

Reference Material Certificate of Analysis

Product identification:	Alcohol Reference Solution (ARS)
CRM:	Ethanol in aqueous solution
Reference concentration:	<u>2.4200</u> g/L
Analytical concentration:	<u>2.4339</u> g/L
Batch size:	<u>355</u> bottles
Lot number:	<u>202010D</u>
Date of production:	<u>2020.10.06</u> (yyyy.mm.dd)

This certificate covers the production, analysis and certification of the Certified Reference Material (CRM) manufactured by Alcohol Countermeasure Systems Corp (ACS), located at 60 International Boulevard, Toronto, ON M9W 6J2 CANADA.

This metrology laboratory is accredited in accordance with international standards ISO/IEC 17025:2017 for competence of testing and calibration laboratories, and ISO/IEC 17034:2016 for the competence of reference material producers, demonstrating technical competence within the defined scope and the operation of a laboratory quality management system.

The analysis for certification of each lot of ARS is conducted within ACS forensic laboratory by an independent chemist using the direct injection, flame ionization gas chromatographic procedure coupled with the internal standard technique commensurate with forensic alcohol analysis.

This certificate is valid only for the ARS lot number identified above and does not extend to any other production lot of alcohol reference solution.

This certificate may only be reproduced in full.

For and on behalf of the company,
ALCOHOL COUNTERMEASURE
SYSTEMS CORP.



Felix JE Comeau, B.Sc (Honours)
Laboratory Director

Certified Value

The ARS identified by lot number and date of production on the first page of this certificate was produced for the reference concentration as noted within an expanded uncertainty range of $\pm 1.2\%$ nominal value.

The ARS is a Certified Reference Material (CRM), where the underlying processes for production and verification of the CRM properties are certified through ISO/IEC 17025:2005 (#4169.01) and ISO 17034:2016 (#4169.02) International Standards.

The CRM properties (analytical concentration) of the ARS was determined by a direct injection, flame ionization, gas-chromatographic procedure coupled with the internal standard technique commensurate with forensic alcohol analysis.

The homogeneity of this CRM was determined and the uncertainty inherent to sample heterogeneity is included within the expanded uncertainty.

The stability of the concentration of this CRM as packaged within high density poly-ethylene with hermetically sealed neck seal was determined to be within ± 1 percent over two years when stored in ambient conditions of $+15$ to $+25$ °C.

The analysis of the ARS and evaluation of the results was completed by an independent (third party) chemist, G.J. Kupferschmidt, B.Sc., M.Sc., MCIC, C. Chem.

The ARS will provide an equivalent vapour alcohol concentration when used in a breath alcohol simulator heated to 34 ± 0.2 °C according to its analytical concentration established by Harger (1950) and Dubowski (1979) as illustrated in the table below.

Property (g/L)	Value (g/dL)
0.242	0.020
0.605	0.050
1.210	0.100
1.815	0.150

Uncertainty Factors of Analytical Verification

Uncertainties related to the CRM property value are specific to the laboratory technique for analytical verification employed. ACS forensic laboratory employs the use of gas chromatographic procedure as described above to analytically verify the CRM property values. The laboratory use of an internal standard technique eliminates the uncertainties related to: changes in gas chromatograph injection volume, small variations in preparation of internal standard and other test solutions.

Primary uncertainty in the CRM property value results from use of NIST SRM in the gas chromatographic analysis and internal standard procedure. The final uncertainty of the CRM is nearly identical to that of the specific NIST SRM used to verify the property values as illustrated in the formula below.

Stated uncertainty for the CRM is $\pm 1.2\%$ at confidence level of $k = 2$, of nominal value.

$$u_{CRM} = \sqrt{u_{ver}^2 + u_{bb}^2 + u_{lts}^2 + u_{sts}^2}$$

Traceability of the CRM property values are analytically verified and traceable to NIST Ethanol-Water Solution.

Standard Reference Material from NIST

- NIST SRM : 2892, 2893, 2894, 2895, 2896

Laboratory processes are traceable and verified through ISO/IEC 17025:2005 and ISO 17034:2016 International Standards.

This CRM consists of a solution of ethanol in water, prepared using a volumetric method and analyzed by the gas chromatography technique using a flame ionization detector, with direct injection procedure, and having n-Propanol as the internal standard.

The CRM is produced in a nominal batch lot and bottled in HDPE plastic bottles of 500 mL each with a hermetically sealed polyethylene neck seal and a tamper proof cap seal.

Analytical Method

The analysis was conducted within ACS forensic laboratory by an independent chemist using the direct injection, flame ionization gas chromatographic procedure coupled with the internal standard technique commensurate with forensic alcohol analysis.

Property	Value
Gas Chromatograph	HP 5890 with integrating recorder
Injection volume	2 μ L
Injector temperature	200 °C
Detector type	FID
Detector temperature	250 °C
Column	4'x1/8" OD; 5% Carbowax 1500 on Poropak Q 80/100 Mesh
Column temperature	120 °C
Carrier gas	Nitrogen
Column pressure	30 psi

Metrological Traceability

The certified value of the CRM has metrological traceability guaranteed by volumetric primary measuring methodology and through purity of the raw materials (distilled, deionized water and absolute ethyl alcohol) used for the ARS preparation.

The analytical procedure identified above provides the traceability to NIST SRM.

Purpose

This CRM is intended to be used for calibration and verification of breath alcohol testing instruments used to determine the concentration of ethanol in the air exhaled from the lungs.

Storage and Handling

- The CRM must be stored away from sunlight and in an ambient temperature between 15 and 25 °C
- The CRM should not be used if the bottle, cap or neck seal is compromised
- The CRM must be used within 24 hours after opening the bottle
- The CRM is non flammable nor toxic due to its low ethanol concentration

Expiry Date

The ARS identified by lot number on the first page of this certificate has a shelf life (validity date) of 24 months from the date of production. This CRM must be handled and stored according to the instructions in this certificate. The certificate shall not be valid in case the CRM is damaged, contaminated or altered. ACS guarantees the integrity of this material up to the moment the inner cap seal is removed from its 500 mL bottle. The contents of the bottle must be used immediately after it is opened.

Note

All information related to the transportation and safety (MSDS) may be requested from Alcohol Countermeasure Systems.

References

R.N. Harger, B.B. Raney, E.G. Bridwell, M.F. Kitchel, "The partition ratio of alcohol between air and water, urine and blood; estimation and identification of alcohol in these liquids from analysis of air equilibrated with them", J. Biological Chemistry, 183(1950)197-213

K.M. Dubowski, "Breath-alcohol simulators: scientific basis and actual performance", J. Anal. Toxicol. 3(1979)177-182.

K.M. Dubowski, N.A. Essary, "Evaluation of commercial breath-alcohol simulators: further studies", J. Anal. Toxicol., 15(1991)272-275

K.M. Dubowski, E.E. Goodson, McBeth Sample, Jr., "Storage stability of simulator ethanol solutions for vapor-alcohol control tests in breath-alcohol analysis", J. Anal. Toxic., 26(2002)406-410.