP (P-Alc- 203) PENDING

8.2 Dubowski , K.M.; " Breath-Alcohol Simulators: Scientific Basis and Actual Performance", Journal of Analytical Toxicology, vol. 3 , Sept./Oct. 1979, pp 177-182.

*See Note on previous page & include manufacturer & lot # for CuSO<sub>4</sub>*

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8.3 Appendix A: Alcohol Solutions Logbook (Alc 666) PENDING

8.4 Appendix B: Simulator Solution Preparation Log, (Chem 642)

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## 1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used for the preparation of aqueous ethanol solutions intended for use in calibration, certification and to act as a control sample during subject testing for DataMaster infrared breath testing instruments.

## 2.0 Responsibility

- 2.1 All staff having the responsibility for preparation of ethanol simulator solutions are responsible for following this procedure. The need for any revisions must be brought as soon as possible to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology program staff. Necessary revisions will be made at that time or when there is an identified need to change this written procedure to be compatible with changing needs in the analytical process.

## 3.0 Precautions and Safety Directives

- 3.1 Absolute ethanol is highly flammable. It must be kept from heat and flame. In case of fire it can be extinguished with water or by proper use of any class of fire extinguisher.
- 3.2 Absolute ethanol is toxic. Do not ingest. Avoid prolonged inhalation of vapors or skin contact.

## 4.0 Procedure

### 4.1 Materials and Supplies

- 4.1.1 Absolute ethanol (EtOH) (200 proof, anhydrous).
- 4.1.2 Class A volumetric pipet.
- 4.1.3 Safety bulb for 4.1.2.
- 4.1.4 Class A Volumetric flasks.
- 4.1.5 Lab pure (e.g., MiliQ) water, organic volatile-free.
- 4.1.6 Plastic Carboy with spigot (20L, 50L)
- 4.1.7 Copper Sulfate crystals (ACS Reagent Grade)
- 4.1.8 Boston round plastic bottles, 500mL
- 4.1.9 Parafilm

### 4.2 Stock Aqueous Ethanol Solution

~~used for~~

myt paper ↓

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		Date Effective:

- 4.2.1 Using volumetric pipets, transfer 77.0 mL of absolute ethanol into a 1L volumetric flask to which about 500 mL of laboratory pure water has been added. Cap the flask and invert to mix thoroughly. Add water to the mark on the volumetric flask.
- 4.2.2 Transfer the solution into two glass screw-cap bottles, attach the solution identification label and seal with Parafilm. This solution has a shelf life of 1 year.
- 4.2.3 Record all preparation information in the Alcohol Solutions logbook (Alc 666)  
PENDING APPROVAL.

### 4.3 Simulator Solutions

- 4.3.1 The following table describes the volume of Stock Aqueous Ethanol Solution required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Ethanol Stock Soln.	Final volume
0.02 g/210L	8.0 mL	2L
0.05 g/210L	20.0 mL	2 L
0.08 g/210L	32.0 mL	2 L
0.10 g/210L	40.0 mL	2L
0.16 g/210L	64.0 ml	2L
0.40 g/210L	160.0 mL	2L

- 4.3.2 Pipet the appropriate amount of Stock Aqueous Ethanol Solution into a volumetric flask which is filled to approximately 1/2 volume with laboratory pure water. Invert to mix.
- 4.3.3 Fill to the mark on the volumetric flask with laboratory pure water and cap. Invert to mix thoroughly.
- 4.3.4 Assign a simulator solution lot number for each solution using the scheme: YY- nn-xxx; where :
  - 4.3.4.1 YY = *fiscal?* The last two digits of the calendar year in which the solution was made;
  - 4.3.4.2 nn= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;
  - 4.3.4.3 xxx = The target concentration expressed to three decimal places.

