

Idaho State Police Forensic Services

Approval for Quality System Controlled Documents



Discipline/Name of Document: Breath Alcohol

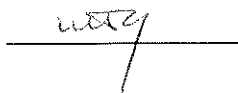
1.0 Approving Premixed Alcohol Simulator Solutions

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APPROVED BY: 
Quality Manager

4/23/2012
Date Signed

Checklist Submitted and Checked 

Approving Premixed Alcohol Simulator Solutions

History Page

Revision #	Effective date	History
0	11/20/2009	Original Issue
1	6/28/2010	Revised section 1.1, 1.4 and added section 1.10
2	4-23-2012	Section 1.8.1.1 modified to read more clearly as to the extent of data evaluation. 1.8.2 clarified.

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1.0 Approving Premixed Alcohol Simulator Solutions.

1.1 BACKGROUND

Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications on a schedule established by the Idaho State Police Forensic Services Laboratory. The verifications are performed using a premixed alcohol simulator solution provided by the Forensic Laboratory or by an approved source. Each premixed alcohol simulator solution lot must be approved by the Idaho State Police according to a procedure established by the ISP Forensic Services Laboratory. The vendor/manufacturer/provider of the premixed alcohol solution lot is approved as the source when ISPFS approves of the corresponding lot.

1.2 SCOPE

This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of premixed ethyl alcohol solutions used for instrument calibration and field performance verifications. Use of approved premixed alcohol simulator solutions (as a quality control) is required. Premixed alcohol simulator solutions are provided by ISPFS or an approved independent contractor and shall meet the standards contained in this method before they will be approved for use by ISP.

1.3 EQUIPMENT

Refer to Toxicology Discipline Analytical Method 4.2, section 4.2.3 EQUIPMENT

1.4 REAGENTS

Refer to Toxicology Discipline Analytical Method 4.2, section 4.2.4 REAGENTS

1.4.1 Premixed Ethyl Alcohol Solution. Premixed ethyl alcohol solutions shall be packaged in plastic bottles capable of maintaining the alcohol solution within specifications until the solutions expire. Each bottle shall be designated to contain 500 mL of solution and have a non-absorptive seal and a screw top lid. Bottles will have an integrity seal to insure the product has not been tampered with prior to its use. Freezing renders the solutions useless; therefore bottles of solution will not be shipped if there is a likelihood they will freeze during shipment. Bottles of solution shall be stored at room temperature or refrigerated (not frozen).

1.5 REFERENCE MATERIAL

Refer to Toxicology Discipline Analytical Method 4.2, section 4.2.5 REFERENCE MATERIAL

Idaho State Police Breath Alcohol Analytical Methods

1.6 SAFETY CONCERNS

Chemicals must be handled according to safety guidelines in the *Idaho State Police Forensic Services Health and Safety Manual*.

1.7 AUTHENTICATION PROCESS

1.7.1 General

1.7.1.1 Refer to Blood Alcohol Analytical Method 1.0 for Gas Chromatograph (GC) configured with a Flame Ionization Detector (FID) analysis requirements.

1.7.1.2 New lots of pre-mixed reference solutions will be provided by ISPFS or an independent contractor and shall meet the following acceptance criteria before they will be released to law enforcement agencies in Idaho.

1.7.1.2.1 The supplier must provide a certificate of analysis, a manufacture date, and an expiration date of the lot from which the sample was taken.

1.7.1.2.2 The supplier shall provide to ISPFS a random sampling of each new lot (manufactured batch) consisting of four (4) 500 mL samples.

1.7.2 Analysis Requirements

1.7.2.1 Two (2) 500 mL samples will be sent to each laboratory performing blood alcohol and other volatiles analysis for analysis by GC-FID following the protocol in the AM 1.0 Analysis of Volatiles by GC-HS. The results obtained from analysis will not be truncated (they will be reported to four digits).

1.7.2.2 A new calibration curve shall be used to analyze premixed alcohol simulator solutions using the GC-FID. Premixed alcohol simulator solution samples to be analyzed may be included as part of a larger run or sequence, but should be run prior to running evidentiary samples. A premixed alcohol simulator solutions sample shall not be the last sample on a run. These samples must be followed by at least one sample or a reagent blank.