- 4.3.5 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.
- 4.3.6 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.
- 4.3.7 Upon solution certification, transfer the solution(s) to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

*Add  
COPPER  
Sulfate*

**4.4 External Standard Preparation**

- 4.4.1 Large batches of simulator solutions are requested for use as a check sample on subject tests in DataMaster instruments in the field.
- 4.4.2 In December and May, one 50 L and one 20 L batch are made for Routine Performance check shipments to DataMaster agencies.
- 4.4.3 The following table describes the volume of absolute ethanol (200 proof anhydrous) required to prepare solutions which will provide the equivalent breath alcohol concentrations [BrAC] listed when equilibrated in a breath-alcohol simulator at 34.0°C:

Equiv. BrAC	mL Absolute EtOH.	Final volume
0.10 g/210L	32 mL	20L
0.10 g/210L	80 mL	50L

- 4.4.4 Fill the carboy approximately half way with MilliQ water.
- 4.4.5 Add the appropriate amount of absolute ethanol to the carboy.
- 4.4.6 Continue filling the carboy to the fill line and shake well.
- 4.4.7 Decant a portion of the solution into a flask and add approximately half a gram of copper sulfate to it. Shake the flask until the copper sulfate is dissolved and add back to the carboy.
- 4.4.8 Assign a simulator solution lot number for each solution using the scheme: YY- nn- xxx; where :
- 4.4.8.1 YY = The last two digits of the calendar year in which the solution was made;
- 4.4.8.2 nn= The next sequential solution lot number for the year as determined from the Simulator Solution Log Book in room 207;
- 4.4.8.3 xxx = The target concentration expressed to three decimal places.

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4.4.9 Record this information in the Simulator Solution Log Book (Chem 642) and in the electronic version located in Seagull→Public→Alcohol→DM Logs.

*Analyze before adding copper sulfate?*

4.4.10 Analyze the samples per the Simulator Solution Certification Procedure in P-Alc-203.

4.4.11 Upon solution certification, transfer the solution to appropriately labeled 500 mL screw-cap Boston round plastic bottles and seal with Parafilm.

## 5.0 Emergency or High Priority Situations

5.1 In the case where there are no unopened bottles of solutions remaining, a request may be made as an emergency. This request should be done in person to the individual assigned to prepare simulator solutions and should be expressed as an emergency. Solutions will be expedited.

*To prepare solution*

*prep.*

## 6.0 Quality Control and Corrective Action

6.1 Solutions not meeting acceptance criteria must be adjusted or remade and then certified as stated in P-Alc-203.

6.2 The concentration characterization is confirmed during the data review portion of the simulator solution analytical procedure (P-Alc-203).

6.3 The analyst will confirm that the information on the storage bottle labels (lot #, concentration) matches the information in the simulator solution log book.

*acceptance range*

## 7.0 Preventive Maintenance and Backup

7.1 If the simulator solution cannot be prepared and characterized in-house, certified simulator solution of similar concentration levels will be purchased from Guth Laboratories or an equivalent provider.

*Vendor.*

5.1 Solutions should be requested via email or by recording them on the white board outside of room 210 when one unopened bottle of solution remains to ensure that a new lot is available when needed.

*room*

## 8.0 References and Appendices

8.1 Simulator Solution Certification SOP (P-Alc- 203) PENDING

8.2 Dubowski, K.M.; " Breath-Alcohol Simulators: Scientific Basis and Actual Performance", Journal of Analytical Toxicology, vol. 3, Sept./Oct. 1979, pp 177-182.

8.3 Appendix A: Alcohol Solutions Logbook (Alc 666) PENDING

8.4 Appendix B: Simulator Solution Preparation Log, (Chem 642)

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**Appendix A**

Alcohol Solutions Logbook pending approval.

**APPENDIX B**  
**SIMULATOR SOLUTION PREPARATION LOG**

Prep. Date	Lot identification	Volume prepared	Solution Components	Target Concentration	Prepared by	GC assay Results	Analyst	Intended use
							Date of analysis	

## **Bryce-Parrott, Cara**

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**From:** Celotti, Stella  
**Sent:** Tuesday, March 17, 2009 8:29 AM  
**To:** Richardson, Darcy; Drawbaugh, Bob  
**Cc:** Bryce-Parrott, Cara  
**Subject:** Procedure Approved

Hello, P-Alc-204, Rev 0, Ethanol Simulator Solution Preparation, has been approved and can be moved to Document Control, thanks, Stella.

Mary Celotti  
Laboratory Director  
Vermont Department of Health Laboratory  
195 Colchester Avenue  
Burlington, Vermont 05401  
Office:802-863-7570  
Fax:802-863-7632  
scelott@vdh.state.vt.us