1.7.2.3 Results in g/100cc shall be converted to g/210L by dividing by the number 1.23. The results from the two ISP labs will be provided to the ISPFS Alcohol Discipline Leader for evaluation.

1.8 SOLUTION ACCEPTANCE CRITERIA

1.8.1 Evaluation and Approval

1.8.1.1 When the results are received from the ISP Laboratories, the ISP Alcohol Discipline Leader will review the results and the accompanying quality control(s). ISPFs will **not** establish a new target value for each solution lot. The raw data points provided by both laboratories will be used to determine a combined mean. The result will be rounded to three significant digits (e.g. 0.200). The standard deviation will also be evaluated. If the values of the tested premixed alcohol simulator solution (the combined mean as reflected in raw data and as the g/100cc converted data) are within the parameters listed below (section 1.8.2.1), a certificate of approval will be issued by the ISPFs Alcohol Discipline Leader. The raw data combined mean result (in g/100cc) shall be converted to g/210L by dividing by the number 1.23.

1.8.2 Approval Criteria

1.8.2.1 Results of analysis must be within +/- 3% or .003 (whichever is greater) of the suppliers target value as listed on their certificate of analysis.

1.8.3 Rejection

1.8.3.1 If the above criteria are not met, the solution lot will be rejected. If a solution lot is rejected, the supplier shall be notified. The supplier will be required to submit a new lot of solution and a new authentication process will be conducted.

1.9 AUTHENTICATION DOCUMENTATION

1.9.1 Approval Documentation

1.9.1.1 Data sheets, chromatograms, the certificate of analysis from the supplier and the lot approval certificate (signed and dated by the Alcohol Discipline Leader) shall be placed in a folder and retained in the Alcohol Section for all approved lots. The approval shall also be posted on the ISP Internet Site.

1.9.2 Rejection Documentation

1.9.2.1 Data sheets, chromatograms, and the lot rejection letter (signed and dated by the Alcohol Discipline Leader) shall be placed in a folder and retained in the Alcohol Section for all rejected lots. A hard copy of an email or fax to the supplier documenting the lot rejection will also be retained.

1.10 VENDOR APPROVAL

1.10.1 Vendor Approval: In conformity with IDAPA 11.03.01.013.05 the vendor approval process will be as follows:

1.10.1.1 ISPFS shall approve the vendor by the vendor agreeing to the technical specifications required by ISPFS, and by the vendor providing a solution that is certified by ISPFS as meeting those specifications.

1.10.1.2 Any proposed vendor shall be provided with the ISPFS current technical specification form. The technical specifications form will detail any solution specifications placed on the manufacture by Idaho State Police Forensic Services. The technical specifications form shall be signed by the Alcohol Discipline Leader and a representative of the manufacture/provider/vendor before any of the lots associated with the vendor will be tested by ISPFS.

1.10.1.3 Each solution lot provided by a potential vendor shall be tested.

1.10.1.3.1 Each new lot of solution will be tested using the criteria in Section 1.7 of this AM.

1.10.1.3.2 Each solution lot will be evaluated and accepted or rejected based on the requirements in sections 1.8 and 1.9 of this AM. Approval of a solution lot explicitly approves the lot for sale/distribution within Idaho, as well as approval of the vendor as the source/manufacture/provider of that lot.

1.10.1.3.3 For lots certified after the date of June 28, 2010, the vendor approval shall be documented on the lot approval certificate for the premixed alcohol simulator solution.

1.10.1.4 The Alcohol Discipline Leader shall keep the signed technical specifications form on file.

1.11 REFERENCES AND RECOMMENDED READING

1.11.1 Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.

1.11.2 Caplan, Y.H., The Determination of Alcohol in Blood and Breath. in: Forensic Science Handbook, edited by Richard Saferstein, pp. 594-648, Prentice-Hall New Jersey, 1982.

1.11.3 Levine, B. and Caplan, Y.H., *Alcohol. in: Principles of Forensic Toxicology*, edited by Barry Levine, pp. 169-184, AACC Press, 2006.

1.11.4 Gullberg, R. (2005). Determining the Air/Water Partition Coefficient to Employ when Calibrating Forensic Breath Alcohol Test Instruments. *Can. Soc. Forensic Sci. J.* , 38 (4), 205-212.

1.11.5 Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.

<http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm>

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